

Name: National Institute for Food and Drug Control

Address: No.31, Huatuo Road, Daxing District, Beijing, China

Registration No. CNAS L0001

Accreditation Criteria: ISO/IEC 17025:2017 and relevant requirements of CNAS

Effective Date: 2025-11-12 Expiry Date: 2030-06-05

SCHEDULE 3 ACCREDITED TESTING SCOPE

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
Drug						
1	Drug	1	Solubility	ChP 2025 Vol I / II / IV general notices		2025-11-12
		2	Weight variation	ChP 2025 Vol IVgeneral rule (0100)		2025-11-12
		3	Foam volume	ChP 2025Vol IVgeneral rule (0101)		2025-11-12
		4	Disintegration and uniformity of dispersion	ChP 2025 Vol IVgeneral rule (0101)		2025-11-12
		5	Total number of deliveries per container;Total number of doses per container;Total number of discharges per	ChP 2025 Vol IVgeneral rule (0111),(0112),(0113)		2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			container			
		6	Leakage rate	ChP 2005 Vol II Appendix I L		2024-07-10
		7	Content of active ingredient in an actuation;Content of active ingredient in a dose;Content of active ingredient in a Unit Spray	ChP 2025 Vol IV general rule ((0111),(0112),(0113)		2025-11-12
		8	Inhaled percentage	ChP 2010Vol II Appendix I L		2024-07-10
		9	Delivery rate	ChP 2025 Vol IV general rule (0113)		2025-11-12
		10	Total amount of spray	ChP 2025 Vol IV general rule (0113)		2025-11-12
		11	Delivery amount in a dose	ChP 2025 Vol IV general rule (0112)		2025-11-12
		12	Optical Rotation	ChP 2025 Vol IV general rule (0621)		2025-11-12
		13	Refractive Index	ChP 2025 Vol IV general rule (0622)		2025-11-12
		14	Acid Value	ChP 2025 Vol IV general rule (0713)		2025-11-12
		15	Saponification Value	ChP 2025Vol IV general rule (0713)		2025-11-12
		16	Hydroxyl Value	ChP 2025 Vol IV general rule (0713)		2025-11-12
		17	Iodine Value	ChP 2025 Vol IV general rule (0713)		2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		18	Peroxide Value	ChP 2025 Vol IV general rule (0713)		2025-11-12
		19	Vitamin A	ChP 2025 Vol IV general rule (0721)		2025-11-12
		20	Vitamin D	ChP 2025 Vol IV general rule (0722)		2025-11-12
		21	Readily Carbonizable Substances	ChP 2025 Vol IV general rule (0842)		2025-11-12
		22	THERMAL ANALYSIS	ChP 2025 Vol IV general rule (0661)		2025-11-12
		23	Total organic carbon	ChP 2025 Vol IV general rule (0682)		2025-11-12
		24	Conductance	ChP 2025 Vol IV general rule (0681)		2025-11-12
		25	Determination of Disintegration	ChP 2025 Vol IV general rule (0921)		2025-11-12
		26	Dissolution Test	ChP 2025 Vol IV general rule (0931)		2025-11-12
		27	Drug Release Test	ChP 2025 Vol IV general rule (0931)		2025-11-12
		28	Tablet Friability	ChP 2025 Vol IV general rule (0923)		2025-11-12
		29	Aerodynamic Assessment of Fine Particles	ChP 2025 Vol IV general rule (0951)		2025-11-12
		30	Identification/Inspect	ChP 2025 Vol IV general rule (identification) (0301)		2025-11-12
				ChP2025 Vol IV General Chapter (Molecular-exclusion Chromatography) (0514)		2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				ChP 2025 Vol IVgeneral rule (High Performance Liquid Chromatography) (0512)		2025-11-12
				ChP 2025 Vol IVgeneral rule (ion chromatography) (0513)		2025-11-12
				ChP2025 Vol I / Vol II/Vol IV (Volumetric Analysis)		2025-11-12
				ChP 2025Vol IVgeneral rule (Infrared Spectrophotometry) (0402)		2025-11-12
				USP-NF <584> (2023)		2024-07-10
				EP 11 <2.2.24>		2024-07-10
				Ph.Int. 2022 <1.7>		2024-07-10
				ChP 2025 Vol IVgeneral rule (Gas Chromatography) (0521)		2025-11-12
				ChP 2025 Vol IVgeneral rule (Raman spectroscopy) (0421)		2025-11-12
				USP-NF <1120> (2023)		2024-07-10
				ChP 2025 Vol IVgeneral rule (Thin-layer Chromatography) (0502)		2025-11-12
				EP11 <2.2.27>		2024-07-10
				USP-NF <201> (2023)		2024-07-10
				ChP 2025 Vol IVgeneral rule(Electrophoresis) (0541)		2025-11-12
				EP 11 (Capillary Electrophoresis) <2.2.47>		2024-07-10
				ChP 2025 Vol IVgeneral rule (Spectrophotometry and Light-		2025-11-12



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		№	Item/ Parameter			
				Scattering) (0401)		
				ChP 2025 Vol IV general rule ICP-OES (0411)		2025-11-12
				USP-NF <611> (2023)		2024-07-10
				Chp 2025 Vol IV general rule (paper chromatography) 0501		2025-11-12
				USP-NF <621> (2023)		2024-07-10
				EP11 <2.2.26>		2024-07-10
				Ph.Int.2022 <1.14.2>		2024-07-10
				ChP 2025 Vol IV general rule (MS) (0431)		2025-11-12
				ChP 2025 Vol IV general rule (XRD) (0451)	Only method 2	2025-11-12
				ChP 2025 Vol IV general rule (0441)		2025-11-12
		31	Related substances	ChP 2025 Vol IV general rule (High Performance Liquid Chromatography) (0512)		2025-11-12
				ChP2025 Vol IV General Chapter (Molecular-exclusion Chromatography) (0514)		2025-11-12
				ChP 2025 Vol IV general rule (ion chromatography) (0513)		2025-11-12
				ChP 2025 Vol IV general rule (Determination of Optical Rotation) (0621)		2025-11-12
				ChP 2025 Vol IV general rule (Potentiometric Titration and Dead-stop Titration) (0701)		2025-11-12



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		№	Item/ Parameter			
				ChP 2025 Vol IV general rule (Non-aqueous Titration) (0702)		2025-11-12
				ChP2025 Vol I / Vol II/Vol IV (Volumetric Analysis)		2025-11-12
				ChP2025 Vol I / Vol II/Vol IV (Gravimetric Analysis)		2025-11-12
				ChP 2025 Vol IV general rule (Gas Chromatography) (0521)		2025-11-12
				ChP 2025 Vol IV general rule (Capillary Electrophoresis) (0542)		2025-11-12
				EP11 (Capillary Electrophoresis) <2.2.47>		2024-07-10
				ChP 2025 Vol IV general rule (ICP-OES) (0411)		2025-11-12
				USP-NF <611> (2023)		2024-07-10
				ChP 2025 Vol IV general rule MS (0431)		2025-11-12
				ChP 2025 Vol IV general rule XRD (0451)	Only method 2	2025-11-12
				Chp 2025 Vol IV general rule(paper chromatography) 0501		2025-11-12
				USP-NF <621> (2023)		2024-07-10
				EP11 <2.2.26>		2024-07-10
				Ph.Int.2022 <1.14.2>		2024-07-10
		32	radiochemical purity	Chp 2025 Vol IV general rule(The test of Radiopharmaceutical Preparations) (1401)		2025-11-12



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		№	Item/ Parameter			
				EP11 radiopharmaceutical preparations-page 943		2025-11-12
				USP-NF <621> (2025)		2025-11-12
		33	radioactivity (radioactive concentration)	Chp 2025 Vol IV general rule(The test of Radiopharmaceutical Preparations) 1401		2025-11-12
				ChP2025 Vol II page 171-172		2025-11-12
				USP-NF <821> (2025)		2025-11-12
				EP11 <2.2.66>		2024-07-10
				Ph.Int.2022 <1.1>		2024-07-10
		34	radionuclide identification	Chp 2025 Vol IV general rule(The test of Radiopharmaceutical Preparations) 1401		2025-11-12
				USP-NF <821> (2025)		2025-11-12
				EP11 <2.2.66>		2024-07-10
				Ph.Int.2022 <1.2>		2024-07-10
		35	radionuclidic purity	Chp 2025 Vol IV general rule(The test of Radiopharmaceutical Preparations) 1401		2025-11-12
				USP-NF <821> (2025)		2025-11-12
				EP11 <2.2.66>		2024-07-10
				Ph.Int.2022 <1.3>		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		36	biodistribution	Chp 2025 Vol IV General Chapter 1402		2025-11-12
		37	size	Chp 2025 Vol II page 1980		2025-11-12
		38	Surface contamination and leakage test	Chp 2025 Vol II page 1980		2025-11-12
		39	radioimmunoassay kit testing	National standards for radioimmunoassay kit and general rules of radioimmunoassay kit WS1-(R-01-92)-2004Z		2024-07-10
		40	Assay	ChP 2025 Vol IV general rule (High Performance Liquid Chromatography) (0512)		2025-11-12
				ChP2025 Vol IV General Chapter (Molecular-exclusion Chromatography) (0514)		2025-11-12
				ChP 2025 Vol IV general rule (ion chromatography) (0513)		2025-11-12
				ChP 2025 Vol IV general rule (Determination of Optical Rotation) (0621)		2025-11-12
				ChP 2025 Vol IV general rule (Potentiometric Titration and Dead-stop Titration) (0701)		2025-11-12
				ChP 2025 Vol IV general rule (Non-aqueous Titration) (0702)		2025-11-12
				ChP 2025 Vol IV general rule (Assay of Vitamin A) (0721)		2025-11-12
				ChP 2025 Vol IV general rule (Assay of Vitamin D) (0722)		2025-11-12
				ChP2025 Vol I / Vol II/Vol IV (Volumetric Analysis)		2025-11-12
				ChP2025 Vol I / Vol II/Vol IV (Gravimetric Analysis)		2025-11-12
				ChP 2025 Vol IV general rule (Gas Chromatography) (0521)		2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				ChP 2025 Vol IV general rule (Protein content) (0731)		2025-11-12
				ChP 2025 Vol IV general rule (Determination of acetic acid in synthetic peptides) (0872)		2025-11-12
				ChP 2025 Vol IV general rule (Capillary Electrophoresis) (0542)		2025-11-12
				ChP 2025 Vol IV general rule (Spectrophotometry and Light-Scattering) (0401)		2025-11-12
				ChP 2025 Vol IV general rule ICP-OES (0411)		2025-11-12
				USP-NF <611> (2023)		2024-07-10
				Chp 2025Vol IV general rule (Microbiological Assay of Antibiotics) (1201)		2025-11-12
				Chp 2025 Vol IV general rule(AAS) (0406)		2025-11-12
				Chp 2025Vol IV general rule(MS) (0431)		2025-11-12
				Chp 2025Vol IV general rule(XRD) (0451)	Only method 2	2025-11-12
				ChP 2025 Vol IV general rule (Nuclear Magnetic Resonance Spectroscopy) (0441)		2025-11-12
		41	Volumetric Analysis	ChP2025 Vol I / Vol II/Vol IV (Volumetric Analysis)		2025-11-12
		42	Gravimetric Analysis	ChP2025 Vol I / Vol II/Vol IV (Gravimetric Analysis)		2025-11-12
		43	Chlorides	ChP 2025 Vol IV general rule (0801)		2025-11-12
				USP-NF <221> (2023)		2024-07-10



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		№	Item/ Parameter			
				EP 11 <2.4.4>		2024-07-10
				Ph. Int. 2022 <2.2.1>		2024-07-10
		44	Sulfates	ChP 2025 Vol IV general rule (0802)		2025-11-12
				USP-NF <221> (2023)		2024-07-10
				EP 11 <2.4.13>		2024-07-10
				Ph.Int. 2022 <2.2.2>		2024-07-10
		45	Sulfide	ChP 2025 Vol IV general rule (0803)		2025-11-12
		46	Cyanides	ChP 2025 Vol IV general rule (0806)		2025-11-12
		47	Iron	ChP 2025 Vol IV general rule (0807)		2025-11-12
				USP-NF <241> (2023)		2024-07-10
		48	Heavy Metals	ChP 2025 Vol IV general rule (0821)		2025-11-12
				EP 11 <2.4.8>	only A/C/D	2024-07-10
				Ph.Int. 2022 <2.4.8>	only Method A	2024-07-10
		49	Ammonium	ChP 2025 Vol IV general rule (0808)		2025-11-12
				EP 11 <2.4.1>	only Method A	2024-07-10
		50	Description	ChP 2025 Vol IV		2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		51	Inorganic iron	ChP2025 Vol I / Vol II/Vol IV		2025-11-12
		52	Arsenic	ChP 2025 Vol IV general rule (0822)		2025-11-12
		53	Ratio of sedimental volume	ChP 2025 Vol IV general rule (0105),(0106),(0123),(0126)		2025-11-12
		54	Metal particles	ChP 2025 Vol IV general rule (0105)		2025-11-12
		55	Determination of Dispersibility	ChP 2025 Vol IV general rule (0100),(0104),(0188)		2025-11-12
		56	Uniformity of appearance	ChP 2025 Vol IV general rule (0115)		2025-11-12
		57	2-Ethyl hexanoic acid	ChP 2025 Vol IV general rule (0873)		2025-11-12
		58	Solvent Residue	ChP 2025 Vol IV general rule (0861)		2025-11-12
		59	Color of Solution	ChP 2025 Vol IV general rule (0901)		2025-11-12
		60	Clarity of Solution	ChP 2025 Vol IV general rule (0902)		2025-11-12
		61	Particulate Matter	ChP 2025 Vol IV general rule (0903)		2025-11-12
		62	Determination of Particle Size	ChP 2025 Vol IV general rule (0104),(0982)		2025-11-12
		63	Minimum Fill	ChP 2025 Vol IV general rule (0942)		2025-11-12
		64	Melting Point	ChP 2025 Vol IV general rule (0612)		2025-11-12
				EP11 <2.2.14>		2024-07-10
				USP-NF <741> (2023)		2024-07-10



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		№	Item/ Parameter			
		65	pH Value	ChP 2025 Vol IV general rule (0631)		2025-11-12
				EP11 <2.2.3>		2024-07-10
				USP-NF <971> (2023)		2024-07-10
		66	Loss on Drying	ChP 2025 Vol IV general rule (0831)		2025-11-12
				EP11 <2.2.32>		2024-07-10
				USP-NF <731> (2023)		2024-07-10
		67	WATER DETERMINATION	ChP 2025 Vol IV general rule (0832)		2025-11-12
				EP11 <2.5.32>		2024-07-10
				USP-NF <921> (2023)		2024-07-10
		68	Residue on Ignition	ChP 2025 Vol IV general rule (0841)		2025-11-12
				EP11 <2.4.16>		2024-07-10
				USP-NF <281> (2023)		2024-07-10
		69	Content Uniformity	ChP 2025 Vol IV general rule (0941)		2025-11-12
				EP11 <2.9.6>		2024-07-10
				USP-NF <905> (2023)		2024-07-10
		70	Adhesive property	ChP 2025 Vol IV general rule (0952)		2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				ChP 2025 Vol IV general rule (0121)		2025-11-12
				ChP 2025 Vol IV general rule (0122)		2025-11-12
		71	TDS adhesion tests	USP-NF <3> (2023)		2024-07-10
		72	Ointment wright	ChP 2025 Vol IV general rule (0122)		2025-11-12
		73	Heat resistance	ChP 2025 Vol IV general rule (0122)		2025-11-12
		74	Transmittance of solution	ChP 2025 Vol IV general rule (0401)		2025-11-12
		75	Absorbance	ChP 2025 Vol IV general rule (0401)		2025-11-12
		76	Determination of Molecular Weight and Molecular Weight Distribution	ChP 2025 Vol IV general rule (0514)		2025-11-12
				European Pharmacopoeia 11 Page 3650		2024-07-10
		77	Protein Content	ChP 2025 Vol IV general rule (0731)		2025-11-12
		78	Acetic acid in synthetic polypeptide	ChP 2025 Vol IV general rule (0872)		2025-11-12
		79	assay of lyophilizing thrombin powder	CHP 2025 Vol II page 1845		2025-11-12
		80	assay of trypsin	CHP 2025 Vol II page 1395		2025-11-12
		81	assay of trypsin in pancreatin	CHP 2025 Vol II page 1397		2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		82	assay of pepsin	CHP 2025 Vol II page 901		2025-11-12
		83	assay of chymotrypsin	CHP 2025 Vol II page 1880		2025-11-12
		84	assay of urokinase	CHP 2025 Vol II page 653		2025-11-12
		85	assay of asparaginase (Escherichia), asparaginase (Ervinia)	CHP 2025 Vol II page 50,52		2025-11-12
		86	assay of defibrase	National Drug Specifications Vol 16 page 88		2024-07-10
		87	assay of lysozyme	Ministry of health drug specifications Vol II ,sixth book,page141		2024-07-10
		88	assay of pancreatic kininogenase	CHP 2025 Vol II page 1399		2025-11-12
				Ministry of health drug specifications Vol II ,sixth book,page111		2024-07-10
		89	Bacterial Endotoxin test	ChP 2025 Vol IV general rule 1143		2025-11-12
				ChP 2025 Vol IV general rule (9251)		2025-11-12
				USP -NF <85> (2020)		2024-07-10
				EP 11.4 <2.6.14> (2023)		2024-07-10
				JP 18 <4.01>(2021)		2024-07-10
		90	osmotic pressure	ChP 2025 Vol IV general notices (0632)		2025-11-12



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		№	Item/ Parameter			
		91	Visible foreign matter	ChP 2025 Vol IV general notices (0904)	Except Method III	2025-11-12
		92	Nitrogen	ChP 2025 Vol IV general rule Method3 (0704)		2025-11-12
		93	Specific absorbance	ChP 2025 Vol IV general rule (Spectrophotometry and Light-Scattering)0401 (0401)		2025-11-12
		94	molar substitution	ChP 2025 Vol IV general rule (0521)		2025-11-12
				Ministry of health drug specifications Vol II ,sixth book, Appendix 7		2024-07-10
				National Drug Specifications YBH15182006, YBH02202010		2024-07-10
		95	Viscosity	ChP 2025 Vol IV general rule (0633)		2025-11-12
		96	Hemorrhagic toxicity	National Drug Specifications Vol 16 page 88		2024-07-10
				Import Drug Registrations JX20010046		2024-07-10
		97	Neurotoxicity	National Drug Specifications Vol 16 page 88		2024-07-10
		98	Thymus peptide biological activity	National Drug Specifications Vol 16 page 118		2024-07-10
		99	Transfer factor biological activity	National Drug Specifications Vol 16 page 104		2024-07-10
		100	Crystallinity	ChP 2025 Vol IV general rule (0981)	Only the second method	2025-11-12
		101	Test for depressor substances	Chp 2025 Volume IV Chp 2015 Volume IV (1145)		2025-11-12
		102	assay of amylopsin in pancreatin	ChP 2025 Vol II page 1397		2025-11-12



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		103	assay of pancrelipase in pancreatin	ChP 2025 Vol II page 1397		2025-11-12
		104	activity determination	National Drug Specifications Vol 16 page 82		2024-07-10
		105	determination of immunogenicity	National Drug Specifications (Trial Implementation)WS1-XG-053-2000-2005		2024-07-10
		106	activity determination of Cytochrome C	ChP 2025 Vol IVgeneral rule (1206)		2025-11-12
		107	shape forming ability	ChP 2025 Vol IVgeneral rule (0122)		2025-11-12
		108	content of alcohol	ChP 2025 Vol IVgeneral rule (0711)	only GC Mthod I (capillary column chromatography)	2025-11-12
		109	Test for Undue Toxicity	Chp 2025Volume IV Chp 2015 Volume IV (1141)		2025-11-12
		110	Test for Allergen	Chp 2025 Volume IV Chp 2015 Volume IV (1147)		2025-11-12
		111	Test for Pyrogen	Chp 2025 Volume IV Chp 2015 Volume IV (1142)		2025-11-12
				General principles of four parts of Chinese Pharmacopoeia 2025 Edition (9301) Monocyte activationtest, MAT		2025-11-12
				EP 11.4 <2.6.8>(2023)		2024-07-10
				USP -NF 38 <151> (2020)		2024-07-10



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		№	Item/ Parameter			
		112	Test for Haemolysis and Agglomeration	Chp2025 volume IV Chp2015 volume IV (1148)		2025-11-12
		113	Biological Assay of Protamine Sulfate	Chp2025 volume IV Chp2015 volume IV (1213)		2025-11-12
		114	Biological Assay of Luteinsing Hormone	Chp2025 volume IV Chp2015 volume IV (1217)		2025-11-12
		115	Biological Assay of Vasopressin	Chp2025 Volume IV General Rules 1205		2025-11-12
		116	Biological Assay of pressor substance	Chp2025 volume IV General Rules 1144		2025-11-12
		117	Toxicity Test of Sodium Stibogluconate	Chp 2025 Volume IV Chp 2015 Volume IV (1215)		2025-11-12
		118	biopotency of chorionic gonadotrophin	ChP 2025Vol IVgeneral rule (1209)		2025-11-12
		119	biopotency of Insulin	ChP 2025 Vol IVgeneral rule (1211)		2025-11-12
				USP-NF <121> (2020)		2024-07-10
		120	potency of solliche-stimulating hormone	ChP 2025 Vol IVgeneral rule (1216)		2025-11-12
		121	biopotency of growth hormone	ChP 2025 Vol IVgeneral rule (1219)		2025-11-12
		122	Disintegration test	ChP2025 Vol IV, general rule 0108		2025-11-12
		123		ChP2025 Vol. IV General Notices 1208		2025-11-12
		124	General quality control method for crude drugs	ChP2025 Vol IV, general rule 0212		2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		125	arsenic	Inductively coupled plasma mass spectrometry ChP2025 Vol IV general notices 0412		2025-11-12
		126	Microscopical indentification	ChP2025 Vol IV, general rule 2001		2025-11-12
		127	cadmium	Inductively coupled plasma mass spectrometry ChP2025 Vol IV general notices 0412		2025-11-12
		128	Foreign Matter	ChP2025 Vol IV, general rule 2301		2025-11-12
		129	mercury	Inductively coupled plasma mass spectrometry ChP2025 Vol IV general notices 0412		2025-11-12
		130	lead	ChP2025 Vol IV, general rule 2321		2025-11-12
		131	lead	Inductively coupled plasma mass spectrometry ChP2025 Vol IV general notices 0412		2025-11-12
		132	cadmium	ChP2025 Vol IV, general rule 2321		2025-11-12
		133	cobalt	Inductively coupled plasma mass spectrometry ChP2025 Vol IV general notices 0412		2025-11-12
		134	arsenic	ChP2025 Vol IV, general rule 2321		2025-11-12
		135	nickel	Inductively coupled plasma mass spectrometry ChP2025 Vol IV general notices 0412		2025-11-12
		136	mercury	ChP2025 Vol IV, general rule 2321		2025-11-12
		137	vanadium	Inductively coupled plasma mass spectrometry ChP2025 Vol IV general notices 0412		2025-11-12
		138	copper	ChP2025 Vol IV, general rule 2321		2025-11-12
		139	palladium	Inductively coupled plasma mass spectrometry ChP2025 Vol IV general notices 0412		2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		140	Ash	ChP2025 Vol IV, general rule 2302		2025-11-12
		141	rhodium	Inductively coupled plasma mass spectrometry ChP2025 Vol IV general notices 0412		2025-11-12
		142				2025-11-12
		143	Indium	Inductively coupled plasma mass spectrometry ChP2025 Vol IV general notices 0412		2025-11-12
		144				2025-11-12
		145				2025-11-12
		146				2025-11-12
		147				2025-11-12
		148				2025-11-12
		149				2025-11-12
		150				2025-11-12
		151				2025-11-12
		152				2025-11-12
		153				2025-11-12
		154				2025-11-12
		155				2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		156				2025-11-12
		157				2025-11-12
		158				2025-11-12
		159				2025-11-12
		160				2025-11-12
		161				2025-11-12
		162				2025-11-12
		163				2025-11-12
		164				2025-11-12
		165				2025-11-12
		166				2025-11-12
		167				2025-11-12
		168				2025-11-12
		169				2025-11-12
		170				2025-11-12
		171				2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		172				2025-11-12
		173				2025-11-12
		174				2025-11-12
		175				2025-11-12
		176				2025-11-12
		177				2025-11-12
		178				2025-11-12
		179				2025-11-12
		180				2025-11-12
		181				2025-11-12
		182				2025-11-12
		183				2025-11-12
		184				2025-11-12
		185				2025-11-12
		186				2025-11-12
		187				2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		188				2025-11-12
		189				2025-11-12
		190				2025-11-12
		191				2025-11-12
		192				2025-11-12
		193				2025-11-12
		194				2025-11-12
		195				2025-11-12
		196				2025-11-12
		197				2025-11-12
		198				2025-11-12
		199				2025-11-12
		200				2025-11-12
		201				2025-11-12
		202				2025-11-12
		203				2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		204				2025-11-12
		205				2025-11-12
		206				2025-11-12
		207				2025-11-12
		208				2025-11-12
		209				2025-11-12
		210				2025-11-12
		211				2025-11-12
		212				2025-11-12
		213				2025-11-12
		214				2025-11-12
		215				2025-11-12
		216				2025-11-12
		217				2025-11-12
		218				2025-11-12
		219				2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		220				2025-11-12
		221				2025-11-12
		222				2025-11-12
		223				2025-11-12
		224				2025-11-12
		225				2025-11-12
		226				2025-11-12
		227				2025-11-12
		228				2025-11-12
		229				2025-11-12
		230				2025-11-12
		231				2025-11-12
		232				2025-11-12
		233				2025-11-12
		234				2025-11-12
		235				2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		236				2025-11-12
		237				2025-11-12
		238				2025-11-12
		239				2025-11-12
		240				2025-11-12
		241				2025-11-12
		242				2025-11-12
		243				2025-11-12
		244				2025-11-12
		245				2025-11-12
		246				2025-11-12
		247				2025-11-12
		248				2025-11-12
		249				2025-11-12
		250				2025-11-12
		251				2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		252				2025-11-12
		253				2025-11-12
		254				2025-11-12
		255				2025-11-12
		256				2025-11-12
		257				2025-11-12
		258				2025-11-12
		259				2025-11-12
		260				2025-11-12
		261				2025-11-12
		262				2025-11-12
		263				2025-11-12
		264				2025-11-12
		265				2025-11-12
		266				2025-11-12
		267				2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		268				2025-11-12
		269				2025-11-12
		270				2025-11-12
		271				2025-11-12
		272				2025-11-12
		273				2025-11-12
		274				2025-11-12
		275				2025-11-12
		276				2025-11-12
		277				2025-11-12
		278				2025-11-12
		279				2025-11-12
		280				2025-11-12
		281				2025-11-12
		282				2025-11-12
		283				2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		284				2025-11-12
		285				2025-11-12
		286				2025-11-12
		287				2025-11-12
		288				2025-11-12
		289				2025-11-12
		290				2025-11-12
		291				2025-11-12
		292				2025-11-12
		293				2025-11-12
		294				2025-11-12
		295				2025-11-12
		296				2025-11-12
		297				2025-11-12
		298				2025-11-12
		299				2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		300				2025-11-12
		301				2025-11-12
		302				2025-11-12
		303				2025-11-12
		304				2025-11-12
		305				2025-11-12
		306				2025-11-12
		307				2025-11-12
		308				2025-11-12
		309				2025-11-12
		310				2025-11-12
		311				2025-11-12
		312				2025-11-12
		313				2025-11-12
		314				2025-11-12
		315				2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		316				2025-11-12
		317				2025-11-12
		318				2025-11-12
		319				2025-11-12
		320				2025-11-12
		321				2025-11-12
		322				2025-11-12
		323				2025-11-12
		324				2025-11-12
		325				2025-11-12
		326				2025-11-12
		327				2025-11-12
		328				2025-11-12
		329				2025-11-12
		330				2025-11-12
		331				2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		332				2025-11-12
		333				2025-11-12
		334				2025-11-12
		335				2025-11-12
		336				2025-11-12
		337				2025-11-12
		338				2025-11-12
		339				2025-11-12
		340				2025-11-12
		341				2025-11-12
		342				2025-11-12
		343				2025-11-12
		344				2025-11-12
		345				2025-11-12
		346				2025-11-12
		347				2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		348				2025-11-12
		349				2025-11-12
		350				2025-11-12
		351				2025-11-12
		352				2025-11-12
		353				2025-11-12
		354				2025-11-12
		355				2025-11-12
		356				2025-11-12
		357				2025-11-12
		358				2025-11-12
		359				2025-11-12
		360				2025-11-12
		361				2025-11-12
		362				2025-11-12
		363				2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		364				2025-11-12
		365				2025-11-12
		366				2025-11-12
		367				2025-11-12
		368				2025-11-12
		369				2025-11-12
		370				2025-11-12
		371				2025-11-12
		372				2025-11-12
		373				2025-11-12
		374				2025-11-12
		375				2025-11-12
		376				2025-11-12
		377				2025-11-12
		378				2025-11-12
		379				2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		380				2025-11-12
		381				2025-11-12
		382				2025-11-12
		383				2025-11-12
		384				2025-11-12
		385				2025-11-12
		386				2025-11-12
		387				2025-11-12
		388				2025-11-12
		389				2025-11-12
		390				2025-11-12
		391				2025-11-12
		392				2025-11-12
		393				2025-11-12
		394				2025-11-12
		395				2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		396				2025-11-12
		397				2025-11-12
		398				2025-11-12
		399	Material about Injection	ChP2025 Vol IV, general rule 2400		2025-11-12
		400	Methanol	ChP2025 Vol IV, general rule 0871		2025-11-12
		401	Residue of Sulfur Dioxide	ChP2025 Vol IV, general rule 2331		2025-11-12
		402	aflatoxin B1	ChP2025 Vol IV, general rule 2351		2025-11-12
		403	aflatoxin B2	ChP2025 Vol IV, general rule 2351		2025-11-12
		404	aflatoxin G1	ChP2025 Vol IV, general rule 2351		2025-11-12
		405	aflatoxin G2	ChP2025 Vol IV, general rule 2351		2025-11-12
		406	zearalenone	ChP2025 Vol IV, general rule 2351		2025-11-12
		407	Extractives	ChP2025 Vol IV, general rule 2201		2025-11-12
		408	Tanninoids	ChP2025 Vol IV, general rule 2202		2025-11-12
		409	Cineol	ChP2025 Vol IV, general rule 2203		2025-11-12
		410	Volatile Oil	ChP2025 Vol IV, general rule 2204		2025-11-12
		411	polymerase chain reaction	ChP2025 Vol IV 1001		2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		412	morphological identification	ChP2025 Vol I, the ordinary case		2025-11-12
Biological product						
1	Biological product	1	virus titration(plaque assay)	ChP2020 Vol III, monographs		2025-11-12
		2	Identity(plaque assay)	ChP2025 Vol III, monographs		2025-11-12
		3	Determination of 2-phenoxyethanol content	ChP2025 Vol III, Monographs		2025-11-12
		4	Host residue protein(ELISA)	ChP2025 Vol III/IV, general rule (3414)		2025-11-12
		5	Residual carbodiimide content	ChP 2025 Vol III/IV general rule (3206)		2025-11-12
		6	O-acetyl content	ChP 2025 Vol III/IV general rule (3117)		2025-11-12
		7	pH	ChP2025 Vol III/IV, general rule (0631)		2025-11-12
		8	protein content (immunodiffusion method)	ChP 2025 Vol III, monographs		2025-11-12
		9	Efficacy (Skin test)	ChP2025 Vol III, monographs		2025-11-12
		10	Analysis of amino acid	Imported drug registration standards JS20200047		2024-07-10
		11	Purity of albumin	ChP2025 Vol III, Monographs		2025-11-12



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		№	Item/ Parameter			
		12	Diphtheria antibody	ChP2025 Vol III/IV, general rule (3513)		2025-11-12
		13	Determination of phenol content	ChP2025 Vol III/IV, general rule (3113)		2025-11-12
				Imported drug registration standards JS20210014、JS20210015 JS20210014、JS20210015		2024-07-10
		14	disintegration test	ChP 2025 Vol III/IV general rule (0921)		2025-11-12
		15	virus titration	ChP2025 Vol III, Monographs, Drug registration standards WS4-(ZB-070)-2010		2025-11-12
		16	Virus Titration (Cytopathic)	ChP2025 Vol III, Monographs, Drug registration standards YBS00482021、YBS00312015、YBS00252021		2025-11-12
		17	virus titration(micro plate CPE)	ChP2025 Vol III, Monographs, Drug registration standards WS4-(ZB-004)-2011		2025-11-12
		18	Test for reversion of neurovirulence in mice	ChP2025 Vol III, monographs		2025-11-12
		19	Identity(single radial immunodiffusion)	ChP2025 Vol III, monographs		2025-11-12
		20	Virus inactivated validation	National Drug Standards YBS00282016		2025-11-12
		21	Test for Adventitious virus(Cell culture method)	ChP 2025 Vol III general rule (3302)		2025-11-12
		22	Determination of insoluble particles	ChP2025 Vol III/IV General rule (0903)		2025-11-12
				EP 11 2.9.19 particulate contamination sub-visible particles		2024-07-10



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		№	Item/ Parameter			
		23	Residual solvents	ChP2025 Vol III/IV General rule (0861)		2025-11-12
		24	Purity(HPLC method)	ChP 2025 Vol III general rule (0512)		2025-11-12
		25	Test for the absence of contaminating organisms	ChP2025 Vol III/IV, general rule, monographs (1101)		2025-11-12
		26	Residue bacteria protein	ChP 2025 Vol III general rule (3412),(3413),(3414)		2025-11-12
		27	Potency of monoclonal antibody	ChP2025 Vol III/IV General rule		2025-11-12
		28	Protein purity(SDS PAGE)	ChP 2025 Vol III general rule (0541)		2025-11-12
		29	Protein purity(HPLC method)	ChP 2025 Vol III general rule (0512)		2025-11-12
		30	Protein molecular weight (SDS PAGE)	ChP 2025 Vol III general rule (0541)		2025-11-12
		31	Protein content	ChP 2025 Vol IV general notices (0731)		2025-11-12
		32	Protein content (TCA-Lowry method)	Imported drug registration standards JS20040032		2024-07-10
		33	Protein nitrogen content	Imported drug registration standards JS20190028/JS20190020		2024-07-10
		34	protein content (Lowry method)	ChP 2025 Vol III/IV, general rule (0731)		2025-11-12
		35	protein content (UV	ChP 2025 Vol III/IV, general rule (0731)		2025-11-12

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			method)			
		36	Nitrogen content	ChP 2025Vol III/IV general rule (0704)		2025-11-12
		37	Isoelectric focusing electrophoresis	ChP 2025 Vol III general rule (0541)		2025-11-12
		38	Test for reversion to toxicity (pertussis vaccine)	ChP2025Vol III, monograph		2025-11-12
		39	Test for reversion to toxicity (toxoid)	ChP2025 Vol III, monograph		2025-11-12
		40	Molecular size distribution	ChP 2025 Vol III/IV general rule (3419)		2025-11-12
		41	polyscharide content	ChP 2025 Vol III/IV general rule (3103)		2025-11-12
		42	polysaccharide content	ChP 2025 Vol III, monographs		2025-11-12
		43	polyscharide content	Drug registration standards, Import drug registration standards YBS00102021、YBS01302021、YBS00392019、YBS00012018, JS21040065, JS20200058		2024-07-10
		44	molecular size test (Vi-PS)	ChP 2025 Vol III/IV general rule (3420)		2025-11-12
		45	Distribution of molecular size	ChP 2025 Vol III/IV general rule (3121) (3122)		2025-11-12
		46	Phenol content	Import drug registration standards JS20200054		2024-07-10
		47	Virurs titer(Cell culture method)	Adenov titration assay NIFDC-SOP-B-T-0580		2024-07-10
		48	moisture content (weight loss	ChP 2025 Vol III/IV, general role (0831)		2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			method)			
		49	content in high molecular weight conjugate	ChP 2025 Vol III/IV general rule (3119)		2025-11-12
		50	total solids	ChP 2025 Vol III/IV general rule (3101)		2025-11-12
		51	Hypersensitive test/Sensitization test	ChP2025 Vol IV, general rule (1147)		2025-11-12
		52	Content (HPLC)	ChP2025 Vol III/IV general rule (0512), (3124)		2025-11-12
		53	Analysis of nucleotide	Import drug registration standards JS20200047		2024-07-10
		54	nucleic acid content	ChP 2025 Vol III/IV general rule (0401)		2025-11-12
		55	polysaccharide content(ribose method)	ChP 2025 Vol III/IV general rule (3421)		2025-11-12
		56	bacteria counting	ChP 2025 Vol III, monographs		2025-11-12
		57	Determination of metacresol content	ChP2025 Vol III/IV, general rule (3144)		2025-11-12
		58	Test for the absence of contaminating organisms (Animal Test)	ChP2025 Vol III, monographs		2025-11-12
		59	Identity test (acid-fast stained smear)	ChP2025 Vol III, monographs		2025-11-12
		60	Identity test	ChP2025 Vol III, Monographs, Drug registration standards		2025-11-12

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				YBS01402011、YBS00482021、YBS00312015、YBS00252021		
		61	Identity test (Immunodot)	ChP2025 Vol III/IV General rule (3402)		2025-11-12
		62	Identity (SDS-PAGE method)	ChP 2025 Vol III/IV general rule (3404)		2025-11-12
		63	Identity (immunodiffusion method)	ChP 2025 Vol III/IV general rule (3403)		2025-11-12
		64	Identity (WB method)	ChP 2025 Vol III/IV general rule (3401)		2025-11-12
		65	Identity test (Immunogenicity)	ChP2025 Vol III, monographs		2025-11-12
		66	Identity test (Intracerebral neutralization test)	ChP2025 Vol III, monographs		2025-11-12
		67	identity test	ChP2025 Vol III, monographs		2025-11-12
		68	Identity test (Gel immunoprecipitation test)	ChP2025 Vol III, monograph		2025-11-12
		69	Identity test (Skin test)	ChP2025 Vol III, monographs		2025-11-12
		70	Identity test of vaccine, live (Plaque method)	ChP2025 Vol III, monographs		2025-11-12
		71	identity test	Drug registration standards, Import drug registration standards JS20140079		2024-07-10
		72	Identity test (Neutralization test)	ChP2025 Vol III, monograph		2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		73	Identification (cell culture)	ChP2025 VolⅢ, Monographs, Drug registration standards WS4-(ZB-004)-2011		2025-11-12
		74	Identity test (Flocculation test)	ChP2025 Vol Ⅲ, monograph		2025-11-12
		75	T cell proliferation	ChP 2025 Vol III R-NIFDC-SOP-B-T-0582-01		2025-11-12
		76	Determination of Residual Polysorbate 80 Content(Colorimetric Method)	ChP 2025 Vol Ⅲ general rule (3203)		2025-11-12
		77	Residual PEG (colorimetric method)	ChP 2025 Vol Ⅲ general rule (3202)		2025-11-12
		78	Inspection for morphology and colony of bacilli	ChP2025 Vol Ⅲ, monographs		2025-11-12
		79	Bacteria/Yeast/Virus Seed Identification (ELISA)	ChP 2025 Vol Ⅲ monograph		2025-11-12
		80	Bacteria/Yeast/Virus seed identification (Nucleic Acid Electrophoresis)	ChP 2025 Vol Ⅲ monograph		2025-11-12
		81	Identification of virus seed/strain (sequencing)	Drug registration standard WS4-(ZB-004)-2011		2024-07-10
		82	Identification of bacteria	Bergey's Manual of Determinative Bacteriology, ChP2025 VolⅢ, Monographs		2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		83	Potency test for antitoxins (Animal test)	ChP2025 Vol III/IV, general rule (3507), (3508), (3509), (3510)		2025-11-12
		84	Determination of glycin content	ChP2025 Vol III, Monographs		2025-11-12
		85	Antibiotic residue (ELISA)	ChP2025 Vol III, Monographs, Drug registration standards YBS00282015		2025-11-12
		86	Test for purity of antisera/antitoxins	ChP2025 Vol III, Monographs		2025-11-12
		87	Ag and Ab content (ELISA method)	ChP 2025 Vol III, Monographs		2025-11-12
		88	Test for Visible Particles	ChP 2025 Vol III general rule (0904)		2025-11-12
				EP 11 2.9.20.PARTICULATE CONTAMINATION: VISIBLE PARTICLES		2024-07-10
		89	Potency test for rabies antiserum (MNT)	ChP2025 Vol III/IV, general rule (3512) 1		2025-11-12
		90	Potency test for rabies antiserum (RIFFT)	ChP2025 Vol III/IV, general rule (3512) 2		2025-11-12
		91	Potency test for rabies vaccine (NIH)	ChP2025 Vol III/IV, general rule (3503)		2025-11-12
		92	Test for purity of toxoid	ChP2025 Vol III, Monographs		2025-11-12
		93	Flocculation unit test of toxoid	ChP2025 Vol III, general rule (3506)		2025-11-12
		94	Potency test for toxoid	ChP2025 Vol III, general rule (3504),(3505)		2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		95	KPI test	Import drug registration standards JS20200047		2024-07-10
		96	Determination of Particle Size Distribution	ChP 2025 Vol III general rule (0982)		2025-11-12
		97	Analysis of phosphorus	Import drug registration standards JS20200047		2024-07-10
		98	Determination of ammonium sulfate content	ChP2025 Vol III, general rule (3104)		2025-11-12
		99	NaCl content	ChP 2025 Vol III/IV general rule (3107)		2025-11-12
		100	saccharide and saccharide alcohols (HPLC)	ChP 2025Vol III, monographs		2025-11-12
		101	Immunogenicity (ELISA)	ChP2025 Vol III, Monographs WS ₄ -(ZB-004)-2011		2025-11-12
		102	immunogenicity	National Drug Standards YBS00282016		2024-07-10
		103	Concentrations	ChP2025 Vol III, monographs		2025-11-12
		104	Aluminum	ChP 2025 Vol III general rule (3106)		2025-11-12
				ChP 2025Vol IV 0411		2025-11-12
				Imported drug registration standards JS20190028		2024-07-10
				Imported drug registration standards JS20190020		2024-07-10
				ChP 2025Vol IV 0412		2025-11-12



№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				JS 20210014		2024-07-10
				JS 20210015		2024-07-10
		105	residual cyanide content	ChP 2025 Vol III/IV general rule (0806)		2025-11-12
		106	residual DOC content	Drug registration standards YBS10282020		2024-07-10
		107	Thermal stability test	ChP2025 Vol III, Monographs, Drug registration standards YBS00282015		2025-11-12
		108	Test for safety and identify of botulinum toxin	Registration Standards JS20120050		2024-07-10
		109	Lactose content	Registration Standards JS20190022		2024-07-10
		110	Determination of osmolality	ChP2025 Vol III/IV, general rule (0632)		2025-11-12
		111	Pyrogen	ChP 2025 Vol III/IV general rule (1142)		2025-11-12
				EP 11.4 <2.6.8> (2023)		2024-07-10
				USP -NF 38 <151> (2020)		2024-07-10
		112	moisture content(volumetric method)	ChP2025 Vol III/IV, general rule (0832)		2025-11-12
		113	Peptide Mapping Analysis (Trypsin Cleavage- Reverse Phase HPLC Method)	ChP 2025 Vol III general rule (3405)		2025-11-12

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		114	in Vitro Relative Potency	ChP 2025 Vol III general rule (3501)		2025-11-12
		115	Test for special toxicity	ChP2025 Vol III, monograph		2025-11-12
		116	sialic acid content	ChP 2025 Vol III/IV general rule, Drug registration standards (3102)		2025-11-12
		117	Appearance	ChP 2025 Vol III monograph		2025-11-12
		118	Host residue DNA	ChP2025 Vol III/IV, general rule (3407)		2025-11-12
		119	The limits of contaminated bacterias	ChP 2025 Vol III/IV general rule (1105),(1106),(1107)		2025-11-12
		120	Thermostability	National Drug Standards WS4-(ZB-070)-2010		2024-07-10
		121	sterility (membrane filtration method)	ChP 2025 Vol III/IV general rule (1101)		2025-11-12
		122	sterility (direct inoculation method)	ChP 2025 Vol III/IV general rule (1101)		2025-11-12
		123	Glutaric dialdehyde content	ChP 2025 Vol III/IV general rule (3204)		2025-11-12
		124	Absorbance (UV-Spectrophotometry)	ChP 2025 Vol III general rule (0401)		2025-11-12
		125	bacterial form and purity	ChP 2025 Vol III		2025-11-12
		126		ChP 2025 Vol III		2025-11-12
				ChP 2025 Vol VI 1143		2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				ChP 2025 Vol IV general rule (9251)		2025-11-12
				EP 11.4 <2.6.14> (2023)		2024-07-10
				USP -NF <85> (2020)		2024-07-10
				JP 18 <4.01> (2021)		2024-07-10
		127	Specific toxicity test (pertussis)	ChP2025 Vol III, monograph		2025-11-12
		128	Specific toxicity test (toxoid)	ChP2025 Vol III, monograph		2025-11-12
		129	Test for calf serum	ChP 2025 Vol III general rule (3604)		2025-11-12
		130	serological test for bacteria	ChP 2025 Vol III, monographs		2025-11-12
		131	residual ethanol content	ChP 2025 Vol III/IV general rule (3201)		2025-11-12
		132	Antigen expression	ChP 2025 Vol III general rule (0731)		2025-11-12
		133	Abnormal toxicity	ChP 2025 Vol III/IV general rule (1141)		2025-11-12
		134	free polysaccharide content	ChP 2025 Vol III/IV general rule (3119) (0401) (0513), Drug registration standards YBS00392019, YBS00012018, Import drug registration standards JS20140065		2025-11-12
		135	Free Formaldehyde (colorimetric method)	ChP 2025 Vol III general rule (3207)		2025-11-12
		136	contaminated bacterias test	ChP 2025 Vol III, monographs		2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		137	Thimerosal content	ChP2025 Vol III/IV, general rule (3115)		2025-11-12
		138	Ovalbumin content	ChP2025 Vol III, monographs		2025-11-12
		139	Protein Content (catalysed oxidising pyrolysis and chemiluminescence)	JS20210014、JS20210015 2.9		2024-07-10
		140	residual bovine serum albumin	ChP2025 Vol III/IV, general rule (3411)		2025-11-12
		141	sucrose content	ChP 2025Vol IVgeneral rule (0621)		2025-11-12
		142	Test for abirritation potency	Registration Standards JS20200047		2024-07-10
		143	Test for Mycoplasma	ChP 20250 Vol IIIgeneral rule (3301)		2025-11-12
		144	Filling	ChP2025 VolIII/IV General rule (0100)		2025-11-12
		145	Content uniformity	ChP20205 VolIII/IV General rule (0100)		2025-11-12
		146	UV spectrum test	ChP 2025 Vol III/IV general rule (0401)		2025-11-12
		147	Analysis of ultraviolet absorption spectroscopy	ChP2025 Vol III/IV, general rule (0401)		2025-11-12
		148	Test for dextrose concentration (Anthrone	ChP2010 VolIII, sup2		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			method)			
		149	Test for minimum filling	ChP2025 Vol III/IV General rule (0942)		2025-11-12
		150	Haemagglutinin content	ChP2025 Vol III, monographs		2025-11-12
		151	Potency test (animal method)	Human papillomavirus vaccine in vivo potency assay NIFDC-SOP-B-T-0545		2024-07-10
		152	Potency test (Serum antibody)	ChP2025 Vol III, monographs		2025-11-12
		153	Potency test (cell method)	Human papillomavirus neutralization assay NIFDC-SOP-B-T-0568		2024-07-10
		154	Potency test (ELISA)	National Drug Standards YBS01402011		2024-07-10
		155	Potency (in-vitro)	ChP 2025 Vol III general rule (3501),(3502)		2025-11-12
		156	Identity test (multi-PCR)	ChP2025 Vol III, monographs, Imported drug registration standards		2025-11-12
		157	NACL content Total Chlorines Titration	Imported drug registration standards JS20210027		2024-07-10
		158	Test for the absence of contaminating organisms (phage bacteriolytic test)	ChP2025 Vol III, monographs		2025-11-12
		159	test for Mycobacteria (culture)	ChP2025 Vol III, monographs		2025-11-12
		160	Capillary gel electrophoresis (reduced and none	ChP2025 Vol III/IV General rule (3127)		2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			reduced CE-SDS)			
		161	Allergen biological activity (UNICAP)	Imported drug registration standards, Drug registration standards, National food and drug administration standards JS20210014、JS20210015、JS20190028、JS20190020, YBS00222019, WS4- (S-012)-2010Z		2024-07-10
		162	Allergen biological activity (ELISA Inhibition)	Imported drug registration standards JS20210014、JS20210015、JS20210027		2024-07-10
		163	Allergen identification	ChP 2025 Vol IV general rule 0512		2025-11-12
				Imported drug registration standards JS20200049 Method 1		2024-07-10
				ChP 2025 Vol IV general rule 0521		2025-11-12
				Imported drug registration standards JS20200049 Method 2		2024-07-10
		164	Allergen Assay	ChP 2025 Vol IV general rule 0512		2025-11-12
				Imported drug registration standards JS20200049 Method 1		2024-07-10
				ChP 2025 Vol III general rule 0405		2025-11-12
				Imported drug registration standards JS20200049 Method 2		2024-07-10
				ChP 2025 Vol IV general rule 0521		2025-11-12
				Imported drug registration standards JS20200049 Method 3		2024-07-10
		165	Antibiotic resistance	ChP 2025 Vol III, Monographs		2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		166	Electron microscopy	ChP2025 VolⅢ,Monographs		2025-11-12
		167	Expression level	ChP2025 VolⅢ,Monographs		2025-11-12
		168	Plasmid examination	ChP2025 VolⅢ,Monographs		2025-11-12
		169	Test for residual virulence	ChP2025 VolⅢ,Monographs		2025-11-12
		170	Tests for dissociation	ChP2025 VolⅢ,Monographs		2025-11-12
		171	Serological test	ChP2025 VolⅢ,Monographs		2025-11-12
		172	Cultural characteristics	ChP2025 VolⅢ,Monographs		2025-11-12
		173	Microscopic examination of stained smears	ChP2025 VolⅢ,Monographs		2025-11-12
		174	Determination of residual polysorbate 20 content	Drug registration standards		2025-11-12
		175	Test for virulence	ChP2025 VolⅢ,Monographs		2025-11-12
		176	sedimentation rate	ChP2025 VolⅢ,Monographs		2025-11-12
		177	test for viability	ChP2025 VolⅢ,Monographs		2025-11-12
		178	test for Antitumor activity	ChP2025 VolⅢ,Monographs		2025-11-12
		179	test for content of CpG	Standard Operation Procedure NIFDC-SOP-B-T-6077		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		180	Hemagglutination inhibition	ChP 2025 Vol III		2025-11-12
		181	Virus identity(RFLP)	ChP 2025 Vol III		2025-11-12
		182	Antibody Titer Detection(FAMA)	ChP 2025 Vol III		2025-11-12
		183	Antibody Titer Detection(pseudovirus neutralization)	ChP 2025 Vol III		2025-11-12
		184	Antibody Titer Detection(micro plate neutralization)	ChP 2025 Vol III		2025-11-12
		185	Determination of residual exogenous DNA	ChP2025 Vol III, general rule (3407)		2025-11-12
		186	Detection of target antigen expression	ChP2025 Vol III, Monographs		2025-11-12
		187	Detection of RCA	ChP2025 Vol III, Monographs		2025-11-12
		188	Virus Titration (Animal)	ChP2025 Vol III, Monographs		2025-11-12
		189	Immunogenicity (Animal)	ChP2025 Vol III, Monographs		2025-11-12
		190	Virus inactivated validation (Animal)	ChP2025 Vol III, Monographs		2025-11-12
		191	Reverse transcriptase	ChP 2025 Vol III general rule 1. 1. Pharmacopoeia of the People's Republic of China 2020, General Principles of Biological Products, Part III, Regulation on preparation and verification of animal cell substrates for the production and verification of		2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				biological products		
		192	Viral nucleic acid (qPCR)	human immunodeficiency virus type 1 RNA detection assay NIFDC-SOP-B-T-0564		2024-07-10
		193	Capillary zone electrophoresis (CZE)	ChP 2025 Vol III general rule (0542)		2025-11-12
		194	Hydrophobic chromatography (HIC - HPLC)	ChP 2025 Vol III general rule (0512)		2025-11-12
		195	Ion exchange chromatography (IEC-HPLC)	ChP 2025 Vol III general rule (0512)		2025-11-12
		196	Reversre Phase chromatography (RP-HPLC)	ChP 2015 Vol III general rule (0512)		2024-07-10
		197	Capillary isoelectric focusing electrophoresis (cIEF)	ChP 2025 Vol III general rule (0542)		2025-11-12
		198	imaged Capillary isoelectric focusing electrophoresis (iCIEF)	ChP 2025 Vol III general rule (0542)		2025-11-12
		199	Dissolution time	Dissolution time test of Monoclonal antibody product NIFDC-SOP-B-T-3030		2024-07-10
		200	Color	ChP 2025 Vol III general rule (0901)		2025-11-12
				EP 11 <2.2.2>		2024-07-10



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		№	Item/ Parameter			
		201	Clarity	ChP 2025 Vol III general rule (0902)		2025-11-12
				EP 11 <2.2.1>		2024-07-10
		202	N-terminal amino acid sequence	ChP 2025 Vol III general rule (0512)		2025-11-12
		203	monocyte activation	General principles of four parts of Chinese Pharmacopoeia 2025 Edition (9301) 9301		2025-11-12
		204		1. Pharmacopoeia of the People's Republic of China 2025, Part III, General Principles of Biological Products, Regulation on preparation and verification of animal cell substrates for the production and verification of biological products 2. EP11.0,01/2018: 50203 (5.2.3) Cell substrates for the production of vaccines for human use3. Pharmacopoeia General Rule 3429, Immunochemistry, labelling immunochemistry-3 Immunofluorescence Analysis, -5 Flow Cytometry Pharmacopoeia of the People's Republic of China 2020, General Principles of Biological Products, Part III, Regulation on preparation and verification of animal cell substrates for the production and verification of biological products	NEW	2025-11-12
		205		1. Pharmacopoeia of the People's Republic of China 2025, Part III, General Principles of Biological Products, Regulation on preparation and verification of animal cell substrates for the production and verification of biological products. 2.EP11.0, 01/2018:50203 (5.2.3) Cell substrates for the production of vaccines for human use Pharmacopoeia of the People's Republic of China 2020, General Principles of Biological Products, Part III, Regulation on preparation and verification of animal cell substrates for the production and verification of biological products		2025-11-12



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		№	Item/ Parameter			
		206		1. Pharmacopoeia of the People's Republic of China 2025, Part III, General Principles of Biological Products, Regulation on preparation and verification of animal cell substrates for the production and verification of biological products. 2.EP11.0, 01/2018:50203 (5.2.3) Cell substrates for the production of vaccines for human use Pharmacopoeia of the People's Republic of China 2020, General Principles of Biological Products, Part III, Regulation on preparation and verification of animal cell substrates for the production and verification of biological products		2025-11-12
		207		1. Pharmacopoeia of the People's Republic of China 2025, Part III, General Principles of Biological Products, Regulation on preparation and verification of animal cell substrates for the production and verification of biological products. 2.EP 11.0, 01/2018:50203 (5.2.3) Cell substrates for the production of vaccines for human use Pharmacopoeia of the People's Republic of China 2020, General Principles of Biological Products, Part III, Regulation on preparation and verification of animal cell substrates for the production and verification of biological products		2025-11-12
		208		1. Pharmacopoeia General Rule 3429, Immunochemistry, labelling immunochemistry-5 Flow Cytometry2. Pharmacopoeia General Rule 3429, Immunochemistry, labelling immunochemistry-3 Immunofluorescence Analysis 3. Pharmacopoeia General Rule 3429, Immunochemistry, labelling immunochemistry-1 enzyme-linked immuno sorbent assay 4. Pharmacopoeia of the People's Republic of China 2025, Part IV, General Principles of Biological Products, Polymerase chain reaction method		2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		209		1. Pharmacopeia General Rule 3429, Immunochemistry, labelling immunochemistry-1 enzyme-linked immuno sorbent assay 2. Pharmacopeia General Rule 3429, Immunochemistry, labelling immunochemistry-2 Western blotting 3. 2. Pharmacopeia General Rule 3429, Immunochemistry, labelling immunochemistry-3 Immunofluorescence Analysis 4. 1. Pharmacopoeia General Rule 3429, Immunochemistry, labelling immunochemistry-5 Flow Cytometry 5. 4. Pharmacopoeia of the People's Republic of China 2025, Part IV, General Principles of Biological Products, Polymerase chain reaction method 6. Detection of markers for cell heredity		2025-11-12
				SOP for Teratoma Formation Pluripotency Testing of Pluripotent Stem Cells (HE Staining) &SOP for Teratoma Formation Pluripotency Testing of Pluripotent Stem Cells (in Vivo Inoculation) NIFDC-SOP-B-T-0704, NIFDC-SOP-B-T-0705		2024-07-10
		210		1. Pharmacopoeia of the People's Republic of China 2025, General Principles of Biological Products, Part III, Regulation on preparation and verification of animal cell substrates for the production and verification of biological products 2. EP11.0, 01/2018:50203 (5.2.3)Cell substrates for the production of vaccines for human use Pharmacopoeia of the People's Republic of China 2020, General Principles of Biological Products, Part III, Regulation on preparation and verification of animal cell substrates for the production and verification of biological products		2025-11-12
				Plasmid DNA Isoforms detection (capillary electrophoresis-capillary gel electrophoresis method, CE-CGE method)Pharmacopoeia General Rule 0542 capillary electrophoresis		2024-07-10
		211				



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		№	Item/ Parameter			
		212		Mycoplasma nucleic acid detection (NAT method), EP11.0 01/2008: 20607 corrected 6.1 (2.6.7) Mycoplasmas		2024-07-10
		213		EP11.0, 01/2018:50203 (5.2.3) Cell substrates for the production of vaccines for human use Pharmacopoeia of the People's Republic of China 2020, General Principles of Biological Products, Part III, Regulation on preparation and verification of animal cell substrates for the production and verification of biological products		2025-11-12
		214	16S ribosomal RNA gene sequencing of Bacteria	China Pharmacopoeia Vol. IV General Notices 1021		2025-11-12
		215	Target gene sequencing	method of Sanger sequencing GB/T 34265 2017	Target gene sequencing of Microorganism and Biological product	2024-07-10
		216	Rapid microbiological method for sterility testing	Rapid microbiological methods (respiratory signal detection technology) for cell-based preparations Chinese Pharmacopoeia, 2025 Edition, Guidelines for rapid microbiological methods for cell-based preparations 9406		2025-11-12
		217	Identification for tissue origin of human mesenchymal stem cells	Identification for tissue origin of human mesenchymal stem cells(Statistical Learning method) NIFDC-SOP-B-T-0720	A statistical learning model was established based on gene expression profile data	2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					to identified the tissue origin of human mesenchymal stem cells	
		218	Test for integrated gene copy numbers of Gene-modified cells	Test for integrated gene copy numbers of Gene-modified cells by digital PCR (ddPCR) NIFDC-SOP-B-T-0721		2024-07-10
		219	Test for Infectious titer of lentivirus vector	Test for lentivirus vector's infectious titer by digital PCR (ddPCR) NIFDC-SOP-B-T-0722		2024-07-10
		220	Hyaluronidase activity	Hyaluronidase activity Drug registration standards JS20220034		2024-07-10
		221	Potency of monoclonal antibody	Surface Plasmon Resonance Drug registration standards JS20210035		2024-07-10
		222	Protein content	Protein content Drug registration standards		2024-07-10
		223	protein content (bradford)	ChP 2025 Vol III general rule 0731		2025-11-12
				Drug registration standards WS4-(S-012)-2010Z		2024-07-10
		224	histamine content	Imported drug registration standards JS20210027		2024-07-10
		225	histamine content	Drug registration standards YBS00222019		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				ChP 2025 1859 页 Vol II		2025-11-12
		226	Glycerin Content	ChP 2025 133 页 Vol II		2025-11-12
				Drug registration standards YBS00222019		2024-07-10
		227	Antibody detection (OPA/MOPA)	Multiplexed opsonophagocytic killing assay (MOPA) Refer to the WHO recommended methods. WHO Workshop on Standardization of Pneumococcal Opsonophagocytic Assay, Geneva, Switzerland, 25-26 January 2007.		2025-07-18
		228	Detection of polysaccharide and free polysaccharide content by ion-exchange chromatography	ion-exchange chromatography Chinese Pharmacopoeia, 2025 Edition, Part 3, 0513		2025-11-12
		229	Telomerase activity detection	Telomerase Activity Detection (RQ-TRAP) Method NIFDC-SOP-B-T-0740		2025-07-18
Laboratory Animals						
1	Laboratory Animals	1	Salmonella spp.	Laboratory animal-Method for examination of Salmonella spp. GB/T14926.1-2001	only for M、R、H、GP、Rab、D、Mon、treeshrew、Gerbil	2024-07-10
				Defection methods of Salmonella for animal and animal products NY/T 550-2002	only for Pig	2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		2	Yersinia spp.	Laboratory animal-Method for examination of Yersinia spp. GB/T14926.3-2001	only for M、R、H、GP、Rab、D、Mon、	2024-07-10
		3	Pathogenic dermal fungi	Laboratory animal-Method for examination of Pathogenic dermal fungi GB/T14926.4-2001	only for M、R、H、GP、Rab、D、Mon、treeshrew、Pig、Gerbil	2024-07-10
		4	Streptobacillus moniliformis	Laboratory animal-Method for examination of Streptobacillus moniliformis GB/T14926.44-2001	only for M、R、H、GP	2024-07-10
		5	Bordetella bronchiseptica	Laboratory animal-Method for examination of Bordetella bronchiseptica GB/T14926.6-2001	only for R、H、GP、Gerbil	2024-07-10
		6	Mycoplasma spp.	Laboratory animal-Method for examination of Mycoplasma spp. GB/T14926.8-2001	only for M、R、Pig、Gerbil	2024-07-10
		7	Corynebacterium kutscheri	Laboratory animal-Method for examination of Corynebacterium kutscheri GB/T14926.9-2001	only for M、R、Gerbil	2024-07-10
		8	Tyzzer's organism	Laboratory animal-Method for examination of Tyzzer's organism	only for	2024-07-10

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				GB/T14926.10-2008	M、R、 H、GP、 Rab、 Gerbil	
		9	Escherichia coli O115 a,C:K(B)	Laboratory animal-Method for examination of Escherichia coli O115 a,C:K(B) GB/T14926.11-2001	only for M、Gerbil	2024-07-10
		10	Pasteurella pneumotropica	Laboratory animal-Method for examination of Pasteurella pneumotropica GB/T14926.12-2001	only for M、R、 H、GP、 Rab、 Gerbil	2024-07-10
		11	Klebsiella pneumonia	Laboratory animal-Method for examination of Klebsiella pneumonia GB/T14926.13-2001	only for M、R、 H、GP、 Rab、 Gerbil	2024-07-10
		12	Staphylococcus aureus	Laboratory animal-Method for examination of Staphylococcus aureus GB/T14926.14-2001	only for M、R、 H、GP、 Rab、 treeshrew 、Gerbil	2024-07-10
		13	Streptococcus pneumonia	Laboratory animal-Method for examination of Streptococcus pneumonia GB/T14926.15-2001	only for M、R、 H、GP、 Rab、 treeshrew 、Gerbil	2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		14	β -hemolytic streptococcus	Laboratory animal-Method for examination of β -hemolytic streptococcus GB/T14926.16-2001	only for M、R、H、GP、Rab、treeshrew、Gerbil	2024-07-10
		15	Pseudomonas aeruginosa	Laboratory animal-Method for examination of Pseudomonas aeruginosa GB/T14926.17-2001	only for M、R、H、GP、Rab、treeshrew、Gerbil	2024-07-10
		16	Pasteurella multocida	Laboratory animal-Method for examination of Pasteurella multocida GB/T14926.5-2001	only for H、GP、Rab、Gerbil	2024-07-10
		17	Brucella spp.	Laboratory animal-Method for examination of Brucella spp. GB/T14926.45-2001	only for D	2024-07-10
		18	Leptospira spp.	Laboratory animal-Method for examination of Leptospira spp. GB/T14926.46-2008	only for D、Pig	2024-07-10
		19	Shigella spp.	Laboratory animal-Method for examination of Shigella spp. GB/T14926.47-2008	only for Mon.	2024-07-10
		20	Mycobacterium tuberculosis	Laboratory animal-Method for examination of Mycobacterium tuberculosis GB/T14926.48-2001	only for Mon.、treeshrew	2024-07-10
		21	Campylobacter jejuni	Laboratory animal-Method for examination of Campylobacter jejuni GB/T14926.49-2001	only for D、Mon.、treeshrew	2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		22	Detection of germ-free(Bacteria and fungi)	Laboratory animal-Method for examination of environment and faeces for GF animals GB/T14926.41-2001	only for M、R、H、GP、Rab、Gerbil、water、fodder、padding、faeces、environmental samples	2024-07-10
		23	Lymphocytic Choriomeningitis Virus	Laboratory animal-Method for examination of Lymphocytic Choriomeningitis Virus GB/T14926.18-2001	only for M、H、GP、Gerbil	2024-07-10
		24	Hantavirus	Laboratory animal-Method for examination of Hantavirus GB/T14926.19-2001	only for M、R、Gerbil	2024-07-10
		25	Ectromelia Virus	Laboratory animal-Method for examination of Ectromelia Virus GB/T14926.20-2001	only for M	2024-07-10
		26	Mouse Hepatitis Virus	Laboratory animal-Method for examination of Mouse Hepatitis Virus GB/T14926.22-2001	only for M、treeshrew、Gerbil	2024-07-10
		27	Sendai Virus	Laboratory animal-Method for examination of Sendai Virus GB/T14926.23-2001	only for M、R、H、GP、Rab、	2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					Gerbil	
		28	Pneumonia Virus of Mice	Laboratory animal-Method for examination of Pneumonia Virus of Mice GB/T14926.24-2001	only for M、R、H、GP、Gerbil	2024-07-10
		29	Reovirus type Ⅲ	Laboratory animal-Method for examination of Reovirus type Ⅲ GB/T14926.25-2001	only for M、R、H、GP、Gerbil	2024-07-10
		30	Minute Virus of Mice	Laboratory animal-Method for examination of Minute Virus of Mice GB/T14926.28-2001	only for M、Gerbil	2024-07-10
		31	Theiler's Mouse Encephalomyelitis Virus	Laboratory animal-Method for examination of Theiler's Mouse Encephalomyelitis Virus GB/T14926.26-2001	only for M	2024-07-10
		32	Mouse Adenovirus	Laboratory animal-Method for examination of Mouse Adenovirus GB/T14926.27-2001	only for M	2024-07-10
		33	Polyoma Virus	Laboratory animal-Method for examination of Polyoma Virus GB/T14926.29-2001	only for M	2024-07-10
		34	Rat Parvovirus (KRV and H-1 strain)	Laboratory animal-Method for examination of Rat Parvovirus(KRV and H-1 strain) GB/T14926.31-2001	only for R	2024-07-10
		35	Rat corona virus (RCV)/sialodacryoadenitis virus (SDAV)	Laboratory animal-Method for examination of rat corona virus (RCV)/sialodacryoadenitis virus (SDAV) GB/T14926.32-2001	only for R	2024-07-10
		36	Rabbit hemorrhagic disease Virus	Laboratory animal-Method for examination of Rabbit Hemorrhagic Disease Virus (RHDV) GB/T14926.21-2008	only for Rab	2024-07-10
		37	Rabbit Rotavirus	Laboratory animal-Method for examination of Rabbit Rotavirus (RRV) GB/T14926.30-2001	only for Rab	2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		38	Rabies Virus	Laboratory animal-Method for examination of Rabies Virus GB/T14926.56-2008	only for D	2024-07-10
		39	Canine Parvovirus	Laboratory animal-Method for examination of Canine Parvovirus GB/T14926.57-2008	only for D	2024-07-10
		40	Canine Distemper Virus	Laboratory animal-Method for examination of Canine Distemper Virus (CDV) GB/T14926.59-2001	only for D	2024-07-10
		41	Infectious Canine Hepatitis Virus	Laboratory animal-Method for examination of Infectious Canine Hepatitis Virus GB/T14926.58-2008	only for D	2024-07-10
		42	Cercopithecine herpesvirus 1 (B virus)	Laboratory animal-Method for examination of cercopithecine herpesvirus 1 (B virus) GB/T14926.60-2001	only for Mon	2024-07-10
		43	Simian Retrovirus D	Laboratory animal-Method for examination of Simian Retrovirus D (SRV) GB/T14926.61-2001	only for Mon	2024-07-10
		44	Simian Immunodeficiency Virus	Laboratory animal-Method for examination of Simian Immunodeficiency Virus (SIV) GB/T14926.62-2001	only for Mon	2024-07-10
		45	Simian T Lymphotropic Virus type	Laboratory animal-Method for examination of Simian T Lymphotropic Virus type 1 (STLV-1) GB/T14926.63-2001	only for Mon	2024-07-10
		46	Simian Pox Virus	Laboratory animal-Method for examination of Simian Pox Virus (SPV) GB/T14926.64-2001	only for Mon	2024-07-10
		47	Detection virus from mice	Chinese Pharmacopoeia ,section 3(2025version) General principle 3303 Detection virus from mice	Biological products from Mice	2025-11-12
		48	Ectoparasites	Laboratory animal-Method for examination of Ectoparasites GB/T18448.1-2001	only for M、R、H、GP、Rab、D、Mon、	2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					treeshrew 、 Pig、 Sheep、 Gerbil	
		49	Toxoplasma gondii	Laboratory animal-Method for examination of Toxoplasma gondii GB/T18448.2-2008	only for M、 R、 H、 GP、 Rab、 D、 Mon、 treeshrew 、 Pig、 sheep、 goat、 Gerbil	2024-07-10
		50	Encephalitozoon cuniculi	Laboratory animal-Method for examination of Encephalitozoon cuniculi GB/T18448.3-2001	only for M、 R、 GP、 Rab、 Gerbil	2024-07-10
		51	Pneumocystis carinii	Laboratory animal-Method for examination of Pneumocystis carinii GB/T18448.4-2001	only for M、 R、 Rab、 Gerbil	2024-07-10
		52	Eimeria spp.	Laboratory animal-Method for examination of Eimeria spp. GB/T18448.5-2001	only for H、 Rab	2024-07-10
		53	Helminth	Laboratory animal-Method for examination of Helminth GB/T18448.6-2001	only for M、 R、 H、 GP、	2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					Rab、D、 Mon、 treeshrew Pig、 Gerbil	
		54	Plasmodium spp.	Laboratory animal-Method for examination of Plasmodium spp. GB/T18448.7-2001	only for Mon	2024-07-10
		55	Dirofilaria immitis	Laboratory animal-Method for examination of Dirofilaria immitis GB/T18448.8-2001	only for D	2024-07-10
		56	Entamoeba histolytica	Laboratory animal-Method for examination of Entamoeba histolytica GB/T18448.9-2001	only for D、 Mon	2024-07-10
		57	Flagellata and ciliata	Laboratory animal--Method for examination of Flagellata and ciliata GB/T18448.10-2001	only for M、 R、 H、 GP、 Rab、 D、 Mon、 treeshrew 、 Gerbil	2024-07-10
		58	Immunogene Monitoring in the Inbred Strain of Mice- Microcytotoxicity Test	Laboratory animal-immunological marker of inbred mice and rats GB/T14927.2-2008	only for M	2024-07-10
		59	Biochemical markers in experimental mice	Laboratory animal-Genetic monitoring: methods for biochemical markers of inbred mice and rats GB/T14927.1-2008	only for M	2024-07-10
		60	Biochemical markers in	Laboratory animal-Genetic monitoring: methods for biochemical markers of inbred mice and rats GB/T14927.1-2008	only for R	2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			experimental rats			
		61	Skin grafting of inbred mice and rats	Laboratory animal-immunological marker of inbred mice and rats GB/T14927.2-2008	only for M、R	2024-07-10
		62	Laboratory animal pathology	Medical Laboratory Animal Monitoring Manual: Laboratory Animal Pathology Monitoring Booklet (Ministry of Public Health,1992) ,Summary of Laboratory Animal Pathology Monitoring(non-standard method)	only do gross anatomy, pathological slices and observation ;and only for M、R、 H、 GP、 Rab、 D、 Mon	2024-07-10
		63	Laboratory animal physiological biochemistry	National Guide to Clinical Laboratory Procedures(Forth Edition)blood, body fluid and chemistry analysis(2015)	only for M、 R、 H、 GP、 Rab、 D、 Mon	2024-07-10
		64	Validation of virus inactivation and clearance	The guidelines for the methods and validation of virus inactivation and clearance in blood products (2002)		2024-07-10
				General principles for review of virus safety assessment techniques for biological tissue extracts and eukaryotic expression products (2005)		2024-07-10
				Medical devices utilizing animal tissues and their derivatives Part 3:Validation of the elimination and/or inactivation of viruses and Transmissible Spongiform Encephalopathy(TSE) agents YY/T		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				0771.3-2009		
				Basic technical requirements of multi component biochemical drug injection (Trial Implementation,2008)		2024-07-10
				viral safety evaluation of biotechnology products derived from cell lines of human or animal origin ICH Q5A (R2) (Adopted on Novemeber 1,2023)		2025-07-18
		65	Salmonella pullorum	SPF chicken-Microbiological surveillance-Part 4: Serum plate agglutination test for SPF chicken GB/T17999.4-2008		2024-07-10
				Diagnostic techniques for fowl typhoid and pullorum disease NY/T 536-2017	only for chicken	2024-07-10
				SPF chicken-Microbiological surveillance-Part 8: Examination of Salmonella pullorum for SPF chicken GB/T17999.8-2008		2024-07-10
				SPF chicken-Microbiological surveillance-Part 9: Tube agglutination test for SPF chicken GB/T17999.9-2008		2024-07-10
		66	Avibacterium paragallinarum	SPF chicken-Microbiological surveillance-Part 4: Serum plate agglutination test for SPF chicken GB/T17999.4-2008		2024-07-10
				SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008		2024-07-10
				Diagnostic techniques for infectious coryza of chickens NY/T 538-2015		2024-07-10
		67	Pasteurella multocida	SPF chicken-Microbiological surveillance-Part 5: Agar gel precipitation test for SPF chicken GB/T17999.5-2008		2024-07-10
				Diagnostic techniques for fowl cholera (avian pasteurellosis) NY/T 563-2016		2024-07-10
		68	Mycoplasma gallisepticum	SPF chicken-Microbiological surveillance-Part 2: Hemagglutination inhibition test for SPF chicken GB/T17999.2-2008		2024-07-10
				SPF chicken-Microbiological surveillance-Part 4: Serum plate agglutination test for SPF chicken GB/T17999.4-2008		2024-07-10



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		69	Mycoplasma synoviae	SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked GB/T17999.6-2008 3		2024-07-10
				Detection of avian mycoplasmas by polymerase chain reaction (PCR) NY/T 553-2015		2024-07-10
				SPF chicken-Microbiological surveillance-Part 2: Hemagglutination inhibition test for SPF chicken GB/T17999.2-2008		2024-07-10
				SPF chicken-Microbiological surveillance-Part 4: Serum plate agglutination test for SPF chicken GB/T17999.4-2008		2024-07-10
				SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008		2024-07-10
				Detection of avian mycoplasmas by polymerase chain reaction (PCR) NY/T 553-2015		2024-07-10
		70	Avian Influenza Virus	SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008		2024-07-10
		71	Newcastle Disease Virus	SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008		2024-07-10
		72	Infectious Bronchitis Virus	SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008		2024-07-10
		73	Infectious Laryngotracheitis Virus	SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008		2024-07-10
		74	Infectious Bursal Disease Virus	SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008		2024-07-10
		75	Lymphoid Leukosis Virus	SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008		2024-07-10
		76	Reticuloendotheliosis Virus	SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008		2024-07-10
		77	Marek's Disease Virus	SPF chicken-Microbiological surveillance-Part 5: Agar gel precipitation test for SPF chicken GB/T17999.5-2008		2024-07-10



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		78	Chicken Infectious Anaemia Virus	SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008		2024-07-10
		79	Avian Reovirus	SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008		2024-07-10
		80	Avian Encephalomyelitis Virus	SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008		2024-07-10
		81	Avian Adenovirus Group I	SPF chicken-Microbiological surveillance-Part 5: Agar gel precipitation test for SPF chicken GB/T17999.5-2008		2024-07-10
		82	Avian Adenovirus Group III	SPF chicken-Microbiological surveillance-Part 2: Hemagglutination inhibition test for SPF chicken GB/T17999.2-2008		2024-07-10
				SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008		2024-07-10
		83	Fowl Pox Virus	SPF chicken-Microbiological surveillance-Part 5: Agar gel precipitation test for SPF chicken GB/T17999.5-2008		2024-07-10
		84	detection of avian virus	ChP. ChP.2025.Vol.III 3308and monographs		2025-11-12
		85	Classical swine fever virus, CSFV	Diagnostic techniques for classical swine fever(hog cholera) GB/T 16551-2020 7.3		2024-07-10
		86	Porcine reproductive and respiratory syndrome virus, PRRSV	Diagnostic techniques for porcine reproductive and respiratory syndrome GB/T 18090-2023 13		2024-07-10
		87	Pseudorabies virus, PrV	Diagnostic method for pseudorabies GB/T 18641-2018 7	only for Pig	2024-07-10
		88	Porcine parvovirus, PPV	Indirect ELISA for detection of antibodies against porcine parvovirus NY/T 2840-2015		2024-07-10



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		89	Porcine circovirus type2, PCV2	Detecting porcine circovirus with polymerase chain reaction GB/T 21674-2008		2024-07-10
		90	Porcine transmissible gastroenteritis virus, TGEV	Quarantine protocol for transmissible gastroenteritis of swine SN/T 1446-2010 5.5		2024-07-10
		91	Swine vesicular disease virus, SVDV	Quarantine protocol for swine vesicular disease SN/T 2702-2010 5.7		2024-07-10
		92	Bordetella bronchiseptica	Detection of infectious atrophic rhinitis for swine NY/T 546-2015 6.2.2.1/6.3.1.1/6.4		2024-07-10
		93	Pasteurella multocida	Detection of infectious atrophic rhinitis for swine NY/T 546-2015 6.2.2.2/6.3.2.1/6.4		2024-07-10
				NY/T 564-2002 Diagnostic techniques for swine pasteurellosis NY/T 564-2016 4.2/4.4		2024-07-10
		94	Actinobacillus pleuropneumoniae, APP	Diagnostic techniques for porcine contagious pleuropneumonia NY/T 537-2023 7-9		2024-07-10
		95	Streptococcus suis type 2	Procedure of plate and tube agglutination for Streptococcus suis type 2 GB/T 19915.1-2005		2024-07-10
				Methods for detection of Streptococcus suis type 2 GB/T 19915.2-2005		2024-07-10
				Method for detection Streptococcus suis type 2 by PCR GB/T 19915.3-2005		2024-07-10
				Method of the real-time PCR for the detection of Streptococcus suis type 2 GB/T 19915.7-2005		2024-07-10
		96	coccidium	Diagnostic techniques for animal coccidiosis GB/T 18647-2020 4.3.1	only for Pig	2024-07-10
		97	Vibrio cholerae	National Food Safety Standards Food microbiological testing Examination of Vibrio Parahaemolyticus GB 4789.7-2013 5	only for fish	2024-07-10



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		№	Item/ Parameter			
		98	Aeromonas hydrophila	Rules for quarantining bacterial diseases of fish Part3: Diagnostic method for bacterial enteritis SC/T 7201.3-2006		2024-07-10
		99	Streptococcus iniae	Method for examination of Streptococcus pneumonia GB/T 14926.15-2001	only for fish	2024-07-10
		100	Flavobacterium columnare	Rules for quarantining bacterial diseases of fish Part 2: Diagnostic method for gill-rot disease SC/T 7201.2-2006		2024-07-10
		101	Aeromonas veronii	Methods for detection of pathogenic aeromonas hydrophila GB/T 18652-2002	only for fish	2024-07-10
		102	Aeromonas jandaei	Methods for detection of pathogenic aeromonas hydrophila GB/T 18652-2002	only for fish	2024-07-10
		103	Saprolegnia spp.	National Food Safety Standards Food microbiological testing Enumeration of molds and yeasts GB 4789.15-2016	only for fish	2024-07-10
		104	Branchiomyces spp.	Protocol of quarantine for branchiomycosis of fish SN/T 2439-2010		2024-07-10
		105	Flavobacterium branchiophilum	Rules for quarantining bacterial diseases of fish Part 2: Diagnostic method for gill-rot disease SC/T 7201.2-2006		2024-07-10
		106	Flavobacterium psychrophilum	Rules for quarantining bacterial diseases of fish Part 2: Diagnostic method for gill-rot disease SC/T 7201.2-2006		2024-07-10
		107	Pseudomonas spp.	Rules for quarantining bacterial diseases of fish Part 4: Diagnostic method for Red-skin disease SC/T 7201.4-2006		2024-07-10
		108	Aeromonas sobri	Methods for detection of pathogenic aeromonas hydrophila GB/T 18652-2002		2024-07-10
		109	Streptococcus spp.	Laboratory animal-Method for examination of Streptococcus pneumonia and β hemolytic streptococcus GB/T 14926.15 and GB/T 14926.16	only for fish	2024-07-10
		110	Erysipelothrix rhusiopathiae	Diagnostic techniques for swine erysipelas NY/T 566-2019		2024-07-10
		111	Haemophilus parasuis	Detection methods for haemophilus parasuis GB/T 34750-2017		2024-07-10



№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		112	Coxiella burnetii	Quarantine protocol for Q fever SN/T 1087-2011 4.3	only for sheep and goat	2024-07-10
		113	Bacillus anthracis	Diagnostic techniques for animal anthrax NY/T 561-2015 6.6	only for sheep and goat	2024-07-10
		114	trichinella	Diagnostic techniques for trichinella spp. GB/T 18642-2021 5	only for Pig	2024-07-10
		115	cysticercus	Diagnostic techniques for cysticercosis cellulosa GB/T 18644-2020 4	only for Pig	2024-07-10
		116	echinococcus	Diagnostic techniques for animal echinococcosis NY/T 1466-2018 3.3	only for sheep and goat	2024-07-10
		117	Highly pathogenic porcine reproductive and respiratory syndrome virus	A multiplex RT-PCR method to differentiate the highly pathogenic and classical porcine reproductive and respiratory syndrome virus GB/T 27517-2011		2024-07-10
		118	SV40 (Simian vacuolating virus)	Pharmacopoeia of the People's Republic of China (2025 edition, part III) general rule 3304	Biological products derived from animal	2025-11-12
		119	Foot and mouth disease virus	Real-time RT-PCR for detection of foot and mouth disease virus GB/T 27528-2011	only for sheep and goat	2024-07-10
				Diagnostic techniques for foot and mouth disease GB/T 18935-2018 15	only for pig	2024-07-10
		120	Peste des petits ruminants virus	Diagnostic techniques for peste des petits ruminants GB/T 27982-2011 6.5		2024-07-10
		121	Sheep/ goat pox	Clinical diagnostic technology for sheep pox and goat pox NY/T		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			virus	576-2015 4.3.5		
		122	Validation of sterilization by liquid sterilants	Sterilization of single — use medical devices incorporating materials of animal origin — Validation and routine control of sterilization by liquid sterilants YY0970-2013	materials of animal origin	2024-07-10
				Sterilization of health care products — Biological indicators — Part 1: General requirements Sterilization of health care products — Biological indicators — Part 1: General requirements GB/T 19973.1-2023		2025-07-18
				Sterilization of medical devices — Microbiological methods— Part 1: Determination of a population of microorganisms on products		2024-07-10
		123	Helicobacter pylori	《BERGEY'S MANUAL OF Systematic Bacteriology, Second Edition》Volume Two, The Proteobacteria, Part C The Alpha-, Beta-, Delta-, and Epsilonproteobacteria. Order I. Campylobacterales ord. nov., Family II. Helicobacteraceae fam. nov., Genus I. Helicobacter	only for M、Gerbil	2024-07-10
		124	Klebsiella oxytoca	《BERGEY'S MANUAL OF Systematic, Bacteriology Second Edition》Volume Two, The Proteobacteria, Part B The Gammaproteobacteria Order XIII. Enterobacteriales. Family I. Enterobacteriaceae, Genus XVI. Klebsiella SN/T 2552.9-2010	only for M、Gerbil	2024-07-10
		125	DNA barcode	Laboratory animal-Quality control of laboratory fish GB/T 39649-2020 4	Except for 4.2.3.3	2024-07-10
		126	microsatellite markers	Laboratory animal-Methods for microsatellite markers of laboratory mice & rats T/CALAS 21-2017	Except for 4.4.6	2024-07-10
		127	Helicobacter spp.	Laboratory animal- PCR Method for the detection of Helicobacter T/CALAS 24-2017	only for Mouse	2024-07-10
		128	Corynebacterium bovis	Laboratory animal-Method for examination of Corynebacterium bovis T/CALAS 20-2017	only for Mouse	2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		129	Mycobacterium tuberculosis	Real-time PCR method for the detection of tuberculosis pathogenic organisms GB/T 27639-2011	only samples of Hamster, monkey	2024-07-10
		130	Burkholderia mallei	WOAH Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2023 Chapter 3.6.11 Glanders and Melioidosis 2.3.3 Real-time PCR assay	only for Equine	2025-07-18
		131	Salmonella abortus equi	Diagnostic techniques for equine abortus salmonellosis NY/T 570-2002		2024-07-10
				Defection methods of salmonella for animal and animal products NY/T 550-2002		2024-07-10
		132	Edwardsiella tarda	Detection methods for Edwardsiella from fish—Part 1:Edwardsiella tarda SC/T 7214.1-2011		2024-07-10
		133	Vibrio vulnificus	National food safety standards, microbiology detection, inspection of Vibrio vulnificus GB 4789.44-2020 5.3	only for Fish	2024-07-10
				Laboratory animal—Quality control of laboratory fish GB/T 39649-2020 C.3	Only for Fish	2024-07-10
		134	Mycobacterium marinum	Laboratory animal-Quality control of laboratory fish GB/T 39649-2020 C.4		2024-07-10
		135	Mycoplasma hyopneumoniae	Diagnostic techniques for mycoplasmal pneumonia of swine NY/T 1186-2017 6.2/6.3.2		2024-07-10
		136	Avian mycoplasmas(Mycoplasma gallisepticum, Mycoplasma synoviae)	Detection of avian mycoplasmas by polymerase chain reaction (PCR) NY/T 553-2015		2024-07-10
		137	Serpul-Mahydysenteriae	Quarantine protocol for swine dysentery SN/T 1207-2011	only for Pig	2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		138	Brucella spp.	Diagnostic techniques for animal brucellosis GB/T 18646-2018 4.4/4.6/4.8/4.13	only for dog, pig , sheep or goat, equine	2024-07-10
		139	Japanese encephalitis virus, JEV	Diagnostic techniques for Japanese encephalitis GB/T 18638-2021 10	only for Pig	2024-07-10
		140	murine norovirus	Laboratory animal-Methods for murine norovirus T/CALAS 22-2017 8		2024-07-10
		141	porcine parvovirus	Quarantine protocol for porcine parvovirus infection SN/T 1919-2016 7.6		2024-07-10
Packaging materials						
1	Packaging materials	1	Test for Skin Sensitization	National standards for pharmaceutical packaging materials Test for Skin Sensitization YBB00052003-2015		2024-07-10
		2	Test for Acute Systemic Toxicity	National standards for pharmaceutical packaging materials Test for Acute Systemic Toxicity YBB00042003-2015		2024-07-10
		3	Test for Pyrogen	National standards for pharmaceutical packaging materials Test for Pyrogen YBB00022003-2015		2024-07-10
		4	Test for Hemolysis	National standards for pharmaceutical packaging materials Test for Hemolysis YBB00032003-2015		2024-07-10
		5	Test for eye Irritation	National standards for pharmaceutical packaging materials Test for eye Irritation YBB00062002-2015, YBB00072002-2015		2024-07-10
		6	Test for Cytotoxicity	National standards for pharmaceutical packaging materials Test for Cytotoxicity YBB00012003-2015		2024-07-10
		7	Test for Intracutaneous Irritation	National standards for pharmaceutical packaging materials Test for Intracutaneous Irritation YBB00062003-2015		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	Test for Primary Skin Irritation	National standards for pharmaceutical packaging materials Test for Primary Skin Irritation YBB00072003-2015		2024-07-10
Non-active medical device						
1	Pulmonary valve conduit	1	All items	Cardiovascular implants-Pulmonary valve conduit-Pulsatile flow test methods YY/T 1564-2017		2024-07-10
		2	All items	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020		2024-07-10
		3	appearance	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.1.1		2024-07-10
		4	specifications	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.1.2		2024-07-10
		5	durability	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.1.3		2024-07-10
		6	fluid dynamics	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.1.4		2024-07-10
		7	opening and closing state	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.1.5		2024-07-10
		8	Expanded inner diameter	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.1.6		2024-07-10
		9	Pipeline tensile strength	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.1.7		2024-07-10
		10	Bursting Strength	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.1.8		2024-07-10
		11	Tensile strength	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.1.9		2024-07-10
		12	permeability	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.1.10		2024-07-10
		13	thickness	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.1.11		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		14	Twist diameter	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.1.12		2024-07-10
		15	compliance	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.1.13		2024-07-10
		16	connection strength	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.1.14		2024-07-10
		17	pH	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.2.1		2024-07-10
		18	Heavy metal	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.2.2		2024-07-10
		19	residue	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.2.3		2024-07-10
		20	Other chemical properties	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.2.4		2024-07-10
		21	Sterility test	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.3.1		2024-07-10
		22	Bacterial Endotoxins Test	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.3.2		2024-07-10
		23	Pyrogen Test	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.3.3		2024-07-10
		24	Calcification	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.3.4		2024-07-10
		25	Biological evaluation	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.3.5		2024-07-10
2	Medical devices for assisted reproductive technology	1	Partial items	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T 1698-2020	Except for ultrasonic detection	2024-07-10
		2	size	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T1698-2020 6.1.1.1		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		3	vacuum leak	Medical devices for human assisted reproductive technology in vitroAssisted reproduction aspiration needles YY/T1698-2020 6.1.1.2		2024-07-10
		4	flow	Medical devices for human assisted reproductive technology in vitroAssisted reproduction aspiration needles YY/T1698-2020 6.1.1.3		2024-07-10
		5	connection strength	Medical devices for human assisted reproductive technology in vitroAssisted reproduction aspiration needles YY/T1698-2020 6.1.1.4		2024-07-10
		6	appearance	Medical devices for human assisted reproductive technology in vitroAssisted reproduction aspiration needles YY/T1698-2020 6.1.2.1		2024-07-10
		7	cleanliness	Medical devices for human assisted reproductive technology in vitroAssisted reproduction aspiration needles YY/T1698-2020 6.1.2.2		2024-07-10
		8	rigidity	Medical devices for human assisted reproductive technology in vitroAssisted reproduction aspiration needles YY/T1698-2020 6.1.2.3		2024-07-10
		9	toughness	Medical devices for human assisted reproductive technology in vitroAssisted reproduction aspiration needles YY/T1698-2020 6.1.2.4		2024-07-10
		10	corrosion resistance	Medical devices for human assisted reproductive technology in vitroAssisted reproduction aspiration needles YY/T1698-2020 6.1.2.5		2024-07-10
		11	Puncture needle protective sleeve	Medical devices for human assisted reproductive technology in vitroAssisted reproduction aspiration needles YY/T1698-2020 6.1.2.7		2024-07-10
		12	appearance	Medical devices for human assisted reproductive technology in vitroAssisted reproduction aspiration needles YY/T1698-2020 6.1.3.1		2024-07-10



№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		13	positioning	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T1698-2020 6.1.3.2		2024-07-10
		14	pipe system	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T1698-2020 6.1.4		2024-07-10
		15	appearance	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T1698-2020 6.1.5.1		2024-07-10
		16	Egg protection	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T1698-2020 6.1.5.2		2024-07-10
		17	Inner cone joint	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T1698-2020 6.1.6		2024-07-10
		18	Reducing substances	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T 1698-2020 6.2.2		2024-07-10
		19	Metal Ion	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T 1698-2020 6.2.3		2024-07-10
		20	pH	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T 1698-2020 6.2.4		2024-07-10
		21	Evaporation residue	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T 1698-2020 6.2.5		2024-07-10
		22	UV Absorbance	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T 1698-2020 6.2.6		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		23	Ethylene oxide residue	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T 1698-2020 6.2.7		2024-07-10
		24	Sterility test	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T 1698-2020 6.3.1		2024-07-10
		25	Bacterial Endotoxins Test	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T 1698-2020 6.3.2		2024-07-10
		26	Pyrogen Test	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T 1698-2020 6.4.2		2024-07-10
		27	Hemolysis	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T 1698-2020 6.4.3		2024-07-10
		28	Acute systemic toxicity	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T 1698-2020 6.4.4		2024-07-10
		29	Cytotoxicity	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T 1698-2020 6.4.5		2024-07-10
		30	Intradermal stimulation	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T 1698-2020 6.4.6		2024-07-10
		31	Sensitization	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T 1698-2020 6.4.7		2024-07-10
		32	Mouse embryo assay	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T 1698-2020 6.4.8		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		33	Partial items	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020	Except for ultrasonic detection	2024-07-10
		34	size	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.1.1		2024-07-10
		35	Distance indicator signs	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.1.2		2024-07-10
		36	appearance	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.1.3		2024-07-10
		37	corrosion resistance	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.1.4		2024-07-10
		38	taper joint	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.1.6		2024-07-10
		39	flow	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.1.7		2024-07-10
		40	tightness	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.1.8		2024-07-10
		41	connection strength	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.1.9		2024-07-10
		42	Reducing substances	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.2.2		2024-07-10
		43	Metal Ion	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.2.3		2024-07-10
		44	pH	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.2.4		2024-07-10
		45	Evaporation residue	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.2.5		2024-07-10
		46	UV Absorbance	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.2.6		2024-07-10



№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		47	Ethylene oxide residue	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.2.7		2024-07-10
		48	Sterility test	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.3.1		2024-07-10
		49	Bacterial Endotoxins Test	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.3.2		2024-07-10
		50	Pyrogen Test	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.4.2		2024-07-10
		51	Cytotoxicity	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.4.3		2024-07-10
		52	Intradermal Test	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.4.4		2024-07-10
		53	Sensitization	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.4.5		2024-07-10
		54	Hemolysis	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.4.6		2024-07-10
		55	Acute systemic toxicity	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.4.7		2024-07-10
		56	Mouse embryo assay	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.4.8		2024-07-10
		57	Partial items	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022	Except for human sperm survival	2024-07-10
		58	size	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.1.1		2024-07-10
		59	appearance	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.1.2		2024-07-10
		60	bending resistance	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.1.3		2024-07-10



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		№	Item/ Parameter			
		61	Connection firmness	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.1.4		2024-07-10
		62	Inner cone joint	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.1.5		2024-07-10
		63	no leakage	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.1.6		2024-07-10
		64	Breaking force of conduit body	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.1.7		2024-07-10
		65	Reducing substances	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.2.2		2024-07-10
		66	Metal Ion	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.2.3		2024-07-10
		67	pH	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.2.4		2024-07-10
		68	Evaporation residue	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.2.5		2024-07-10
		69	UV Absorbance	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.2.6		2024-07-10
		70	Ethylene oxide residue	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.2.7		2024-07-10
		71	Other residues	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.2.8		2024-07-10
		72	Sterility test	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.3		2024-07-10
		73	Bacterial Endotoxins Test	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.4		2024-07-10
		74	Mouse embryo assay	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.5		2024-07-10
		75	Pyrogen Test	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.6.2		2024-07-10



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		№	Item/ Parameter			
		76	Cytotoxicity	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.6.3		2024-07-10
		77	Sensitization	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.6.4		2024-07-10
		78	vaginal irritation	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.6.5		2024-07-10
		79	Hemolysis	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.6.6		2024-07-10
		80	All items	Medical devices for human assisted reproductive technology-Determination of ammonium in human assisted reproductive media YY/T 1852-2022		2024-07-10
		81	Ion chromatography (Arbitration method)	Medical devices for human assisted reproductive technology-Determination of ammonium in human assisted reproductive media YY/T 1852-2022 4		2024-07-10
		82	Enzymatic method	Medical devices for human assisted reproductive technology-Determination of ammonium in human assisted reproductive media YY/T 1852-2022 5		2024-07-10
		83	Partial items	Medical devices for human assisted reproductive technology-General requirements of apparatus products YY/T 1914-2023	Except for human sperm survival	2024-07-10
		84	size	Medical devices for human assisted reproductive technology-General requirements of apparatus products YY/T 1914-2023 3.2.1		2024-07-10
		85	appearance	Medical devices for human assisted reproductive technology-General requirements of apparatus products YY/T 1914-2023 3.2.2		2024-07-10
		86	mechanical property	Medical devices for human assisted reproductive technology-General requirements of apparatus products YY/T 1914-2023 3.2.3		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		87	Other performance	Medical devices for human assisted reproductive technology-General requirements of apparatus products YY/T 1914-2023 3.2.4		2024-07-10
		88	Reducing substances	Medical devices for human assisted reproductive technology-General requirements of apparatus products YY/T 1914-2023 3.3.2		2024-07-10
		89	Metal Ion	Medical devices for human assisted reproductive technology-General requirements of apparatus products YY/T 1914-2023 3.3.3		2024-07-10
		90	pH	Medical devices for human assisted reproductive technology-General requirements of apparatus products YY/T 1914-2023 3.3.4		2024-07-10
		91	Evaporation residue	Medical devices for human assisted reproductive technology-General requirements of apparatus products YY/T 1914-2023 3.3.5		2024-07-10
		92	UV Absorbance	Medical devices for human assisted reproductive technology-General requirements of apparatus products YY/T 1914-2023 3.3.6		2024-07-10
		93	Ethylene oxide residue	Medical devices for human assisted reproductive technology-General requirements of apparatus products YY/T 1914-2023 3.3.7		2024-07-10
		94	Other residues	Medical devices for human assisted reproductive technology-General requirements of apparatus products YY/T 1914-2023 3.3.8		2024-07-10
		95	Sterility test	Medical devices for human assisted reproductive technology-General requirements of apparatus products YY/T 1914-2023 3.4		2024-07-10
		96	Bacterial Endotoxins Test	Medical devices for human assisted reproductive technology-General requirements of apparatus products YY/T 1914-2023 3.5		2024-07-10
		97	Biological evaluation	Medical devices for human assisted reproductive technology-General requirements of apparatus products YY/T 1914-2023 3.6		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		98	Safety evaluation of gametes and embryos	Medical devices for human assisted reproductive technology-General requirements of apparatus products YY/T 1914-2023 3.7		2024-07-10
3	Additive manufacturing	1	All items	Medical grade Ti-6Al-4V/Ti-6Al-4V ELI powder used for additive manufacturing YY/T 1701-2020		2024-07-10
		2	Chemical composition	Medical grade Ti-6Al-4V/Ti-6Al-4V ELI powder used for additive manufacturing YY/T 1701-2020 4.1		2024-07-10
		3	Appearance	Medical Ti-6Al-4V and Ti-6Al-4VELI powders for additive manufacturing YY/T 1701-2020 4.2.1		2024-07-10
		4	particle morphology	Medical Ti-6Al-4V and Ti-6Al-4VELI powders for additive manufacturing YY/T 1701-2020 4.2.2		2024-07-10
		5	Apparent density	Medical Ti-6Al-4V and Ti-6Al-4VELI powders for additive manufacturing YY/T 1701-2020 4.2.3		2024-07-10
		6	Tap density	Medical Ti-6Al-4V and Ti-6Al-4VELI powders for additive manufacturing YY/T 1701-2020 4.2.4		2024-07-10
		7	Mobility	Medical Ti-6Al-4V and Ti-6Al-4VELI powders for additive manufacturing YY/T 1701-2020 4.2.5		2024-07-10
		8	All items	Medical pure tantalum powder for additive manufacturing YY/T 1851-2022		2024-07-10
		9	Chemical composition	Medical pure tantalum powder for additive manufacturing YY/T 1851-2022 4.1		2024-07-10
		10	Appearance	Medical pure tantalum powder for additive manufacturing YY/T 1851-2022 4.2.1		2024-07-10
		11	particle morphology	Medical pure tantalum powder for additive manufacturing YY/T 1851-2022 4.2.2		2024-07-10
		12	Apparent density	Medical pure tantalum powder for additive manufacturing YY/T 1851-2022 4.2.3		2024-07-10
		13	Tap density	Medical pure tantalum powder for additive manufacturing YY/T 1851-2022 4.2.4		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		14	Mobility	Medical pure tantalum powder for additive manufacturing YY/T 1851-2022 4.2.5		2024-07-10
		15	Hollow powder rate	Medical pure tantalum powder for additive manufacturing YY/T1851-2022 4.2.6		2024-07-10
		16	Partial items	Medical-grade beta-tricalcium phosphate powder for additive manufacturing YY/T 1910-2023	Except for X-ray diffraction beta-tricalcium phosphate content, calcium phosphorus atomic ratio, specific surface area	2024-07-10
		17	Appearance	Medical-grade beta-tricalcium phosphate powder for additive manufacturing YY/T 1910-2023 4.1		2024-07-10
		18	infrared absorption spectrum	Medical-grade beta-tricalcium phosphate powder for additive manufacturing YY/T 1910-2023 4.5		2024-07-10
		19	Particle size and distribution	Medical-grade beta-tricalcium phosphate powder for additive manufacturing YY/T 1910-2023 4.6		2024-07-10
		20	Powder morphology	Medical-grade beta-tricalcium phosphate powder for additive manufacturing YY/T 1910-2023 4.7		2024-07-10
		21	pH	Medical-grade beta-tricalcium phosphate powder for additive manufacturing YY/T1910-2023 4.8		2024-07-10
		22	Content of trace elements and total amount of heavy	Medical-grade beta-tricalcium phosphate powder for additive manufacturing YY/T1910-2023 4.9		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			metals			
		23	water content	Medical-grade beta-tricalcium phosphate powder for additive manufacturing YY/T1910-2023 4.10		2024-07-10
		24	Apparent density	Medical-grade beta-tricalcium phosphate powder for additive manufacturing YYT 1910-2023 4.12		2024-07-10
		25	Tap density	Medical-grade beta-tricalcium phosphate powder for additive manufacturing YYT 1910-2023 4.13		2024-07-10
		26	Mobility	Medical-grade beta-tricalcium phosphate powder for additive manufacturing YYT 1910-2023 4.14		2024-07-10
4	Preclinical animal study of medical devices	1	Partial items	Preclinical animal study of medical devices-Part 2: Model of skin defect in induced diabetic rats YY/T 1754.2-2020	Except for histopathology	2024-07-10
5	Implants for surgery	1	All items	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022		2024-07-10
		2	appearance	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.1.1		2024-07-10
		3	thickness	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.1.2		2024-07-10
		4	tensile strength	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.1.3		2024-07-10
		5	tensile elongation	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.1.4		2024-07-10
		6	seam strength	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.1.5		2024-07-10
		7	Bursting Strength	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.1.6		2024-07-10
		8	tear strength	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.1.7		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	aperture	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.1.8		2024-07-10
		10	Connecting Force	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.1.9		2024-07-10
		11	pH	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.2.2		2024-07-10
		12	Total heavy metals and trace elements	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.2.3		2024-07-10
		13	Reducing substances	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.2.4		2024-07-10
		14	UV Absorbance	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.2.5		2024-07-10
		15	evaporation residue	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.2.6		2024-07-10
		16	infrared spectrum	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.2.7		2024-07-10
		17	Supplementary inspection items	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.2.8		2024-07-10
		18	Ethylene oxide residue	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.2.9		2024-07-10
		19	Sterility test	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.3.2		2024-07-10
		20	Bacterial endotoxins test	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.3.3		2024-07-10
		21	Biological evaluation	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.3.4		2024-07-10
		22	Partial items	Implants for surgery -Synthetic non-absorbable patch-Dura patch YY/T 1816-2022	Except for surface structure	2024-07-10



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		№	Item/ Parameter			
		23	appearance	Implants for surgery -Synthetic non-absorbable patch-Dura patch YY/T 1816-2022 4.1.1		2024-07-10
		24	thickness	Implants for surgery -Synthetic non-absorbable patch-Dura patch YY/T 1816-2022 4.1.2		2024-07-10
		25	tensile strength	Implants for surgery -Synthetic non-absorbable patch-Dura patch YY/T 1816-2022 4.1.4		2024-07-10
		26	seam strength	Implants for surgery -Synthetic non-absorbable patch-Dura patch YY/T 1816-2022 4.1.5		2024-07-10
		27	elongation at break	Implants for surgery -Synthetic non-absorbable patch-Dura patch YY/T 1816-2022 4.1.6		2024-07-10
		28	Anti permeability performance	Implants for surgery -Synthetic non-absorbable patch-Dura patch YY/T 1816-2022 4.1.7		2024-07-10
		29	taper joint	Implants for surgery -Synthetic non-absorbable patch-Dura patch YY/T 1816-2022 4.1.8		2024-07-10
		30	pH	Implants for surgery -Synthetic non-absorbable patch-Dura patch YY/T 1816-2022 4.2.2		2024-07-10
		31	Total heavy metals and trace elements	Implants for surgery -Synthetic non-absorbable patch-Dura patch YY/T 1816-2022 4.2.3		2024-07-10
		32	Reducing substances	Implants for surgery -Synthetic non-absorbable patch-Dura patch YY/T 1816-2022 4.2.4		2024-07-10
		33	UV Absorbance	Implants for surgery -Synthetic non-absorbable patch-Dura patch YY/T 1816-2022 4.2.5		2024-07-10
		34	evaporation residue	Implants for surgery -Synthetic non-absorbable patch-Dura patch YY/T 1816-2022 4.2.6		2024-07-10
		35	infrared spectrum	Implants for surgery -Synthetic non-absorbable patch-Dura patch YY/T 1816-2022 4.2.7		2024-07-10
		36	Supplementary inspection items	Implants for surgery -Synthetic non-absorbable patch-Dura patch YY/T 1816-2022 4.2.8		2024-07-10
		37	Ethylene oxide residue	Implants for surgery -Synthetic non-absorbable patch-Dura patch YY/T 1816-2022 4.2.9		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		38	Bacterial Endotoxins Test	Implants for surgery -Synthetic non-absorbable patch-Dura patch YY/T 1816-2022 4.3.2		2024-07-10
		39	Sterility test	Implants for surgery -Synthetic non-absorbable patch-Dura patch YY/T 1816-2022 4.3.3		2024-07-10
		40	Biological evaluation	Implants for surgery -Synthetic non-absorbable patch-Dura patch YY/T 1816-2022 4.3.4		2024-07-10
		41	All items	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021		2024-07-10
		42	appearance	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.2.1		2024-07-10
		43	size	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.2.2		2024-07-10
		44	structural feature	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.2.3		2024-07-10
		45	tensile strength	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.2.4		2024-07-10
		46	seam strength	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.2.5		2024-07-10
		47	elongation at break	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.2.6		2024-07-10
		48	Bursting Strength	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.2.7		2024-07-10
		49	tear strength	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.2.8		2024-07-10
		50	Anti permeability performance	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.2.9		2024-07-10
		51	pH	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.3.1		2024-07-10
		52	Total heavy metals and trace elements	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.3.2		2024-07-10



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		№	Item/ Parameter			
		53	Ethylene oxide residue	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.3.3		2024-07-10
		54	Main components	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.3.4		2024-07-10
		55	Other Items	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.3.5		2024-07-10
		56	Sterility test	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.4.1		2024-07-10
		57	Bacterial Endotoxins Test	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.4.2		2024-07-10
		58	Biological evaluation	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.4.3		2024-07-10
		59	Immunogenicity evaluation	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.4.4		2024-07-10
6	Allogeneic bone grafts	1	All items	Allogeneic bone grafts Part3: Demineralized allogeneic bone grafts YY/T 0513.3-2009		2024-07-10
		2	Specification	Allogeneic bone grafts Part3: Demineralized allogeneic bone grafts YY/T 0513.3-2009 6.1	Only used when cited or requested by a customer	2025-07-18
		3	Appearance	Allogeneic bone grafts Part3: Demineralized allogeneic bone grafts YY/T 0513.3-2009 6.2	Only used when cited or requested by a customer	2025-07-18
		4	pH value	Allogeneic bone grafts Part3: Demineralized allogeneic bone grafts YY/T 0513.3-2009 6.3	Only used when cited	2025-07-18



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					or requested by a customer	
		5	Water content	Allogeneic bone grafts Part3: Demineralized allogeneic bone grafts YY/T 0513.3-2009 6.4	Only used when cited or requested by a customer	2025-07-18
		6	Cytotoxicity	Allogeneic bone grafts Part3: Demineralized allogeneic bone grafts YY/T 0513.3-2009 6.5.1	Only used when cited or requested by a customer	2025-07-18
		7	Sensitization	Allogeneic bone grafts Part3: Demineralized allogeneic bone grafts YY/T 0513.3-2009 6.5.2	Only used when cited or requested by a customer	2025-07-18
		8	Genotoxicity test	Allogeneic bone grafts Part3: Demineralized allogeneic bone grafts YY/T 0513.3-2009 6.5.3	Only used when cited or requested by a customer	2025-07-18
		9	Implant test	Allogeneic bone grafts Part3: Demineralized allogeneic bone grafts YY/T 0513.3-2009 6.5.4	Only used when cited	2025-07-18



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					or requested by a customer	
		10	Test for the introduction of ectopic osteogenesis	Allogeneic bone grafts Part3: Demineralized allogeneic bone grafts YY/T 0513.3-2009 6.5.5	Only used when cited or requested by a customer	2025-07-18
		11	Sterility test	Allogeneic bone grafts Part3: Demineralized allogeneic bone grafts YY/T 0513.3-2009 6.6	Only used when cited or requested by a customer	2025-07-18
		12	Degree of Demineralization	Allogeneic bone grafts Part3: Demineralized allogeneic bone grafts YY/T 0513.3-2009 6.7	Only used when cited or requested by a customer	2025-07-18
7	Heart valve substitutes implanted by transcatheter techniques	1	Partial items	Cardiovascular implants—Cardiac valve prostheses—Part 3:Heart valve substitutes implanted by transcatheter techniques YY/T 1449.3-2016	Except for visibility and MRI safety	2024-07-10
		2	Packaging, labeling and sterilization	Cardiovascular implants—Cardiac valve prostheses—Part 3:Heart valve substitutes implanted by transcatheter techniques YY/T 1449.3-2016 6.2.4		2024-07-10
		3	Hydrodynamic	Cardiovascular implants—Cardiac valve prostheses—Part		2024-07-10



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			performance assessment	3:Heart valve substitutes implanted by transcatheter techniques YY/T 1449.3-2016 7.2.3		
		4	Structural performance assessment	Cardiovascular implants—Cardiac valve prostheses—Part 3:Heart valve substitutes implanted by transcatheter techniques YY/T 1449.3-2016 7.2.4		2024-07-10
		5	Device migration resistance	Cardiovascular implants—Cardiac valve prostheses—Part 3:Heart valve substitutes implanted by transcatheter techniques YY/T 1449.3-2016 7.2.5.1		2024-07-10
		6	Implant foreshortening	Cardiovascular implants—Cardiac valve prostheses—Part 3:Heart valve substitutes implanted by transcatheter techniques YY/T 1449.3-2016 7.2.5.3		2024-07-10
		7	Crush resistance	Cardiovascular implants—Cardiac valve prostheses—Part 3:Heart valve substitutes implanted by transcatheter techniques YY/T 1449.3-2016 7.2.5.4		2024-07-10
		8	Recoil	Cardiovascular implants—Cardiac valve prostheses—Part 3:Heart valve substitutes implanted by transcatheter techniques YY/T 1449.3-2016 7.2.5.5		2024-07-10
		9	Size	Cardiovascular implants—Cardiac valve prostheses—Part 3:Heart valve substitutes implanted by transcatheter techniques YY/T 1449.3-2016 7.2.5.6		2024-07-10
		10	Radial resistive force	Cardiovascular implants—Cardiac valve prostheses—Part 3:Heart valve substitutes implanted by transcatheter techniques YY/T 1449.3-2016 7.2.5.7		2024-07-10
		11	Chronic outward force	Cardiovascular implants—Cardiac valve prostheses—Part 3:Heart valve substitutes implanted by transcatheter techniques YY/T 1449.3-2016 7.2.5.8		2024-07-10
		12	Delivery system design evaluation requirements	Cardiovascular implants—Cardiac valve prostheses—Part 3:Heart valve substitutes implanted by transcatheter techniques YY/T 1449.3-2016 7.2.6		2024-07-10



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		13	Testing related to specific designs	Cardiovascular implants—Cardiac valve prostheses—Part 3:Heart valve substitutes implanted by transcatheter techniques YY/T 1449.3-2016 7.2.7		2024-07-10
8	Vascular stents	1	All items	Standard test methods for in vitro pulsatile durability testing of vascular stents YY/T 0808-2010		2024-07-10
9	Stainless steel needle tubing for the manufacture of medical devices	1	All items	Stainless steel needle tubing for the manufacture of medical devices GB/T 18457-2015		2024-07-10
		2	Size	Stainless steel needle tubing for the manufacture of medical devices GB/T 18457-2015 4		2024-07-10
		3	Specification annotation	Stainless steel needle tubing for the manufacture of medical devices GB/T 18457-2015 5		2024-07-10
		4	surface	Stainless steel needle tubing for the manufacture of medical devices GB/T 18457-2015 6		2024-07-10
		5	cleanliness	Stainless steel needle tubing for the manufacture of medical devices GB/T 18457-2015 7		2024-07-10
		6	pH value	Stainless steel needle tubing for the manufacture of medical devices GB/T 18457-2015 8		2024-07-10
		7	rigidity	Stainless steel needle tubing for the manufacture of medical devices GB/T 18457-2015 9		2024-07-10
		8	toughness	Stainless steel needle tubing for the manufacture of medical devices GB/T 18457-2015 10		2024-07-10
		9	corrosion resistance	Stainless steel needle tubing for the manufacture of medical devices GB/T 18457-2015 11		2024-07-10
10	Stainless Steel Needles for Prefilled Syringes	1	All items	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015		2024-07-10
		2	appearance	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015		2024-07-10
		3	rigidity	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015		2024-07-10



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		4	toughness	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015		2024-07-10
		5	corrosion resistance	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015		2024-07-10
		6	Foreign objects on the inner surface of the needle tube	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015		2024-07-10
		7	Needle hole patency	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015		2024-07-10
		8	Puncture force of needle tip	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015		2024-07-10
		9	Connection force between needle and needle seat	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015		2024-07-10
		10	Pullout force of needle protective cap	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015		2024-07-10
		11	pH value	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015		2024-07-10
		12	Cadmium ion	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015		2024-07-10
		13	Heavy metals	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015		2024-07-10
		14	Cytotoxicity	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015		2024-07-10
		15	Sensitization	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015		2024-07-10
		16	Irritation	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
11	medical devices	17	Acute systemic toxicity	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015		2024-07-10
		18	Hemolysis test	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015		2024-07-10
		1	Pyrogen Test	ChP 2025 年版四部 通则 (1142)		2025-11-12
		2	Bacterial Endotoxins Test	ChP 2025 年版四部 通则 (1143)		2025-11-12
		3	Sterility Test Technology	ChP 2025 年版四部 通则 (1101)		2025-11-12
		4	Protein content determination method	ChP 2025 年版四部 通则 (0731)		2025-11-12
		5	molecular-exclusion chromatography method	ChP 2025 年版四部 通则 (0514)	"Except for Size Exclusion Chromatography-Static Light Scattering (SEC-SLS) Method"	2025-11-12
		6	transformation temperature	Standard test method for transformation temperature of nickel-Titanium alloys by thermal analysis YY/T 0641-2008		2024-07-10
		7	Vickers hardness test	Metallic materials--Vickers hardness test—Part1: Test method GB/T 4340.1-2009		2024-07-10
		8	corrosion resistance	Medical instruments of stain less steel-Test methods of corrosion resistance YY/T 0149-2006		2024-07-10
		9	corrosion resistance	Standard test method for conducting cyclic potentiodynamic polarization measurements to determine the corrosion		2024-07-10



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		№	Item/ Parameter			
				susceptibility of small Implant devices YY/T 0695-2008		
		10	MS	ChP 2025 年版四部 通则 (0431)		2025-11-12
		11	In vitro mammalian chromosome aberration test	Test for genotoxicity of medical devices—Part 2:In vitro mammalian chromosome aberration test YY/T 0870.2-2019		2024-07-10
		12	TK gene mutation test	Test for genotoxicity of medical devices—Part 3:TK gene mutation test using mouse lymphoma cells YY/T 0870.3-2019		2024-07-10
		13	pH measurement method	ChP 2025 年版四部 通则 (0631)		2025-11-12
		14	Heavy metal inspection method	ChP 2025 年版四部 通则 (0821)		2025-11-12
		15	Infrared spectrophotometry method	ChP 2025 年版四部 通则 (0402)		2025-11-12
		16	ultraviolet-visible spectrophotometry method	ChP 2025 年版四部 通则 (0401)		2025-11-12
		17	Clarity	ChP 2025 年版四部 通则 (0902)		2025-11-12
		18	Color	ChP 2025 年版四部 通则 (0901)		2025-11-12
		19	Residue on Ignition	ChP 2025 年版四部 通则 (0841)		2025-11-12
		20	Residual solvents	ChP 2025 年版四部 通则 (0861)		2025-11-12
		21	Atomic absorption spectrophotometry method	ChP 2025 年版四部 通则 (0406)		2025-11-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
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		22	High Performance Liquid Chromatography	ChP 2025 年版四部 通则 (0512)	不做多维液相色谱法	2025-11-12
		23	Gas Chromatography	ChP 2025 年版四部 通则 (0521)		2025-11-12
		24	Microbial limits test	ChP 2025 年版四部 通则 (1105), (1106)		2025-11-12
		25	X-ray fluorescence spectroscopy	ChP 2025 VOL IV (0461)		2025-11-12
		26	characterization of hydrogels	Tissue engineering medical products-Standard guide for characterization of hydrogels YY/T 1435-2016		2024-07-10
		27	T lymphocyte transformation test in vitro	T lymphocyte transformation test in vitro YY/T 1465.1—2016		2024-07-10
		28	anti-calcification evaluation	Anti-calcification evaluation of animal derived cardiovascular implants—Test for rat subcutaneous implantation YY/T 1859-2022		2024-07-10
		29	In vivo evaluation of osteoinductive potential	Allogeneic grafts -In vivo evaluation of osteoinductive potential for materials containing demineralized bone YY/T 1680-2020		2024-07-10
		30	Determination of silver contents in biological samples	Nanotechnology—Determination of silver contents in biological samples — Inductively coupled plasma mass spectrometry GB/T 38261-2019		2024-07-10
		31	Method to measure cell migration in porous materials	Tissue engineering medical products-Bioactive ceramics-Method to measure cell migration in porous materials YY/T 1744-2020		2024-07-10
12	Cardiovascular implants-	32	pyrogen	Pyrogen test for medical devices— Monocyte-activation test Human whole blood ELISA method YY/T 1500-2016		2024-07-10
		1	All Parameters	Cardiovascular implants-Cardiac valve prostheses GB 12279-2008		2024-07-10



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		№	Item/ Parameter			
	Cardiac valve prostheses	2	Biological evaluation	Cardiovascular implants-Cardiac valve prostheses GB 12279-2008 5.4		2024-07-10
		3	Material and mechanical property test	Cardiovascular implants-Cardiac valve prostheses GB 12279-2008 5.5.1		2024-07-10
		4	Steady forward flow test	Cardiovascular implants-Cardiac valve prostheses GB 12279-2008 6.3		2024-07-10
		5	Steady back flow leakage test	Cardiovascular implants-Cardiac valve prostheses GB 12279-2008 6.4		2024-07-10
		6	Pulsatile hydrodynamic test	Cardiovascular implants-Cardiac valve prostheses GB 12279-2008 6.5		2024-07-10
		7	Implant durability assessment	Cardiovascular implants-Cardiac valve prostheses GB 12279-2008 7		2024-07-10
		8	Sterilization	Cardiovascular implants-Cardiac valve prostheses GB 12279-2008 10.2.4		2024-07-10
13	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches	1	All Parameters	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021		2024-07-10
		2	Residual chemical substances	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 8.5.1		2024-07-10
		3	Biological evaluation	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 8.5.2		2024-07-10
		4	Permeability	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 8.7.2.1		2024-07-10
		5	Mechanical strength	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 8.7.2.2		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	Length	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 8.7.2.3		2024-07-10
		7	Relaxed internal diameter	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 8.7.2.4		2024-07-10
		8	Pressurized internal diameter	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 8.7.2.5		2024-07-10
		9	Wall thickness	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 8.7.2.6		2024-07-10
		10	Suture retention strength	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 8.7.2.7		2024-07-10
		11	Kink diameter/radium	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 8.7.2.8		2024-07-10
		12	Dynamic radial compliance	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 8.7.2.9		2024-07-10
		13	Permeability	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 8.7.3.1		2024-07-10
		14	Mechanical strength	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 8.7.3.2		2024-07-10
		15	Length and width	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 8.7.3.3		2024-07-10



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		№	Item/ Parameter			
		16	Wall thickness	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 8.7.3.4		2024-07-10
		17	Suture retention strength	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 8.7.3.5		2024-07-10
		18	Preclinical in vivo evaluation of vascular prostheses	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 9		2024-07-10
		19	Sterility	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 12		2024-07-10
		20	Packaging and Labeling	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 13		2024-07-10
14	Mammary implants	1	All items	Non-active surgical implants-Particular requirements of mammary implants YY/T 0647-2021		2024-07-10
		2	cytotoxicity	Non-active surgical implants-Particular requirements of mammary implants YY/T 0647-2021 6.2		2024-07-10
		3	residual low molecular weight oligomers	Non-active surgical implants-Particular requirements of mammary implants YY/T 0647-2021 6.3		2024-07-10
		4	trace elements	Non-active surgical implants-Particular requirements of mammary implants YY/T 0647-2021 6.4		2024-07-10
		5	Mechanical test	Non-active surgical implants-Particular requirements of mammary implants YY/T 0647-2021 7.2.2		2024-07-10
		6	physical evaluation	Non-active surgical implants-Particular requirements of mammary implants YY/T 0647-2021 7.2.3		2024-07-10
		7	sterility	Non-active surgical implants-Particular requirements of mammary implants YY/T 0647-2021 9		2024-07-10



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		№	Item/ Parameter			
15	Hip joint prostheses	1	All items	Joint replacement implants-Hip joint prostheses YY 0118-2016		2024-07-10
		2	Metal Material	Joint replacement implants-Hip joint prostheses YY 0118-2016 7.2		2024-07-10
		3	Ultra-High Molecular Weight Polyethylene (UHMWPE) Material	Joint replacement implants-Hip joint prostheses YY 0118-2016 7.3		2024-07-10
		4	Ceramic Materials	Joint replacement implants-Hip joint prostheses YY 0118-2016 7.4		2024-07-10
		5	Coating Materials	Joint replacement implants-Hip joint prostheses YY 0118-2016 7.5		2024-07-10
		6	Appearance	Joint replacement implants-Hip joint prostheses YY 0118-2016 8.2		2024-07-10
		7	Surface defects	Joint replacement implants-Hip joint prostheses YY 0118-2016 8.3		2024-07-10
		8	Surface roughness	Joint replacement implants-Hip joint prostheses YY 0118-2016 8.4		2024-07-10
		9	Dimensions and tolerances of important parts	Joint replacement implants-Hip joint prostheses YY 0118-2016 8.5		2024-07-10
		10	Static mechanical properties	Joint replacement implants-Hip joint prostheses YY 0118-2016 8.6		2024-07-10
		11	Dynamic mechanics	Joint replacement implants-Hip joint prostheses YY 0118-2016 8.7		2024-07-10
		12	Min and Max Angles	Joint replacement implants-Hip joint prostheses YY 0118-2016 8.8		2024-07-10
		13	Sterility	Joint replacement implants-Hip joint prostheses YY 0118-2016 10		2024-07-10



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16	Knee joint prostheses	1	All items	Joint replacement implants- Knee joint prostheses YY 0502-2016		2024-07-10
		2	Metal Material	Joint replacement implants- Knee joint prostheses YY 0502-2016 7.2		2024-07-10
		3	Ultra-High Molecular Weight Polyethylene (UHMWPE) Material	Joint replacement implants- Knee joint prostheses YY 0502-2016 7.3		2024-07-10
		4	Ceramic Materials	Joint replacement implants- Knee joint prostheses YY 0502-2016 7.4		2024-07-10
		5	Coating Materials	Joint replacement implants- Knee joint prostheses YY 0502-2016 7.5		2024-07-10
		6	appearance	Joint replacement implants- Knee joint prostheses YY 0502-2016 8.2		2024-07-10
		7	Surface defects	Joint replacement implants- Knee joint prostheses YY 0502-2016 8.3		2024-07-10
		8	Surface roughness	Joint replacement implants- Knee joint prostheses YY 0502-2016 8.4		2024-07-10
		9	Dimensions and tolerances of important parts	Joint replacement implants- Knee joint prostheses YY 0502-2016 8.5		2024-07-10
		10	dynamic mechanics	Joint replacement implants- Knee joint prostheses YY 0502-2016 8.6		2024-07-10
		11	Relative angular motion range	Joint replacement implants-Knee joint prostheses YY 0502-2016 8.7		2024-07-10
		12	Sterility	Joint replacement implants-Knee joint prostheses YY 0502-2016 10		2024-07-10
17	Metallic bone screws	1	All items	Implants for osteosynthesis-Metallic bone screws YY 0018—2016		2024-07-10



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		№	Item/ Parameter			
		2	Material	Implants for osteosynthesis--Metallic bone screws YY 0018-2016 5.1		2024-07-10
		3	Maximum torque and breaking torque angle	Implants for osteosynthesis--Metallic bone screws YY 0018-2016 5.2.1		2024-07-10
		4	hardness	Implants for osteosynthesis--Metallic bone screws YY 0018-2016 5.2.2		2024-07-10
		5	Axial extraction force	Implants for osteosynthesis--Metallic bone screws YY 0018-2016 5.2.3		2024-07-10
		6	Screw in torque and screw out torque	Implants for osteosynthesis--Metallic bone screws YY 0018-2016 5.2.4		2024-07-10
		7	Self tapping performance	Implants for osteosynthesis--Metallic bone screws YY 0018-2016 5.2.5		2024-07-10
		8	corrosion resistance	Implants for osteosynthesis--Metallic bone screws YY 0018-2016 5.3		2024-07-10
		9	Surface defects	Implants for osteosynthesis--Metallic bone screws YY 0018-2016 5.4.1		2024-07-10
		10	Surface roughness	Implants for osteosynthesis--Metallic bone screws YY 0018-2016 5.4.2		2024-07-10
		11	appearance	Implants for osteosynthesis--Metallic bone screws YY 0018-2016 5.4.3		2024-07-10
		12	Surface Treatment	Implants for osteosynthesis--Metallic bone screws YY 0018-2016 5.4.4		2024-07-10
		13	size	Implants for osteosynthesis--Metallic bone screws YY 0018-2016 5.5		2024-07-10
18	Metallic medullary pins	1	All items	Implants for surgery-Intramedullary nailing systems - Part 2: Medullary pins YY/T 0019.2-2011		2024-07-10
		2	Material	Implants for surgery-Intramedullary nailing systems - Part 2: Medullary pins YY/T 0019.2-2011 3		2024-07-10



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		№	Item/ Parameter			
		3	appearance	Implants for surgery-Intramedullary nailing systems - Part 2: Medullary pins YY/T 0019.2-2011 5		2024-07-10
		4	size	Implants for surgery-Intramedullary nailing systems - Part 2: Medullary pins YY/T 0019.2-2011 6		2024-07-10
19	Metallic spinal screws	1	All items	Spinal implants-Components used in the surgical fixation of the spinal skeletal system-Part2: Metallic spinal screws YY/T 0119.2-2014		2024-07-10
		2	Geometric characteristics	Spinal implants-Components used in the surgical fixation of the spinal skeletal system-Part2: Metallic spinal screws YY/T 0119.2-2014 5.1		2024-07-10
		3	Rotational connection	Spinal implants-Components used in the surgical fixation of the spinal skeletal system-Part2: Metallic spinal screws YY/T 0119.2-2014 5.2		2024-07-10
		4	Torsion property	Spinal implants-Components used in the surgical fixation of the spinal skeletal system-Part2: Metallic spinal screws YY/T 0119.2-2014 5.3		2024-07-10
		5	Rotational torque	Spinal implants-Components used in the surgical fixation of the spinal skeletal system-Part2: Metallic spinal screws YY/T 0119.2-2014 5.4		2024-07-10
		6	Axial extraction force	Spinal implants-Components used in the surgical fixation of the spinal skeletal system-Part2: Metallic spinal screws YY/T 0119.2-2014 5.5		2024-07-10
		7	Flexural properties	Spinal implants-Components used in the surgical fixation of the spinal skeletal system-Part2: Metallic spinal screws YY/T 0119.2-2014 5.6		2024-07-10
20	Metallic spinal rods	1	All items	Spinal implants-Components used in the surgical fixation of the spinal skeletal system-Part4: Metallic spinal rods YY/T 0119.4-2014		2024-07-10
		2	Geometric characteristics	Spinal implants-Components used in the surgical fixation of the spinal skeletal system-Part4: Metallic spinal rods YY/T 0119.4-		2024-07-10



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		№	Item/ Parameter			
				2014 5.1		
		3	Static and fatigue tests	Spinal implants-Components used in the surgical fixation of the spinal skeletal system-Part4:Metallic spinal rods YY/T 0119.4-2014 5.2		2024-07-10
21	Metal bone pins	1	All items	Implants for surgery—Metallic skeletal pins and wires-Part 1:General requirements YY/T 0345.1-2020		2024-07-10
		2	Mechanical properties	Implants for surgery—Metallic skeletal pins and wires-Part 1:General requirements YY/T 0345.1-2020 4		2024-07-10
		3	Manufacturing method	Implants for surgery—Metallic skeletal pins and wires-Part 1:General requirements YY/T 0345.1-2020 5		2024-07-10
		4	Surface quality	Implants for surgery—Metallic skeletal pins and wires-Part 1:General requirements YY/T 0345.1-2020 6		2024-07-10
		5	Sterilization	Implants for surgery—Metallic skeletal pins and wires-Part 1:General requirements YY/T 0345.1-2020 7		2024-07-10
		6	All items	Implants for surgery-Skeletal pins and wires-Part2:Steinmann skeletal pins-Dimensions YY/T 0345.2-2014		2024-07-10
		7	size	Implant for surgery-Skeletal pins and wires-Part2:Steinmann skeletal pins-Dimensions YY/T 0345.2-2014 2		2024-07-10
		8	end	Implant for surgery-Skeletal pins and wires-Part2:Steinmann skeletal pins-Dimensions YY/T 0345.2-2014 3		2024-07-10
		9	All items	Implants for surgery-Skeletal pins and wires-Part 3:kirschner skeletal wires YY/T 0345.3-2014		2024-07-10
		10	size	Implants for surgery-Skeletal pins and wires-Part 3:kirschner skeletal wires YY/T 0345.3-2014 3		2024-07-10
		11	end	Implants for surgery-Skeletal pins and wires-Part 3:kirschner skeletal wires YY/T 0345.3-2014 4		2024-07-10
22	Metallic bone plates	1	All items	Implants for osteosynthesis- Metallic bone plates YY 0017-2016		2024-07-10
		2	Material	Implants for osteosynthesis- Metallic bone plates YY 0017-2016		2024-07-10



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				4.1		
		3	Hardness	Implants for osteosynthesis- Metallic bone plates YY 0017-2016 4.2.1		2024-07-10
		4	Bending strength and equivalent bending stiffness	Implants for osteosynthesis- Metallic bone plates YY 0017-2016 4.2.2		2024-07-10
		5	Fatigue performance	Implants for osteosynthesis- Metallic bone plates YY 0017-2016 4.2.3		2024-07-10
		6	the corrosion susceptibility	Implants for osteosynthesis- Metallic bone plates YY 0017-2016 4.3		2024-07-10
		7	Surface defects	Implants for osteosynthesis- Metallic bone plates YY 0017-2016 4.4.1		2024-07-10
		8	Surface roughness	Implants for osteosynthesis- Metallic bone plates YY 0017-2016 4.4.2		2024-07-10
		9	Appearance	Implants for osteosynthesis- Metallic bone plates YY 0017-2016 4.4.3		2024-07-10
		10	Surface Treatment	Implants for osteosynthesis- Metallic bone plates YY 0017-2016 4.4.4		2024-07-10
		11	Geometric characteristics	Implants for osteosynthesis- Metallic bone plates YY 0017-2016 4.5		2024-07-10
23	Metallic fixation screw for femur neck	1	All items	Implants for osteosynthesis-Metallic fixation screw for femur neck YY/T 0346-2022		2024-07-10
		2	Maximum torque and torsion angle at break	Implants for osteosynthesis-Metallic fixation screw for femur neck YY/T 0346-2022 4.2.1		2024-07-10
		3	hardness	Implants for osteosynthesis-Metallic fixation screw for femur neck YY/T 0346-2022 4.2.2		2024-07-10
		4	Axial insertion force	Implants for osteosynthesis-Metallic fixation screw for femur neck YY/T 0346-2022 4.2.3		2024-07-10



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		5	Axial pull-out force	Implants for osteosynthesis-Metallic fixation screw for femur neck YY/T 0346-2022 4.2.4		2024-07-10
		6	Screw-in torque and spin-out torque	Implants for osteosynthesis-Metallic fixation screw for femur neck YY/T 0346-2022 4.2.5		2024-07-10
		7	Self-tapping performance	Implants for osteosynthesis-Metallic fixation screw for femur neck YY/T 0346-2022 4.2.6		2024-07-10
		8	Static bending performance	Implants for osteosynthesis-Metallic fixation screw for femur neck YY/T 0346-2022 4.2.7		2024-07-10
		9	Fatigue bending performance	Implants for osteosynthesis-Metallic fixation screw for femur neck YY/T 0346-2022 4.2.8		2024-07-10
		10	Corrosion resistance	Implants for osteosynthesis-Metallic fixation screw for femur neck YY/T 0346-2022 4.3		2024-07-10
		11	Surface roughness	Implants for osteosynthesis-Metallic fixation screw for femur neck YY/T 0346-2022 4.4.2		2024-07-10
		12	appearance	Implants for osteosynthesis-Metallic fixation screw for femur neck YY/T 0346-2022 4.4.3		2024-07-10
		13	Anodized surface treatment (cytotoxicity)	Implants for osteosynthesis-Metallic fixation screw for femur neck YY/T 0346-2022 4.4.4		2024-07-10
		14	size	Implants for osteosynthesis-Metallic fixation screw for femur neck YY/T 0346-2022 4.5		2024-07-10
		15	Fit performance	Implants for osteosynthesis-Metallic fixation screw for femur neck YY/T 0346-2022 4.6		2024-07-10
24	Forgings, castings for bone joint prostheses-Ti6Al4V titanium alloy	1	All items	Implants for surgery-Forgings, castings for bone joint prostheses-Ti6Al4V titanium alloy forgings YY 0117.1-2005		2024-07-10
		2	Raw Material and Forged Material Chemical Composition	Implants for surgery-Forgings, castings for bone joint prostheses-Ti6Al4V titanium alloy forgings YY 0117.1-2005 3.1.2		2024-07-10



№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	forgings	3	Mechanical	Implants for surgery-Forgings, castings for bone joint prostheses-Ti6Al4V titanium alloy forgings YY 0117.1-2005 3.4		2024-07-10
		4	surface quality	Implants for surgery-Forgings, castings for bone joint prostheses-Ti6Al4V titanium alloy forgings YY 0117.1-2005 3.5		2024-07-10
		5	Internal Quality	Implants for surgery-Forgings, castings for bone joint prostheses-Ti6Al4V titanium alloy forgings YY 0117.1-2005 3.6		2024-07-10
		6	Outline dimensions of forgings	Implants for surgery-Forgings, castings for bone joint prostheses-Ti6Al4V titanium alloy forgings YY 0117.1-2005 3.7		2024-07-10
25	Forgings, castings for bone joint prostheses-ZTi6Al4V alloy castings	1	All items	Implants for surgery-Forgings, castings for bone joint prostheses-ZTi6Al4V alloy castings YY 0117.2-2005		2024-07-10
		2	Alloy Chemical Composition	Implants for surgery-Forgings, castings for bone joint prostheses-ZTi6Al4V alloy castings YY 0117.2-2005 3.1.2		2024-07-10
		3	Casting Chemical Composition	Implants for surgery-Forgings, castings for bone joint prostheses-ZTi6Al4V alloy castings YY 0117.2-2005 3.2		2024-07-10
		4	Mechanical	Implants for surgery-Forgings, castings for bone joint prostheses-ZTi6Al4V alloy castings YY 0117.2-2005 3.5		2024-07-10
		5	surface quality	Implants for surgery-Forgings, castings for bone joint prostheses-ZTi6Al4V alloy castings YY 0117.2-2005 3.6		2024-07-10
		6	Internal Quality	Implants for surgery-Forgings, castings for bone joint prostheses-ZTi6Al4V alloy castings YY 0117.2-2005 3.7		2024-07-10
		7	Outline dimensions of forgings	Implants for surgery-Forgings, castings for bone joint prostheses-ZTi6Al4V alloy castings YY 0117.2-2005 3.8		2024-07-10
26	Forgings, castings for bone joint prostheses-Cobalt chromium molybdenum alloy castings	1	All items	Implants for surgery-Forgings, castings for bone joint prostheses-Cobalt chromium molybdenum alloy castings YY 0117.3-2005		2024-07-10
		2	Alloy and Casting Chemical Composition	Implants for surgery-Forgings, castings for bone joint prostheses-Cobalt chromium molybdenum alloy castings YY 0117.3-2005 3.1		2024-07-10
		3	Mechanical	Implants for surgery-Forgings, castings for bone joint prostheses-Cobalt chromium molybdenum alloy castings YY 0117.3-2005 3.4		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	Surface quality	Implants for surgery-Forgings, castings for bone joint prostheses-Cobalt chromium molybdenum alloy castings YY 0117.3-2005 3.5		2024-07-10
		5	Internal Quality	Implants for surgery-Forgings, castings for bone joint prostheses-Cobalt chromium molybdenum alloy castings YY 0117.3-2005 3.6		2024-07-10
		6	Outline dimensions of forgings	Implants for surgery-Forgings, castings for bone joint prostheses-Cobalt chromium molybdenum alloy castings YY 0117.3-2005 3.7		2024-07-10
27	Implants for surgery Fundamental principles	1	All items	Implants for surgery Fundamental principles YY/T 0340-2009		2024-07-10
28	Non-active surgical implants-Osteosynthesis and spinal implants	1	All items	Non-active surgical implants-Osteosynthesis and spinal implants-Part 1: Particular requirements for osteosynthesis implants YY 0341.1-2020		2024-07-10
		2	hardness	Non-active surgical implants-Osteosynthesis and spinal implants-Part 1: Particular requirements for osteosynthesis implants YY 0341.1-2020 4.2		2024-07-10
		3	Static and/or dynamic mechanical properties	Non-active surgical implants-Osteosynthesis and spinal implants-Part 1: Particular requirements for osteosynthesis implants YY 0341.1-2020 4.3		2024-07-10
		4	Corrosion resistance	Non-active surgical implants-Osteosynthesis and spinal implants-Part 1: Particular requirements for osteosynthesis implants YY 0341.1-2020 4.4		2024-07-10
		5	Surface roughness	Non-active surgical implants-Osteosynthesis and spinal implants-Part 1: Particular requirements for osteosynthesis implants YY 0341.1-2020 4.5.2		2024-07-10
		6	appearance	Non-active surgical implants-Osteosynthesis and spinal implants-Part 1: Particular requirements for osteosynthesis implants YY		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				0341.1-2020 4.5.3		
		7	Important part size	Non-active surgical implants-Osteosynthesis and spinal implants-Part 1: Particular requirements for osteosynthesis implants YY 0341.1-2020 4.6		2024-07-10
		8	Fit performance	Non-active surgical implants-Osteosynthesis and spinal implants-Part 1: Particular requirements for osteosynthesis implants YY 0341.1-2020 4.7		2024-07-10
		9	sterility	Non-active surgical implants-Osteosynthesis and spinal implants-Part 1: Particular requirements for osteosynthesis implants YY 0341.1-2020 4.8		2024-07-10
		10	All items	Non-active surgical implants-Osteosynthesis and spinal implants-Part 2: Particular requirements for spinal implants YY 0341.2-2020		2024-07-10
		11	hardness	Non-active surgical implants-Osteosynthesis and spinal implants-Part 2: Particular requirements for spinal implants YY 0341.2-2020 4.2		2024-07-10
		12	Static and/or dynamic mechanical properties	Non-active surgical implants-Osteosynthesis and spinal implants-Part 2: Particular requirements for spinal implants YY 0341.2-2020 4.3		2024-07-10
		13	Corrosion resistance	Non-active surgical implants-Osteosynthesis and spinal implants-Part 2: Particular requirements for spinal implants YY 0341.2-2020 4.4		2024-07-10
		14	Surface roughness	Non-active surgical implants-Osteosynthesis and spinal implants-Part 2: Particular requirements for spinal implants YY 0341.2-2020 4.5.2		2024-07-10
		15	appearance	Non-active surgical implants-Osteosynthesis and spinal implants-Part 2: Particular requirements for spinal implants YY 0341.2-2020 4.5.3		2024-07-10
		16	Important part size	Non-active surgical implants-Osteosynthesis and spinal implants-		2024-07-10

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Part 2: Particular requirements for spinal implants YY 0341.2-2020 4.6		
		17	hydroxyapatite coating	Non-active surgical implants-Osteosynthesis and spinal implants-Part 2: Particular requirements for spinal implants YY 0341.2-2020 4.7.1		2024-07-10
		18	Metal spine implant Thermal spraying pure titanium coating	Non-active surgical implants-Osteosynthesis and spinal implants-Part 2: Particular requirements for spinal implants YY 0341.2-2020 4.7.2		2024-07-10
		19	Fit performance	Non-active surgical implants-Osteosynthesis and spinal implants-Part 2: Particular requirements for spinal implants YY 0341.2-2020 4.8		2024-07-10
		20	sterility	Non-active surgical implants-Osteosynthesis and spinal implants-Part 2: Particular requirements for spinal implants YY 0341.2-2020 4.9		2024-07-10
29	Hygienic standard for yuangong intrauterine device of specially designed inserter	1	All items	Hygienic standard for yuangong intrauterine device of specially designed inserter YY/T 0470-2004		2024-07-10
		2	Usage performance	Hygienic standard for yuangong intrauterine device of specially designed inserter YY/T 0470-2004 4.1		2024-07-10
		3	Ethylene Oxide Residue	Hygienic standard for yuangong intrauterine device of specially designed inserter YY/T 0470-2004 4.2.2		2024-07-10
		4	appearance	Hygienic standard for yuangong intrauterine device of specially designed inserter YY/T 0470-2004 4.3		2024-07-10
30	Uterine cavity form intra-uterine devices	1	All items	Uterine cavity form intra-uterine devices GB 11234-2006	Use only when quoted or requested by the customer	2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		2	Material	Uterine cavity form intra-uterine devices GB 11234-2006 3.1		2024-07-10
		3	appearance	Uterine cavity form intra-uterine devices GB 11234-2006 4.1		2024-07-10
		4	size	Uterine cavity form intra-uterine devices GB 11234-2006 4.2		2024-07-10
		5	performance	Uterine cavity form intra-uterine devices GB 11234-2006 4.3		2024-07-10
		6	Sterility	Uterine cavity form intra-uterine devices GB 11234-2006 4.4		2024-07-10
		7	Ethylene Oxide Residue	Uterine cavity form intra-uterine devices GB 11234-2006 4.5		2024-07-10
		8	Biological evaluation	Uterine cavity form intra-uterine devices GB 11234-2006 4.6		2024-07-10
31	OCu intra-uterine devices	1	All items	OCu intra-uterine devices GB 3156-2006		2024-07-10
		2	Material	OCu intra-uterine devices GB 3156-2006 3.1		2024-07-10
		3	package	OCu intra-uterine devices GB 3156-2006 4.1		2024-07-10
		4	appearance	OCu intra-uterine devices GB 3156-2006 4.2		2024-07-10
		5	performance	OCu intra-uterine devices GB 3156-2006 4.3		2024-07-10
		6	Sterility	OCu intra-uterine devices GB 3156-2006 4.4		2024-07-10
		7	Ethylene Oxide Residue	OCu intra-uterine devices GB 3156-2006 4.5		2024-07-10
		8	Biological evaluation	OCu intra-uterine devices GB 3156-2006 4.6		2024-07-10
32	VCu intra-uterine devices	1	All items	VCu intra-uterine devices GB 11235-2006	Use only when	2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					quoted or requested by the customer	
		2	Material	VCu intra-uterine devices GB 11235-2006 3.1		2024-07-10
		3	appearance	VCu intra-uterine devices GB 11235-2006 4.1		2024-07-10
		4	package	VCu intra-uterine devices GB 11235-2006 4.2		2024-07-10
		5	central filaments corrosion preventive	VCu intra-uterine devices GB 11235-2006 4.3		2024-07-10
		6	central filaments roughness	VCu intra-uterine devices GB 11235-2006 4.4		2024-07-10
		7	copper wire surface area	VCu intra-uterine devices GB 11235-2006 4.5		2024-07-10
		8	Tail tensile resistance	VCu intra-uterine devices GB 11235-2006 4.6		2024-07-10
		9	Length and appearance	VCu intra-uterine devices GB 11235-2006 4.7		2024-07-10
		10	Center wire hardness	VCu intra-uterine devices GB 11235-2006 4.8		2024-07-10
		11	elasticity	VCu intra-uterine devices GB 11235-2006 4.9		2024-07-10
		12	resistance to displacement	VCu intra-uterine devices GB 11235-2006 4.10		2024-07-10
		13	Sterility	VCu intra-uterine devices GB 11235-2006 4.11		2024-07-10
		14	Ethylene Oxide Residue	VCu intra-uterine devices GB 11235-2006 4.12		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		15	Biological evaluation	VCu intra-uterine devices GB 11235-2006 4.13		2024-07-10
33	Copper-bearing contraceptive intrauterine devices	1	Partial items	Copper-bearing contraceptive intrauterine devices-Requirements and tests GB11236-2021	Except for X-ray detectability	2024-07-10
		2	shape	Copper-bearing contraceptive intrauterine devices-Requirements and tests GB11236-2021 5.2		2024-07-10
		3	measurement	Copper-bearing contraceptive intrauterine devices-Requirements and tests GB11236-2021 5.3		2024-07-10
		4	pulling force	Copper-bearing contraceptive intrauterine devices-Requirements and tests GB11236-2021 5.4		2024-07-10
		5	Deformation recovery	Copper-bearing contraceptive intrauterine devices-Requirements and tests GB11236-2021 5.5		2024-07-10
		6	barium sulfate content	Copper-bearing contraceptive intrauterine devices-Requirements and tests GB11236-2021 5.7		2024-07-10
34	Vascular stents	1	Partial items	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016	Except for visibility, MRI safety and compatibility	2024-07-10
		2	Size	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 4.2		2024-07-10
		3	Material	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 7		2024-07-10
		4	Bond strength	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.1.2		2024-07-10
		5	Component size compatibility	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.1.3		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	Size	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.1.4		2024-07-10
		7	Remove force	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.1.5		2024-07-10
		8	Bending/Discounting	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.1.6		2024-07-10
		9	Profile/diameter testing	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.1.7		2024-07-10
		10	Pushability	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.1.8		2024-07-10
		11	simulated use	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.1.9		2024-07-10
		12	Torsion	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.1.10		2024-07-10
		13	Torsional bonding strength	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.1.11		2024-07-10
		14	traceability	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.1.12		2024-07-10
		15	Bond strength	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.2.2		2024-07-10
		16	Balloon filling time	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.2.3		2024-07-10
		17	Balloon decompression time	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.2.4		2024-07-10
		18	Rated burst pressure of balloon	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.2.5		2024-07-10
		19	Balloon rated fatigue	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.2.6		2024-07-10
		20	Component size compatibility	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.2.7		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		21	Size	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.2.8		2024-07-10
		22	Remove force	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.2.9		2024-07-10
		23	Dog bone effect	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.2.10		2024-07-10
		24	release force	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.2.11		2024-07-10
		25	simulated use	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.2.12		2024-07-10
		26	Bond strength	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.3.2		2024-07-10
		27	Component size compatibility	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.3.3		2024-07-10
		28	Dimensional verification	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.3.4		2024-07-10
		29	Bending/Discounting	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.3.5		2024-07-10
		30	simulated use	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.3.6		2024-07-10
		31	Torsional bonding strength	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.3.7		2024-07-10
		32	Tensile strength of pipes	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.3.8		2024-07-10
		33	Biological evaluation	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.4		2024-07-10
		34	Dimensional compatibility	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.5.2		2024-07-10
		35	Dimensional verification	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.5.3		2024-07-10



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		36	Hemostatic evaluation	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.5.4		2024-07-10
		37	The relationship between bracket length and diameter	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.1.2		2024-07-10
		38	Contour effect/bell mouth	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.1.3		2024-07-10
		39	Simulated use	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.1.4		2024-07-10
		40	Wall adhesion performance	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.2.2		2024-07-10
		41	Radial anti extrusion performance	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.2.3		2024-07-10
		42	Resistance to parallel plate extrusion performance	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.2.4		2024-07-10
		43	Local extrusion	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.2.5		2024-07-10
		44	Radial strength	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.2.6		2024-07-10
		45	Retract	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.2.7		2024-07-10
		46	Simulated use	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.2.8		2024-07-10
		47	Immediate coating integrit	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.3.2		2024-07-10
		48	Coating dimensions and other coating	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.3.3		2024-07-10



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			parameters (Such as porosity, density distribution, mass)			
		49	corrosiveness	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.3.4		2024-07-10
		50	Fatigue durability performance test	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.3.5.4		2024-07-10
		51	Durability of coating	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.3.5.5		2024-07-10
		52	Coating particle generation	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.3.5.6		2024-07-10
		53	Visual inspection	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.3.6		2024-07-10
		54	Dimensional verification	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.4.2		2024-07-10
		55	The relationship between stent diameter and balloon filling pressure	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.4.3		2024-07-10
		56	Retract	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.4.4		2024-07-10
		57	Simulated use	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.4.5		2024-07-10
		58	The relationship between bracket length and diameter	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.4.6		2024-07-10
		59	Radial anti extrusion performance	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.5.2		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
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		60	Resistance to parallel plate extrusion performance	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.5.3		2024-07-10
		61	Bending/Breaking	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.5.4		2024-07-10
		62	Local extrusion	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.5.5		2024-07-10
		63	Radial strength	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.5.6		2024-07-10
		64	Simulated use	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.5.7		2024-07-10
		65	Blank surface area of bracket and outer surface area of bracket	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.5.8		2024-07-10
		66	Biological evaluation	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.7		2024-07-10
		67	Drug-eluting	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.8.2		2024-07-10
		68	Sterilization Residue	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 11.3		2024-07-10
35	Biological evaluation of medical devices	1	Tests for genotoxicity, carcinogenicity and reproductive toxicity	Biological evaluation of medical devices-Part3:Tests for genotoxicity,carcinogenicity and reproductive toxicity GB/T16886.3-2019		2024-07-10
		2	Selection of tests for interactions with blood	Biological evaluation of medical devices-Part4:Selection of tests for interactions with blood GB/T16886.4-2022	Except for in vivo experiment	2024-07-10



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		№	Item/ Parameter			
					S	
		3	Tests for in vitro cytotoxicity	Biological evaluation of medical devices-Part 5:Tests for in vitro cytotoxicity GB/T 16886.5-2017		2024-07-10
		4	Tests for local effects after implantation	Biological evaluation of medical devices-Part6:Tests for local effects after implantation GB/T16886.6-2022		2024-07-10
		5	Ethylene oxide sterilization residuals	Biological evaluation of medical devices-Part 7:Ethylene oxide sterilization residuals GB/T16886.7-2015		2024-07-10
		6	Framework for identification and quantification of potential degradation products	Biological evaluation of medical devices-Part9:Framework for identification and quantification of potential degradation products GB/T16886.9-2022		2024-07-10
		7	Tests for irritation and skin sensitization	Biological evaluation of medical devices-Part10:Tests for irritation and skin sensitization GB/T 16886.10-2024	Except for local lymph node test in mice	2025-07-18
		8	Tests for systemic toxicity	Biological evaluation of medical devices-Part11:Tests for systemic toxicity GB/T 16886.11-2021		2024-07-10
		9	Maximum dose test in guinea pigs	Biological evaluation of medical devices-Part10:Tests for irritation and skin sensitization GB/T 16886.10-2024 6.5		2025-07-18
		10	Sample preparation and reference materials	Biological evaluation of medical devices-Part12:Sample preparation and reference materials GB/T16886.12-2017		2024-07-10
		11	Occlusion patch test	Biological evaluation of medical devices-Part10:Tests for irritation and skin sensitization GB/T 16886.10-2024 6.6		2025-07-18
		12	Identification and	Biological evaluation of medical devices-Part 13: Identification		2024-07-10

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
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			quantification of degradation products from polymeric medical devices	and quantification of degradation products from polymeric medical devices GB/T16886.13-2017		
		13	Identification and quantification of degradation products from ceramics	Biological evaluation of medical devices-Part 14: Identification and quantification of degradation products from ceramics GB/T16886.14-2003		2024-07-10
		14	Identification and quantification of degradation products from metals and alloys	Biological evaluation of medical devices-Part15:Identification and quantification of degradation products from metals and alloys GB/T16886.15-2022		2024-07-10
		15	Toxicokinetic study design for degradation products and leachables	Biological evaluation of medical devices-Part16:Toxicokinetic study design for degradation products and leachables GB/T16886.16-2021		2024-07-10
		16	Establishment of allowable limits for leachable substances	Biological evaluation of medical devices-Part17:Establishment of allowable limits for leachable substances GB/T16886.17-2005		2024-07-10
		17	Chemical characterization of medical device materials	Biological evaluation of medical devices-Part18:Chemical characterization of medical device materials within a risk management process GB/T16886.18-2022	Only material analysis using gas chromatography, liquid chromatogr	2024-07-10



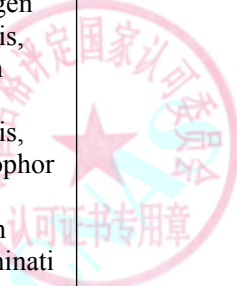
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					aphy, ion chromatography, mass spectrometry, nuclear magnetic resonance spectroscopy, atomic absorption, ultraviolet, infrared, X-ray fluorescence, differential scanning calorimetry, oxygen nitrogen hydrogen analysis, carbon sulfur analysis, electrophoresis, protein determination, titration,	

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					and colorimetric analysis methods	
		18	Physico-chemical, morphological and topographical characterization of materials	Biological evaluation of medical devices-Part19:Physico-chemical,morphological and topographical characterization of materials GB/T16886.19-2022	Only surface shape and form, hardness, roughness, chemical identification of particle, protein adsorption	2024-07-10
		19	Principles and methods for immunotoxicology testing of medical devices	Biological evaluation of medical devices-Part20: Principles and methods for immunotoxicology testing of medical devices GB/T 16886.20-2015		2024-07-10
		20	product of complement activation	Test for complement activation of medical devices- Part 3: Assay for the product of complement activation (C3 and SC5b-9) YY/T 0878.3-2019		2024-07-10
		21	Biological evaluation of absorbable medical devices	Biological evaluation of absorbable medical devices—Part 1:Guidance for absorbable implants YY/T 1775.1-2021		2024-07-10
		22	implantation assessment of	Tissue engineering medical products-Standard practice for implantation assessment of absorbable/resorbable biomaterials		2024-07-10



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		№	Item/ Parameter			
			absorbable medical products	YY/T 1576-2017		
		23	Partial Items	Biological evaluation of medical devices—Part23: Tests for irritation GB/T 16886.23-2023	Except for human skin irritation test	2025-07-18
		24		Tests for hemolysis of medical devices—Part 1: Material induced hemolysis assay YY/T 1651.1-2019		2024-07-10
		25	Partial Items	Biological evaluation of medical devices—Part23: Tests for irritation GB/T 16886.23-2023 6		2025-07-18
		26		Immunogenic evaluation method of medical devices--Part 6: Determination of animal spleen lymphocyte subsets by flow cytometry YY/T 1465.6-2019		2024-07-10
		27	Partial Items	Biological evaluation of medical devices—Part23: Tests for irritation GB/T 16886.23-2023 7		2025-07-18
		28		Immunogenic evaluation method of medical devices--Part 7: Liquid phase multiplex protein quantification technique by flow cytometry YY/T 1465.7-2021		2024-07-10
		29	In Vitro skin irritation test for medical devices	In Vitro skin irritation test for medical devices YY/T 1808-2021		2024-07-10
36	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements	1	Partial items	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements YY 0285.1—2017	Except for X-ray detectability	2024-07-10
		2	External Surface	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements YY 0285.1—2017 4.4		2024-07-10
		3	Corrosion resistance	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements YY 0285.1—2017 4.5		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
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		4	Peak tensile force	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements YY 0285.1—2017 4.6		2024-07-10
		5	Leakage	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements YY 0285.1—2017 4.7		2024-07-10
		6	seat	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements YY 0285.1—2017 4.8		2024-07-10
		7	Flow	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements YY 0285.1—2017 4.9		2024-07-10
		8	Power injection	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements YY 0285.1—2017 4.10		2024-07-10
		9	Lateral aperture	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements YY 0285.1—2017 4.11		2024-07-10
		10	End head end	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements YY 0285.1—2017 4.12		2024-07-10
		11	Identification of nominal size	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements YY 0285.1—2017 5		2024-07-10
37	Sterile, single-use intravascular catheters-Part 2: Angiographic catheters	1	Partial items	Sterile, single-use intravascular catheters-Part 2: Angiographic catheters YY 0285.2-1999	Except for X-ray detectability	2024-07-10
		2	Identification of nominal size	Sterile, single-use intravascular catheters-Part 2: Angiographic catheters YY 0285.2-1999 4.3		2024-07-10
		3	Tip configuration	Sterile, single-use intravascular catheters-Part 2: Angiographic catheters YY 0285.2-1999 4.4.1		2024-07-10
		4	No leakage and damage under high static pressure	Sterile, single-use intravascular catheters-Part 2: Angiographic catheters YY 0285.2-1999 4.4.2		2024-07-10
		5	Lateral aperture	Sterile, single-use intravascular catheters-Part 2: Angiographic catheters YY 0285.2-1999 4.4.3		2024-07-10



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38	Intravascular catheters—Sterile and single-use catheters—Part 3: Central venous catheters	1	All items	Intravascular catheters—Sterile and single-use catheters—Part 3: Central venous catheters YY 0285.3-2017	Except for X-ray detectability	2024-07-10
		2	Distance identification	Intravascular catheters—Sterile and single-use catheters—Part 3: Central venous catheters YY 0285.3-2017 4.2		2024-07-10
		3	Lumen identification	Intravascular catheters—Sterile and single-use catheters—Part 3: Central venous catheters YY 0285.3-2017 4.3		2024-07-10
		4	Peak tensile force	Intravascular catheters—Sterile and single-use catheters—Part 3: Central venous catheters YY 0285.3-2017 4.4		2024-07-10
39	Intravascular catheters—Sterile and single-use catheters—Part 4 : Balloon dilatation catheters	1	Partial items	Intravascular catheters—Sterile and single-use catheters—Part 4 : Balloon dilatation catheters YY 0285.4-2017	Except for X-ray detectability	2024-07-10
		2	Identification of nominal specifications	Intravascular catheters—Sterile and single-use catheters—Part 4 : Balloon dilatation catheters YY 0285.4-2017 4.3		2024-07-10
		3	Rated Burst Pressure (RBP) of Balloon	Intravascular catheters—Sterile and single-use catheters—Part 4 : Balloon dilatation catheters YY 0285.4-2017 4.4.1		2024-07-10
		4	Balloon fatigue, No leakage or damage during charging	Intravascular catheters—Sterile and single-use catheters—Part 4 : Balloon dilatation catheters YY 0285.4-2017 4.4.2		2024-07-10
		5	Balloon decompression time	Intravascular catheters—Sterile and single-use catheters—Part 4 : Balloon dilatation catheters YY 0285.4-2017 4.4.3		2024-07-10
		6	The relationship between balloon diameter and filling pressure	Intravascular catheters—Sterile and single-use catheters—Part 4 : Balloon dilatation catheters YY 0285.4-2017 4.4.4		2024-07-10



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40	Sterile, single-use intravascular catheters-Over-needle peripheral catheters	1	All items	Intravascular catheters--Sterile and single-use catheters-Part 5:Over-needle peripheral catheters YY 0285.5-2018		2024-07-10
		2	Multicavity catheter	Intravascular catheters--Sterile and single-use catheters-Part 5:Over-needle peripheral catheters YY 0285.5-2018 4.2		2024-07-10
		3	Color code	Intravascular catheters--Sterile and single-use catheters-Part 5:Over-needle peripheral catheters YY 0285.5-2018 4.3.1		2024-07-10
		4	Conduit Assembly	Intravascular catheters--Sterile and single-use catheters-Part 5:Over-needle peripheral catheters YY 0285.5-2018 4.3.2		2024-07-10
		5	Material	Intravascular catheters--Sterile and single-use catheters-Part 5:Over-needle peripheral catheters YY 0285.5-2018 4.3.3.1		2024-07-10
		6	Needle tip	Intravascular catheters--Sterile and single-use catheters-Part 5:Over-needle peripheral catheters YY 0285.5-2018 4.3.3.2		2024-07-10
		7	Needle holder	Intravascular catheters--Sterile and single-use catheters-Part 5:Over-needle peripheral catheters YY 0285.5-2018 4.3.3.3		2024-07-10
		8	Connection strength between needle tube and needle base	Intravascular catheters--Sterile and single-use catheters-Part 5:Over-needle peripheral catheters YY 0285.5-2018 4.3.3.4		2024-07-10
		9	Exhaust connector	Intravascular catheters--Sterile and single-use catheters-Part 5:Over-needle peripheral catheters YY 0285.5-2018 4.3.4		2024-07-10
41	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers	1	Partial items	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020	Except for X-ray detectability	2024-07-10
		2	surface	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 4.3		2024-07-10
		3	corrosion resistance	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 4.4		2024-07-10
		4	Specification identification	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 5.2		2024-07-10



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		5	Needle tip	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 5.3		2024-07-10
		6	taper joint	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 5.4.1		2024-07-10
		7	Connection strength between needle tube and needle base	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 5.4.2		2024-07-10
		8	head end	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 6.2		2024-07-10
		9	Peak tensile force	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 6.3		2024-07-10
		10	seat	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 6.4		2024-07-10
		11	Specification identification	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 6.5		2024-07-10
		12	Specification identification	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 7.2		2024-07-10
		13	No leakage in the sheath of the catheter	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 7.3		2024-07-10
		14	No leakage of hemostasis valve	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 7.4		2024-07-10
		15	seat	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 7.5		2024-07-10
		16	Peak tensile force	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 7.6		2024-07-10
		17	Specification identification	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 8.2		2024-07-10
		18	security thread	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 8.3		2024-07-10



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		19	Rupture test	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 8.4		2024-07-10
		20	Bending test	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 8.5		2024-07-10
		21	Peak tension of guide wire	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 8.6		2024-07-10
		22	Specification identification	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 9.3		2024-07-10
		23	seat	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 9.3		2024-07-10
		24	Connection strength between needle tube and needle base	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 11		2024-07-10
42	Accessory devices for sterile single-use intravascular catheters-Part 2:Obturators for over-needle peripheral catheters	1	Partial items	Accessory devices for sterile single-use intravascular catheters-Part 2:Obturators for over-needle peripheral catheters YY 0450.2-2003	Except for X-ray detectability	2024-07-10
		2	surface	Accessory devices for sterile single-use intravascular catheters-Part 2:Obturators for over-needle peripheral catheters YY 0450.2-2003 4.3		2024-07-10
		3	Breaking force	Accessory devices for sterile single-use intravascular catheters-Part 2:Obturators for over-needle peripheral catheters YY 0450.2-2003 4.4		2024-07-10
		4	Ruhr joint	Accessory devices for sterile single-use intravascular catheters-Part 2:Obturators for over-needle peripheral catheters YY 0450.2-2003 4.5		2024-07-10
		5	outside diameter	Accessory devices for sterile single-use intravascular catheters-Part 2:Obturators for over-needle peripheral catheters YY 0450.2-2003 4.6		2024-07-10



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		6	active length	Accessory devices for sterile single-use intravascular catheters-Part 2:Obturators for over-needle peripheral catheters YY 0450.2-2003 4.7		2024-07-10
		7	Color code	Accessory devices for sterile single-use intravascular catheters-Part 2:Obturators for over-needle peripheral catheters YY 0450.2-2003 4.8		2024-07-10
43	Infusion sets for single use	1	All items	Infusion sets for single use-Gravity feed GB 8368-2018		2024-07-10
		2	Particle contamination	Infusion sets for single use-Gravity feed GB 8368-2018 6.1		2024-07-10
		3	Leakage	Infusion sets for single use-Gravity feed GB 8368-2018 6.2		2024-07-10
		4	tensile strength	Infusion sets for single use-Gravity feed GB 8368-2018 6.3		2024-07-10
		5	Bottle stopper puncture device	Infusion sets for single use-Gravity feed GB 8368-2018 6.4		2024-07-10
		6	Air intake device	Infusion sets for single use-Gravity feed GB 8368-2018 6.5		2024-07-10
		7	piping	Infusion sets for single use-Gravity feed GB 8368-2018 6.6		2024-07-10
		8	Liquid filter	Infusion sets for single use-Gravity feed GB 8368-2018 6.7		2024-07-10
		9	Drip bucket and dropper	Infusion sets for single use-Gravity feed GB 8368-2018 6.8		2024-07-10
		10	regulator	Infusion sets for single use-Gravity feed GB 8368-2018 6.9		2024-07-10
		11	Infusion flow rate	Infusion sets for single use-Gravity feed GB 8368-2018 6.10		2024-07-10
		12	Injection parts	Infusion sets for single use-Gravity feed GB 8368-2018 6.11		2024-07-10
		13	Outer cone joint	Infusion sets for single use-Gravity feed GB 8368-2018 6.12		2024-07-10



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		14	protective sheath	Infusion sets for single use-Gravity feed GB 8368-2018 6.13		2024-07-10
		15	Reducing Substances (Readily oxidation substance)	Infusion sets for single use-Gravity feed GB 8368-2018 7.1		2024-07-10
		16	Metal Ions	Infusion sets for single use-Gravity feed GB 8368-2018 7.2		2024-07-10
		17	Acid-Base Titration	Infusion sets for single use-Gravity feed GB 8368-2018 7.3		2024-07-10
		18	Residue on Evaporation	Infusion sets for single use-Gravity feed GB 8368-2018 7.4		2024-07-10
		19	Ultraviolet Absorbance of Extraction Liquid	Infusion sets for single use-Gravity feed GB 8368-2018 7.5		2024-07-10
		20	Ethylene Oxide Residue	Infusion sets for single use-Gravity feed GB 8368-2018 7.6		2024-07-10
		21	Sterility	Infusion sets for single use-Gravity feed GB 8368-2018 8.2		2024-07-10
		22	Pyrogen	Infusion sets for single use-Gravity feed GB 8368-2018 8.3		2024-07-10
		23	Hemolysis test	Infusion sets for single use-Gravity feed GB 8368-2018 8.4		2024-07-10
		24	Biological evaluation	Infusion sets for single use-Gravity feed GB 8368-2018 8.5		2024-07-10
44	Transfusion sets for single use	1	All items	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019		2024-07-10
		2	Particle contamination	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 5.1		2024-07-10
		3	Leakage	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 5.2		2024-07-10



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		4	Tensile strength	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 5.3		2024-07-10
		5	Transfusion faucet	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 5.4		2024-07-10
		6	puncture set piping	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 5.5		2024-07-10
		7	Blood and blood component filters	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 5.6		2024-07-10
		8	Drip bucket and dropper	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 5.7		2024-07-10
		9	regulator	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 5.8		2024-07-10
		10	Flow rate of blood and blood components	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 5.9		2024-07-10
		11	Injection parts	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 5.10		2024-07-10
		12	Outer cone joint	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 5.11		2024-07-10
		13	protective sheath	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 5.12		2024-07-10
		14	Reducing Substances (Readily oxidation substance)	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 6.1		2024-07-10
		15	Metal Ions	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 6.2		2024-07-10
		16	Acid-Base Titration	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 6.3		2024-07-10
		17	Residue on Evaporation	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 6.4		2024-07-10



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		18	Ultraviolet Absorbance of Extraction Liquid	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 6.5		2024-07-10
		19	Ethylene Oxide Residue	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 6.6		2024-07-10
		20	Sterility	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 7.2		2024-07-10
		21	Pyrogen	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 7.3		2024-07-10
		22	Hemolysis test	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 7.4		2024-07-10
		23	Biological evaluation	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 7.5		2024-07-10
45	Infusion sets for single use with micropore filters	1	All items	Infusion sets for special purpose-Part 1 :Infusion sets for single use with micropore filters YY 0286.1-2019		2024-07-10
		2	design	Infusion sets for special purpose-Part 1 :Infusion sets for single use with micropore filters YY 0286.1-2019 7.2.1		2024-07-10
		3	Particle contamination	Infusion sets for special purpose-Part 1 :Infusion sets for single use with micropore filters YY 0286.1-2019 7.2.2		2024-07-10
		4	Requirements for filtration performance of sterilization grade liquid filters	Infusion sets for special purpose-Part 1 :Infusion sets for single use with micropore filters YY 0286.1-2019 7.2.3		2024-07-10
		5	Nominal bore 1.2 µm Filtration performance requirements of solution filter	Infusion sets for special purpose-Part 1 :Infusion sets for single use with micropore filters YY 0286.1-2019 7.2.4		2024-07-10



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		№	Item/ Parameter			
		6	Nominal bore 2.0 μm ~5.0 μm Liquid filter filtration performance requirements	Infusion sets for special purpose-Part 1 :Infusion sets for single use with micropore filters YY 0286.1-2019 7.2.5		2024-07-10
		7	Vent (if any)	Infusion sets for special purpose-Part 1 :Infusion sets for single use with micropore filters YY 0286.1-2019 7.2.6		2024-07-10
		8	Infusion flow rate	Infusion sets for special purpose-Part 1 :Infusion sets for single use with micropore filters YY 0286.1-2019 7.3		2024-07-10
		9	Chemical Requirements	Infusion sets for special purpose-Part 1 :Infusion sets for single use with micropore filters YY 0286.1-2019 8		2024-07-10
		10	Biological requirements	Infusion sets for special purpose-Part 1 :Infusion sets for single use with micropore filters YY 0286.1-2019 9		2024-07-10
46	Burette-type infusion sets for single use-Gravity feed	1	All items	Special infusion sets-Part 2: Burette-type infusion sets for single use-Gravity feed YY 0286.2-2006		2024-07-10
		2	design	Special infusion sets-Part 2: Burette-type infusion sets for single use-Gravity feed YY 0286.2-2006 6.2		2024-07-10
		3	Burette capacity	Special infusion sets-Part 2: Burette-type infusion sets for single use-Gravity feed YY 0286.2-2006 6.3		2024-07-10
		4	scale	Special infusion sets-Part 2: Burette-type infusion sets for single use-Gravity feed YY 0286.2-2006 6.4		2024-07-10
		5	Chemical Requirements	Special Infusion sets-Part 2 :Burette-Type Infusion sets for single use- Gravity feed YY 0286.2-2006 7		2024-07-10
		6	Biological requirements	Special Infusion sets-Part 2 :Burette-Type Infusion sets for single use- Gravity feed YY 0286.2-2006 8		2024-07-10
47	A.V.fistula needle sets for single use	1	All items	A.V.fistula needle sets for single use YY/T 0328-2015		2024-07-10
		2	particle contamination	A.V.fistula needle sets for single use YY/T 0328-2015 5.1		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		3	Sealing performance	A.V.fistula needle sets for single use YY/T 0328-2015 5.2		2024-07-10
		4	connection strength	A.V.fistula needle sets for single use YY/T 0328-2015 5.3		2024-07-10
		5	flow	A.V.fistula needle sets for single use YY/T 0328-2015 5.4		2024-07-10
		6	hose	A.V.fistula needle sets for single use YY/T 0328-2015 5.5		2024-07-10
		7	puncture needle	A.V.fistula needle sets for single use YY/T 0328-2015 5.6		2024-07-10
		8	Stop clamp	A.V.fistula needle sets for single use YY/T 0328-2015 5.7		2024-07-10
		9	Inner cone joint	A.V.fistula needle sets for single use YY/T 0328-2015 5.8		2024-07-10
		10	case	A.V.fistula needle sets for single use YY/T 0328-2015 5.9		2024-07-10
		11	Reducing Substances	A.V.fistula needle sets for single use YY/T 0328-2015 6.2		2024-07-10
		12	Metal Ions	A.V.fistula needle sets for single use YY/T 0328-2015 6.3		2024-07-10
		13	Acid-Base Titration	A.V.fistula needle sets for single use YY/T 0328-2015 6.4		2024-07-10
		14	Residue on Evaporation	A.V.fistula needle sets for single use YY/T 0328-2015 6.5		2024-07-10
		15	Ultraviolet Absorbance	A.V.fistula needle sets for single use YY/T 0328-2015 6.6		2024-07-10
		16	Ethylene Oxide Residue	A.V.fistula needle sets for single use YY/T 0328-2015 6.7		2024-07-10
		17	Biological evaluation	A.V.fistula needle sets for single use YY/T 0328-2015 7.1		2024-07-10
		18	Sterility	A.V.fistula needle sets for single use YY/T 0328-2015 7.2		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		19	Bacterial endotoxins	A.V.fistula needle sets for single use YY/T 0328-2015 7.3		2024-07-10
48	Conventional blood containers	1	All items	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020		2024-07-10
		2	size	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020 4.1		2024-07-10
		3	air content	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020 5.2		2024-07-10
		4	Pressure evacuation	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020 5.3		2024-07-10
		5	Blood sample identification	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020 5.4		2024-07-10
		6	Acquisition speed	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020 5.5		2024-07-10
		7	Blood collection and transfer tubes	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020 5.6		2024-07-10
		8	blood taking needle	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020 5.7		2024-07-10
		9	Blood transfusion socket	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020 5.8		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		10	hang	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020 5.9		2024-07-10
		11	transparency	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020 6.2.3		2024-07-10
		12	colour and lustre	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020 6.2.4		2024-07-10
		13	thermal stability	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020 6.2.5		2024-07-10
		14	Water vapor leakage	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020 6.2.6		2024-07-10
		15	Anti leakage	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020 6.2.7		2024-07-10
		16	particle contamination	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020 6.2.8		2024-07-10
		17	Chemical requirements	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020 6.3		2024-07-10
		18	Biological requirements	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020 6.4		2024-07-10
49	Plunger seal of syringes for	1	All items	Plunger seal of syringes for single use YY/T 0243-2016		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
single use		2	appearance	Plunger seal of syringes for single use YY/T 0243-2016 5.1		2024-07-10
		3	Hardness (shore A)	Plunger seal of syringes for single use YY/T 0243-2016 5.2.1		2024-07-10
		4	compression set	Plunger seal of syringes for single use YY/T 0243-2016 5.2.2		2024-07-10
		5	Change rate of tensile strength	Plunger seal of syringes for single use YY/T 0243-2016 5.2.3		2024-07-10
		6	Change rate of elongation at break	Plunger seal of syringes for single use YY/T 0243-2016 5.2.4		2024-07-10
		7	pH	Plunger seal of syringes for single use YY/T 0243-2016 5.3.1		2024-07-10
		8	Extractable Metal Content	Plunger seal of syringes for single use YY/T 0243-2016 5.3.2		2024-07-10
		9	Reducing Substances	Plunger seal of syringes for single use YY/T 0243-2016 5.3.3		2024-07-10
		10	Ultraviolet Absorbance	Plunger seal of syringes for single use YY/T 0243-2016 5.3.4		2024-07-10
		11	Ash Content	Plunger seal of syringes for single use YY/T 0243-2016 5.3.5		2024-07-10
		12	Pyrogen	Plunger seal of syringes for single use YY/T 0243-2016 5.4.1		2024-07-10
		13	Cytotoxicity	Plunger seal of syringes for single use YY/T 0243-2016 5.4.2		2024-07-10
		14	Hemolysis test	Plunger seal of syringes for single use YY/T 0243-2016 5.4.3		2024-07-10
		15	Irritation	Plunger seal of syringes for single use YY/T 0243-2016 5.4.4		2024-07-10
		16	Sensitization	Plunger seal of syringes for single use YY/T 0243-2016 5.4.5		2024-07-10
		17	Acute systemic toxicity	Plunger seal of syringes for single use YY/T 0243-2016 5.4.6		2024-07-10

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		№	Item/ Parameter			
50	Blood flow products for single use-General specification	1	All items	Blood flow products for single use-General specification GB/T 19335-2022		2024-07-10
		2	protective sheath	Blood flow products for single use-General specification GB/T 19335-2022 6.1		2024-07-10
		3	Injection parts	Blood flow products for single use-General specification GB/T 19335-2022 6.2		2024-07-10
		4	Connector	Blood flow products for single use-General specification GB/T 19335-2022 6.3		2024-07-10
		5	Blood and blood component filter screen	Blood flow products for single use-General specification GB/T 19335-2022 6.4		2024-07-10
		6	switch	Blood flow products for single use-General specification GB/T 19335-2022 6.5		2024-07-10
		7	Pressure monitoring connector/sensor protector	Blood flow products for single use-General specification GB/T 19335-2022 6.6		2024-07-10
		8	appearance	Blood flow products for single use-General specification GB/T 19335-2022 7.2.1		2024-07-10
		9	Tightness	Blood flow products for single use-General specification GB/T 19335-2022 7.2.2		2024-07-10
		10	Connection firmness	Blood flow products for single use-General specification GB/T 19335-2022 7.2.3		2024-07-10
		11	particle contamination	Blood flow products for single use-General specification GB/T 19335-2022 7.2.4		2024-07-10
		12	color code	Blood flow products for single use-General specification GB/T 19335-2022 7.2.5		2024-07-10
		13	color	Blood flow products for single use-General specification GB/T 19335-2022 7.3.2		2024-07-10
		14	reducing substance	Blood flow products for single use-General specification GB/T 19335-2022 7.3.3		2024-07-10



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		№	Item/ Parameter			
		15	metal ions	Blood flow products for single use-General specification GB/T 19335-2022 7.3.4		2024-07-10
		16	PH	Blood flow products for single use-General specification GB/T 19335-2022 7.3.5		2024-07-10
		17	Evaporation residue	Blood flow products for single use-General specification GB/T 19335-2022 7.3.6		2024-07-10
		18	Ultraviolet absorption	Blood flow products for single use-General specification GB/T 19335-2022 7.3.7		2024-07-10
		19	ethylene oxide residue	Blood flow products for single use-General specification GB/T 19335-2022 7.4		2024-07-10
		20	sterility	Blood flow products for single use-General specification GB/T 19335-2022 7.5.2		2024-07-10
		21	bacterial endotoxin	Blood flow products for single use-General specification GB/T 19335-2022 7.5.3		2024-07-10
		22	haemocompatible	Blood flow products for single use-General specification GB/T 19335-2022 7.5.4		2024-07-10
51	Single-use containers for human venous blood specimen collection	1	All items	Single-use containers for human venous blood specimen collection YY/T 0314-2021		2024-07-10
		2	Suction volume	Single-use containers for human venous blood specimen collection YY/T 0314-2021 5		2024-07-10
		3	structure	Single-use containers for human venous blood specimen collection YY/T 0314-2021 7		2024-07-10
		4	Sterility and specific microbial status	Single-use containers for human venous blood specimen collection YY/T 0314-2021 8		2024-07-10
		5	additive	Single-use containers for human venous blood specimen collection YY/T 0314-2021 9		2024-07-10
		6	Identification of collection containers	Single-use containers for human venous blood specimen collection YY/T 0314-2021 11		2024-07-10
52	Infusion sets for single use-	1	All items	Infusion sets for single use-Gravity feed GB 8368-2018		2024-07-10



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		№	Item/ Parameter			
	Gravity feed	2	Particle contamination	Infusion sets for single use-Gravity feed GB 8368-2018 6.1		2024-07-10
		3	leakage	Infusion sets for single use-Gravity feed GB 8368-2018 6.2		2024-07-10
		4	tensile strength	Infusion sets for single use-Gravity feed GB 8368-2018 6.3		2024-07-10
		5	Bottle stopper puncture device	Infusion sets for single use-Gravity feed GB 8368-2018 6.4		2024-07-10
		6	Air intake device	Infusion sets for single use-Gravity feed GB 8368-2018 6.5		2024-07-10
		7	piping	Infusion sets for single use-Gravity feed GB 8368-2018 6.6		2024-07-10
		8	Liquid filter	Infusion sets for single use-Gravity feed GB 8368-2018 6.7		2024-07-10
		9	Drip bucket and dropper	Infusion sets for single use-Gravity feed GB 8368-2018 6.8		2024-07-10
		10	regulator	Infusion sets for single use-Gravity feed GB 8368-2018 6.9		2024-07-10
		11	Infusion flow rate	Infusion sets for single use-Gravity feed GB 8368-2018 6.10		2024-07-10
		12	Injection parts	Infusion sets for single use-Gravity feed GB 8368-2018 6.11		2024-07-10
		13	Outer cone joint	Infusion sets for single use-Gravity feed GB 8368-2018 6.12		2024-07-10
		14	protective sheath	Infusion sets for single use-Gravity feed GB 8368-2018 6.13		2024-07-10
		15	Reducing Substances	Infusion sets for single use-Gravity feed GB 8368-2018 7.1		2024-07-10
		16	Metal Ions	Infusion sets for single use-Gravity feed GB 8368-2018 7.2		2024-07-10
		17	Acid-Base Titration	Infusion sets for single use-Gravity feed GB 8368-2018 7.3		2024-07-10



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		№	Item/ Parameter			
		18	Residue on Evaporation	Infusion sets for single use-Gravity feed GB 8368-2018 7.4		2024-07-10
		19	Ultraviolet Absorbance of Extraction Liquid	Infusion sets for single use-Gravity feed GB 8368-2018 7.5		2024-07-10
		20	Ethylene Oxide Residue	Infusion sets for single use-Gravity feed GB 8368-2018 7.6		2024-07-10
		21	Sterility	Infusion sets for single use-Gravity feed GB 8368-2018 8.2		2024-07-10
		22	Pyrogen	Infusion sets for single use-Gravity feed GB 8368-2018 8.3		2024-07-10
		23	Hemolysis test	Infusion sets for single use-Gravity feed GB 8368-2018 8.4		2024-07-10
		24	Biological evaluation	Infusion sets for single use-Gravity feed GB 8368-2018 8.5		2024-07-10
53	Human blood containers for UV transmission therapy for single use	1	All items	Human blood containers for UV transmission therapy for single use YY 0327-2002		2024-07-10
		2	materials	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.1		2024-07-10
		3	structure	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.2		2024-07-10
		4	appearance	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.3		2024-07-10
		5	Particle contamination	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.4.1		2024-07-10
		6	tightness	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.4.2		2024-07-10
		7	connection strength	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.4.3		2024-07-10
		8	UV transmittance	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.4.4		2024-07-10

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		№	Item/ Parameter			
		9	intake pipe	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.4.5		2024-07-10
		10	Suspension device	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.4.6		2024-07-10
		11	protective sheath;	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.4.7		2024-07-10
		12	Reducing Substances	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.5.1		2024-07-10
		13	Metal Ions	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.5.2		2024-07-10
		14	pH	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.5.3		2024-07-10
		15	Residue on Evaporation	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.5.4		2024-07-10
		16	Ultraviolet Absorbance	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.5.5		2024-07-10
		17	Color	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.5.6		2024-07-10
		18	Ethylene Oxide Residue	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.5.7		2024-07-10
		19	Sterility	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.6.1		2024-07-10
		20	Pyrogen	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.6.2		2024-07-10
		21	Hemolysis test	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.6.3		2024-07-10
		22	Acute systemic toxicity	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.6.4		2024-07-10
54	Implantable drug-supplying	1	Partial items	Implantable drug-supplying device YY 0332-2011	Except for X-ray	2024-07-10



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		№	Item/ Parameter			
	device				detectability	
		2	General requirements	Implantable drug-supplying device YY 0332-2011 5.1		2024-07-10
		3	appearance	Implantable drug-supplying device YY 0332-2011 5.2.1		2024-07-10
		4	puncture resistance	Implantable drug-supplying device YY 0332-2011 5.2.2.1		2024-07-10
		5	Puncture of chips	Implantable drug-supplying device YY 0332-2011 5.2.2.2		2024-07-10
		6	Puncture limit	Implantable drug-supplying device YY 0332-2011 5.2.2.3		2024-07-10
		7	Bubble discharge	Implantable drug-supplying device YY 0332-2011 5.2.2.4		2024-07-10
		8	size	Implantable drug-supplying device YY 0332-2011 5.2.3.1		2024-07-10
		9	Bending resistance	Implantable drug-supplying device YY 0332-2011 5.2.3.2		2024-07-10
		10	Dynamic fracture strength	Implantable drug-supplying device YY 0332-2011 5.2.4		2024-07-10
		11	Tightness	Implantable drug-supplying device YY 0332-2011 5.2.5		2024-07-10
		12	Sterility	Implantable drug-supplying device YY 0332-2011 5.3		2024-07-10
		13	Bacterial endotoxins	Implantable drug-supplying device YY 0332-2011 5.4		2024-07-10
		14	Ethylene Oxide Residue	Implantable drug-supplying device YY 0332-2011 5.5		2024-07-10
55	Soft-tissue expander device	1	All items	Soft-tissue expander device YY 0333-2010		2024-07-10
		2	shell	Soft-tissue expander device YY 0333-2010 9.2		2024-07-10



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		№	Item/ Parameter			
		3	Pipeline shell connection strength	Soft-tissue expander device YY 0333-2010 9.3		2024-07-10
		4	Injection seat performance	Soft-tissue expander device YY 0333-2010 9.4		2024-07-10
		5	Expansion resistance	Soft-tissue expander device YY 0333-2010 9.5		2024-07-10
		6	Joint strength	Soft-tissue expander device YY 0333-2010 9.6		2024-07-10
		7	Needle punched limit piece	Soft-tissue expander device YY 0333-2010 9.7		2024-07-10
		8	Adhesive joint	Soft-tissue expander device YY 0333-2010 9.8		2024-07-10
		9	Ethylene Oxide Residue	Soft-tissue expander device YY 0333-2010 10.2		2024-07-10
56	General specification for surgical implants made of silicone elastomer	1	All items	General specification for surgical implants made of silicone elastomer YY/T 0334-2022		2024-07-10
		2	appearance	General specification for surgical implants made of silicone elastomer YY/T 0334-2022 4		2024-07-10
		3	biological evaluation	General specification for surgical implants made of silicone elastomer YY/T 0334-2022 5.2		2024-07-10
		4	Drying loss	General specification for surgical implants made of silicone elastomer YY/T 0334-2022 5.3.1		2024-07-10
		5	Trace element	General specification for surgical implants made of silicone elastomer YY/T 0334-2022 5.3.2		2024-07-10
		6	Identify	General specification for surgical implants made of silicone elastomer YY/T 0334-2022 5.3.3		2024-07-10
		7	Solution appearance	General specification for surgical implants made of silicone elastomer YY/T 0334-2022 5.4.1		2024-07-10
		8	Evaporation residue	General specification for surgical implants made of silicone elastomer YY/T 0334-2022 5.4.2		2024-07-10



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		№	Item/ Parameter			
		9	pH	General specification for surgical implants made of silicone elastomer YY/T 0334-2022 5.4.3		2024-07-10
		10	Catalyst residue	General specification for surgical implants made of silicone elastomer YY/T 0334-2022 5.4.4		2024-07-10
		11	Reducing substance	General specification for surgical implants made of silicone elastomer YY/T 0334-2022 5.4.5		2024-07-10
		12	Ultraviolet absorption	General specification for surgical implants made of silicone elastomer YY/T 0334-2022 5.4.6		2024-07-10
		13	Heavy metal	General specification for surgical implants made of silicone elastomer YY/T 0334-2022 5.4.7		2024-07-10
		14	Sterility	General specification for surgical implants made of silicone elastomer YY/T 0334-2022 6		2024-07-10
57	Cervix dilator	1	All items	Cervix dilator YY 0091-2013		2024-07-10
		2	appearance	Cervix dilator YY 0091-2013 4.1		2024-07-10
		3	size	Cervix dilator YY 0091-2013 4.2		2024-07-10
		4	roughness	Cervix dilator YY 0091-2013 4.3		2024-07-10
		5	cladding material	Cervix dilator YY 0091-2013 4.4		2024-07-10
		6	Corrosion Resistance	Cervix dilator YY 0091-2013 4.5		2024-07-10
58	Sterile vaginal dilator for single use	1	All items	Sterile vaginal dilator for single use YY 0336-2020		2024-07-10
		2	appearance	Sterile vaginal dilator for single use YY 0336-2020 4.1		2024-07-10
		3	measurement	Sterile vaginal dilator for single use YY 0336-2020 4.2		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	usability	Sterile vaginal dilator for single use YY 0336-2020 4.3		2024-07-10
		5	physical quantity	Sterile vaginal dilator for single use YY 0336-2020 4.4		2024-07-10
		6	sterility	Sterile vaginal dilator for single use YY 0336-2020 4.5		2024-07-10
		7	ethylene oxide residue	Sterile vaginal dilator for single use YY 0336-2020 4.6		2024-07-10
		8	biological evaluation	Sterile vaginal dilator for single use YY 0336-2020 4.7		2024-07-10
59	Commonly-used tubes and connectors	1	All items	Tracheal tubes Part 1:- Commonly-used tubes and connectors YY 0337.1-2002		2024-07-10
		2	Specification identification	Tracheal tubes Part 1:-Commonly-used tubes and connectors YY 0337.1-2002 4.1		2024-07-10
		3	size	Tracheal tubes Part 1:-Commonly-used tubes and connectors YY 0337.1-2002 4.2		2024-07-10
		4	bevel	Tracheal tubes Part 1:-Commonly-used tubes and connectors YY 0337.1-2002 4.4		2024-07-10
		5	cuff	Tracheal tubes Part 1:-Commonly-used tubes and connectors YY 0337.1-2002 4.5		2024-07-10
		6	cuff inflating tube	Tracheal tubes Part 1:-Commonly-used tubes and connectors YY 0337.1-2002 4.6		2024-07-10
		7	tube radius	Tracheal tubes Part 1:-Commonly-used tubes and connectors YY 0337.1-2002 4.7		2024-07-10
		8	Murphy hole size	Tracheal tubes Part 1:-Commonly-used tubes and connectors YY 0337.1-2002 5.1		2024-07-10
		9	Murphy hole position	Tracheal tubes Part 1:-Commonly-used tubes and connectors YY 0337.1-2002 5.2		2024-07-10
		10	Sterility	Tracheal tubes Part 1:-Commonly-used tubes and connectors YY 0337.1-2002 6.1		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
60	Cole type tube	1	All items	Tracheal tubes-Part2: Cole type tube YY 0337.2-2002		2024-07-10
		2	size	Tracheal tubes-Part2: Cole type tube YY 0337.2-2002 7		2024-07-10
		3	bevel	Tracheal tubes-Part2: Cole type tube YY 0337.2-2002 8		2024-07-10
		4	shoulder	Tracheal tubes-Part2: Cole type tube YY 0337.2-2002 9		2024-07-10
		5	tube radian	Tracheal tubes-Part2: Cole type tube YY 0337.2-2002 10		2024-07-10
		6	sign	Tracheal tubes-Part2: Cole type tube YY 0337.2-2002 11		2024-07-10
61	Anaesthetic and respiratory equipment- Conical connectors- Part 1: Cones and sockets	1	All items	Anaesthetic and respiratory equipment-Conical connectors-Part 1: Cones and sockets YY/T 1040.1-2015		2024-07-10
		2	common requirements	Anaesthetic and respiratory equipment-Conical connectors-Part 1: Cones and sockets YY/T 1040.1-2015 4.1		2024-07-10
		3	additional requirements for 22mm outer conical connectors	Anaesthetic and respiratory equipment-Conical connectors-Part 1: Cones and sockets YY/T 1040.1-2015 4.2		2024-07-10
		4	additional requirements for 8.5mm conical connectors	Anaesthetic and respiratory equipment-Conical connectors-Part 1: Cones and sockets YY/T 1040.1-2015 4.3		2024-07-10
		5	common requirements	Anaesthetic and respiratory equipment-Conical connectors-Part 1: Cones and sockets YY/T 1040.1-2015 5.1		2024-07-10
		6	additional requirements for 22mm conical connectors	Anaesthetic and respiratory equipment-Conical connectors-Part 1: Cones and sockets YY/T 1040.1-2015 5.2		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	additional requirements for 8.5mm conical connectors	Anaesthetic and respiratory equipment-Conical connectors-Part 1: Cones and sockets YY/T 1040.1-2015 5.3		2024-07-10
		8	22 mm latching connector	Anaesthetic and respiratory equipment-Conical connectors-Part 1: Cones and sockets YY/T 1040.1-2015 6		2024-07-10
62	Portable infusion devices for single use	1	All items	Portable infusion devices for single use-Non electrically driven YY 0451-2010		2024-07-10
		2	joint	Portable infusion devices for single use-Non electrically driven YY 0451-2010 4.3.2		2024-07-10
		3	filter	Portable infusion devices for single use-Non electrically driven YY 0451-2010 4.3.3		2024-07-10
		4	piping	Portable infusion devices for single use-Non electrically driven YY 0451-2010 4.3.4		2024-07-10
		5	Storage sac	Portable infusion devices for single use-Non electrically driven YY 0451-2010 4.3.5		2024-07-10
		6	Particle contamination	Portable infusion devices for single use-Non electrically driven YY 0451-2010 4.3.6		2024-07-10
		7	Sterility and Pyrogen	Portable infusion devices for single use-Non electrically driven YY 0451-2010 4.4		2024-07-10
		8	Reducing Substances	Portable infusion devices for single use-Non electrically driven YY 0451-2010 4.5.2		2024-07-10
		9	Metal Ions	Portable infusion devices for single use-Non electrically driven YY 0451-2010 4.5.3		2024-07-10
		10	PH	Portable infusion devices for single use-Non electrically driven YY 0451-2010 4.5.4		2024-07-10
		11	Residue on Evaporation	Portable infusion devices for single use-Non electrically driven YY 0451-2010 4.5.5		2024-07-10
		12	Ultraviolet Absorbance	Portable infusion devices for single use-Non electrically driven YY 0451-2010 4.5.6		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		13	Ethylene Oxide Residue	Portable infusion devices for single use-Non electrically driven YY 0451-2010 4.5.7		2024-07-10
		14	Flow	Portable infusion devices for single use-Non electrically driven YY 0451-2010 5.1.1		2024-07-10
		15	Automatic liquid feeding	Portable infusion devices for single use-Non electrically driven YY 0451-2010 5.1.2		2024-07-10
63	Sterile urethral catheter for single use	1	Partial items	Sterile urethral catheter for single use YY/T 0325-2022	Except for detectability	2024-07-10
		2	biocompatibility	Sterile urethral catheter for single use YY/T 0325-2022 5.2		2024-07-10
		3	appearance	Sterile urethral catheter for single use YY/T 0325-2022 5.4		2024-07-10
		4	measurement	Sterile urethral catheter for single use YY/T 0325-2022 5.5		2024-07-10
		5	Connector	Sterile urethral catheter for single use YY/T 0325-2022 5.7		2024-07-10
		6	sterilization	Sterile urethral catheter for single use YY/T 0325-2022 5.8		2024-07-10
		7	ethylene oxide residue	Sterile urethral catheter for single use YY/T 0325-2022 5.9		2024-07-10
		8	strength	Sterile urethral catheter for single use YY/T 0325-2022 6.1		2024-07-10
		9	Connector security	Sterile urethral catheter for single use YY/T 0325-2022 6.2		2024-07-10
		10	Balloon reliability	Sterile urethral catheter for single use YY/T 0325-2022 6.3		2024-07-10
		11	Integrity of catheter inflation chamber and Volume maintenance	Sterile urethral catheter for single use YY/T 0325-2022 6.4		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		12	rate of flow	Sterile urethral catheter for single use YY/T 0325-2022 6.5		2024-07-10
		13	corrosion preventive	Sterile urethral catheter for single use YY/T 0325-2022 6.6		2024-07-10
		14	Twist stability	Sterile urethral catheter for single use YY/T 0325-2022 6.7		2024-07-10
		15	Peak tensile force	Sterile urethral catheter for single use YY/T 0325-2022 6.8		2024-07-10
		16	balloon tensile strength	Sterile urethral catheter for single use YY/T 0325-2022 6.9		2024-07-10
64	Polyethylene material for manufacture of infusion, transfusion and injection equipments for medical use	1	Partial items	Polyethylene material for manufacture of infusion, transfusion and injection equipments for medical use YY/T 0114-2008	Except for tensile yield stress, bending modulus, cantilever beam notch impact strength	2024-07-10
		2	particle appearance	Polyethylene material for manufacture of infusion, transfusion and injection equipments for medical use YY/T 0114-2008 3.1		2024-07-10
		3	pH	Polyethylene material for manufacture of infusion, transfusion and injection equipments for medical use YY/T 0114-2008 3.2		2024-07-10
		4	Heavy Metal Content	Polyethylene material for manufacture of infusion, transfusion and injection equipments for medical use YY/T 0114-2008 3.2		2024-07-10
		5	Cadmium Content	Polyethylene material for manufacture of infusion, transfusion and injection equipments for medical use YY/T 0114-2008 3.2		2024-07-10
		6	Ultraviolet Absorbance	Polyethylene material for manufacture of infusion, transfusion and injection equipments for medical use YY/T 0114-2008 3.2		2024-07-10
		7	Biological evaluation	Polyethylene material for manufacture of infusion, transfusion and injection equipments for medical use YY/T 0114-2008 3.4		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
65	Plasticized poly(vinyl chloride) compounds for transfusion(infusion) equipment	1	Partial items	Plasticized poly(vinyl chloride) compounds for transfusion(infusion) equipment GB/T 15593-2020	Except for aluminum and mercury	2024-07-10
		2	Water absorption rate	Plasticized poly(vinyl chloride) compounds for transfusion(infusion) equipment GB/T 15593-2020 3.3.1		2024-07-10
		3	hardness	Plasticized poly(vinyl chloride) compounds for transfusion(infusion) equipment GB/T 15593-2020 3.3.1		2024-07-10
		4	Tensile strength and tensile strain at break	Plasticized poly(vinyl chloride) compounds for transfusion(infusion) equipment GB/T 15593-2020 3.3.1		2024-07-10
		5	180 °C thermal stability time	Plasticized poly(vinyl chloride) compounds for transfusion(infusion) equipment GB/T 15593-2020 3.3.1		2024-07-10
		6	Low temperature impact embrittlement temperature	Plasticized poly(vinyl chloride) compounds for transfusion(infusion) equipment GB/T 15593-2020 3.3.1		2024-07-10
		7	Reducing Substances in PVC Plastic Aqueous Extracts	Plasticized poly(vinyl chloride) compounds for transfusion(infusion) equipment GB/T 15593-2020 3.3.2.1		2024-07-10
		8	pH of PVC Plastic Aqueous Extracts	Plasticized poly(vinyl chloride) compounds for transfusion(infusion) equipment GB/T 15593-2020 3.3.2.1		2024-07-10
		9	Color of PVC Plastic Aqueous Extracts	Plasticized poly(vinyl chloride) compounds for transfusion(infusion) equipment GB/T 15593-2020 3.3.2.1		2024-07-10
		10	Ultraviolet Absorbance of PVC Plastic Aqueous Extracts	Plasticized poly(vinyl chloride) compounds for transfusion(infusion) equipment GB/T 15593-2020 3.3.2.1		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		11	Residue on Evaporation of PVC Plastic Aqueous Extracts	Plasticized poly(vinyl chloride)compounds for transfusion(infusion) equipment GB/T 15593-2020 3.3.2.1		2024-07-10
		12	zinc of PVC Plastic Aqueous Extracts	Plasticized poly(vinyl chloride)compounds for transfusion(infusion) equipment GB/T 15593-2020 3.3.2.1		2024-07-10
		13	Metal Ion Content in PVC Plastic Aqueous Extracts	Plasticized poly(vinyl chloride)compounds for transfusion(infusion) equipment GB/T 15593-2020 3.3.2.1		2024-07-10
		14	Total Heavy Metal Content in PVC Plastic Aqueous Extracts	Plasticized poly(vinyl chloride)compounds for transfusion(infusion) equipment GB/T 15593-2020 3.3.2.1		2024-07-10
		15	Alcoholic Extracts (DEHP) of PVC Plastic	Plasticized poly(vinyl chloride)compounds for transfusion(infusion) equipment GB/T 15593-2020 3.3.2.1		2024-07-10
		16	Ash Content of PVC Plastic	Plasticized poly(vinyl chloride)compounds for transfusion(infusion) equipment GB/T 15593-2020 3.2.2		2024-07-10
		17	Vinyl Chloride Monomer Content of PVC Plastic	Plasticized poly(vinyl chloride)compounds for transfusion(infusion) equipment GB/T 15593-2020 3.2.2		2024-07-10
		18	Biological evaluation	Plasticized poly(vinyl chloride)compounds for transfusion(infusion) equipment GB/T 15593-2020 3.3.3		2024-07-10
66	Polypropylene material for manufacture of infusion,transfusion and injection equipments for	1	Partial items	Polypropylene material for manufacture of infusion,transfusion and injection equipments for medical use YY/T 0242-2007	Except for tensile yield stress, bending modulus, cantilever beam notch	2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	medical use				impact strength and haze	
		2	appearance	Polypropylene material for manufacture of infusion,transfusion and injection equipments for medical use YY/T 0242-2007 4.2		2024-07-10
		3	melt mass-flow rate	Polypropylene material for manufacture of infusion,transfusion and injection equipments for medical use YY/T 0242-2007 4.2		2024-07-10
		4	density	Polypropylene material for manufacture of infusion,transfusion and injection equipments for medical use YY/T 0242-2007 4.2		2024-07-10
		5	pH (Difference from Blank Control Liquid)	Polypropylene material for manufacture of infusion,transfusion and injection equipments for medical use YY/T 0242-2007 4.3		2024-07-10
		6	Heavy Metal Content	Polypropylene material for manufacture of infusion,transfusion and injection equipments for medical use YY/T 0242-2007 4.3		2024-07-10
		7	Cadmium Content	Polypropylene material for manufacture of infusion,transfusion and injection equipments for medical use YY/T 0242-2007 4.3		2024-07-10
		8	Ultraviolet Absorbance	Polypropylene material for manufacture of infusion,transfusion and injection equipments for medical use YY/T 0242-2007 4.3		2024-07-10
		9	Yellowing Index after Radiation	Polypropylene material for manufacture of infusion,transfusion and injection equipments for medical use YY/T 0242-2007 4.3		2024-07-10
		10	Biological evaluation	Polypropylene material for manufacture of infusion,transfusion and injection equipments for medical use YY/T 0242-2007 4.4		2024-07-10
67	Natural rubber latex male condoms-Requirements and test methods	1	All items	Natural rubber latex male condoms-Requirements and test methods GB/T 7544-2019		2024-07-10
		2	Biological evaluation	Natural rubber latex male condoms-Requirements and test methods GB/T 7544-2019 6		2024-07-10
		3	Microbial limit	Natural rubber latex male condoms-Requirements and test methods GB/T 7544-2019 7		2024-07-10
		4	edge curl	Natural rubber latex male condoms-Requirements and test methods GB/T 7544-2019 9.1		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
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		5	Total lubricant amount	Natural rubber latex male condoms—Requirements and test methods GB/T 7544-2019 9.2		2024-07-10
		6	size	Natural rubber latex male condoms-Requirements and test methods GB/T 7544-2019 9.3		2024-07-10
		7	Blasting Volum and pressure	Natural rubber latex male condoms-Requirements and test methods GB/T 7544-2019 10		2024-07-10
		8	Stability and storage	Natural rubber latex male condoms-Requirements and test methods GB/T 7544-2019 11		2024-07-10
		9	pinhole	Natural rubber latex male condoms-Requirements and test methods GB/T 7544-2019 12		2024-07-10
		10	Visible defects	Natural rubber latex male condoms-Requirements and test methods GB/T 7544-2019 13		2024-07-10
		11	integrity of individual packaging	Natural rubber latex male condoms-Requirements and test methods GB/T 7544-2019 14		2024-07-10
68	Cardiopulmonary bypass systems-Extracorporeal blood circuit	1	All items	Cardiopulmonary bypass systems-Extracorporeal blood circuit YY 1048-2016		2024-07-10
		2	appearance	Cardiopulmonary bypass systems-Extracorporeal blood circuit YY 1048-2016 4.1		2024-07-10
		3	physical property	Cardiopulmonary bypass systems-Extracorporeal blood circuit YY 1048-2016 4.2		2024-07-10
		4	Biological evaluation	Cardiopulmonary bypass systems-Extracorporeal blood circuit YY 1048-2016 4.3.1		2024-07-10
		5	Sterility	Cardiopulmonary bypass systems-Extracorporeal blood circuit YY 1048-2016 4.3.2		2024-07-10
		6	Pyrogen	Cardiopulmonary bypass systems-Extracorporeal blood circuit YY 1048-2016 4.3.3		2024-07-10
		7	Residual amount of ethylene oxide	Cardiopulmonary bypass systems-Extracorporeal blood circuit YY 1048-2016 4.3.4		2024-07-10



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		8	Reducing Substances	Cardiopulmonary bypass systems-Extracorporeal blood circuit YY 1048-2016 4.4.1		2024-07-10
		9	Heavy Metals	Cardiopulmonary bypass systems-Extracorporeal blood circuit YY 1048-2016 4.4.2		2024-07-10
		10	pH	Cardiopulmonary bypass systems-Extracorporeal blood circuit YY 1048-2016 4.4.3		2024-07-10
		11	Residue on Evaporation	Cardiopulmonary bypass systems-Extracorporeal blood circuit YY 1048-2016 4.4.4		2024-07-10
		12	Ultraviolet Absorbance	Cardiopulmonary bypass systems-Extracorporeal blood circuit YY 1048-2016 4.4.5		2024-07-10
		13	Color	Cardiopulmonary bypass systems-Extracorporeal blood circuit YY 1048-2016 4.4.6		2024-07-10
		14	Shelf Life	Cardiopulmonary bypass systems-Extracorporeal blood circuit YY 1048-2016 4.5		2024-07-10
69	Silicone tubes and elastomeric parts for infusion and transfusion	1	All items	Silicone tubes and elastomeric parts for infusion and transfusion YY/T 0031-2008		2024-07-10
		2	appearance	Silicone tubes and elastomeric parts for infusion and transfusion YY/T 0031-2008 4.1		2024-07-10
		3	Physical and mechanical properties of silicone rubber materials	Silicone tubes and elastomeric parts for infusion and transfusion YY/T 0031-2008 4.2		2024-07-10
		4	Physical properties of elastic components	Silicone tubes and elastomeric parts for infusion and transfusion YY/T 0031-2008 4.3		2024-07-10
		5	Color of Tubing and Elastic Components	Silicone tubes and elastomeric parts for infusion and transfusion YY/T 0031-2008 4.4		2024-07-10
		6	pH of Tubing and Elastic Components	Silicone tubes and elastomeric parts for infusion and transfusion YY/T 0031-2008 4.4		2024-07-10



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		7	Residue on Evaporation of Tubing and Elastic Components	Silicone tubes and elastomeric parts for infusion and transfusion YY/T 0031-2008 4.4		2024-07-10
		8	Reducing Substances in Tubing and Elastic Components	Silicone tubes and elastomeric parts for infusion and transfusion YY/T 0031-2008 4.4		2024-07-10
		9	Heavy Metal Content in Tubing and Elastic Components	Silicone tubes and elastomeric parts for infusion and transfusion YY/T 0031-2008 4.4		2024-07-10
		10	Ultraviolet Absorbance of Tubing and Elastic Components	Silicone tubes and elastomeric parts for infusion and transfusion YY/T 0031-2008 4.4		2024-07-10
		11	Biological evaluation	Silicone tubes and elastomeric parts for infusion and transfusion YY/T 0031-2008 4.5		2024-07-10
70	Dimethiconum	1	All items	ChP 2025 Vol II		2025-11-12
71	hydroxypropyl methylcellulose	1	All items	ChP 2025 Vol IV		2025-11-12
72	Test methods for infusion, transfusion, injection equipments for medical use Part 1:	1	All items	Test methods for infusion, transfusion, injection equipments for medical use Part 1: Chemical analysis methods GB/T 14233.1-2022		2024-07-10
		2	clarity and colour	Test methods for infusion, transfusion, injection equipments for medical use Part 1: Chemical analysis methods GB/T 14233.1-2022 5.1		2024-07-10
		3	reducing substance	Test methods for infusion, transfusion, injection equipments for		2024-07-10



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	Chemical analysis methods		(oxidables)	medical use Part 1: Chemical analysis methods GB/T 14233.1-2022 5.2		
		4	chloride	Test methods for infusion, transfusion, injection equipments for medical use Part 1: Chemical analysis methods GB/T 14233.1-2022 5.3		2024-07-10
		5	pH	Test methods for infusion, transfusion, injection equipments for medical use Part 1: Chemical analysis methods GB/T 14233.1-2022 5.4		2024-07-10
		6	evaporation residue	Test methods for infusion, transfusion, injection equipments for medical use Part 1: Chemical analysis methods GB/T 14233.1-2022 5.5		2024-07-10
		7	the total content of heavy metal ions	Test methods for infusion, transfusion, injection equipments for medical use Part 1: Chemical analysis methods GB/T 14233.1-2022 5.6		2024-07-10
		8	ultraviolet absorbancy degree	Test methods for infusion, transfusion, injection equipments for medical use Part 1: Chemical analysis methods GB/T 14233.1-2022 5.7		2024-07-10
		9	ammonium	Test methods for infusion, transfusion, injection equipments for medical use Part 1: Chemical analysis methods GB/T 14233.1-2022 5.8		2024-07-10
		10	partial heavy metals	Test methods for infusion, transfusion, injection equipments for medical use Part 1: Chemical analysis methods GB/T 14233.1-2022 5.9		2024-07-10
		11	analytical method of total content of heavy metal ions in material	Test methods for infusion, transfusion, injection equipments for medical use Part 1: Chemical analysis methods GB/T 14233.1-2022 6		2024-07-10
		12	analytical method of partial heavy metals in material	Test methods for infusion, transfusion, injection equipments for medical use Part 1: Chemical analysis methods GB/T 14233.1-2022 7		2024-07-10



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		13	residue on ignition	Test methods for infusion, transfusion, injection equipments for medical use Part 1: Chemical analysis methods GB/T 14233.1-2022 8		2024-07-10
		14	determination of ethylene oxide residue-GC method	Test methods for infusion, transfusion, injection equipments for medical use Part 1: Chemical analysis methods GB/T 14233.1-2022 9		2024-07-10
73	Test methods for infusion, transfusion, injection equipment for medical use-Part 2: Biological test methods	1	All items	Test methods for infusion, transfusion, injection equipment for medical use-Part 2: Biological test methods GB/T 14233.2-2005		2024-07-10
		2	Sterility	Test methods for infusion, transfusion, injection equipment for medical use-Part 2: Biological test methods GB/T 14233.2-2005 3		2024-07-10
		3	Bacterial endotoxins	Test methods for infusion, transfusion, injection equipment for medical use-Part 2: Biological test methods GB/T 14233.2-2005 4		2024-07-10
		4	Pyrogen	Test methods for infusion, transfusion, injection equipment for medical use-Part 2: Biological test methods GB/T 14233.2-2005 5		2024-07-10
		5	Acute systemic toxicity	Test methods for infusion, transfusion, injection equipment for medical use-Part 2: Biological test methods GB/T 14233.2-2005 6		2024-07-10
		6	Hemolysis test	Test methods for infusion, transfusion, injection equipment for medical use-Part 2: Biological test methods GB/T 14233.2-2005 7		2024-07-10
		7	Cytotoxicity	Test methods for infusion, transfusion, injection equipment for medical use-Part 2: Biological test methods GB/T 14233.2-2005 8		2024-07-10
		8	Sensitization	Test methods for infusion, transfusion, injection equipment for medical use-Part 2: Biological test methods GB/T 14233.2-2005 9		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
74	Conical fittings with a 6% taper for syringes, needles and certain other medical equipment	9	Irritation	Test methods for infusion, transfusion, injection equipment for medical use-Part 2: Biological test methods GB/T 14233.2-2005 10		2024-07-10
		10	Implantation test	Test methods for infusion, transfusion, injection equipment for medical use-Part 2: Biological test methods GB/T 14233.2-2005 11		2024-07-10
		1	All items	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment-Part1: General requirement GB/T 1962.1-2015		2024-07-10
		2	size	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment-Part1: General requirement GB/T 1962.1-2015 4.1		2024-07-10
		3	Liquid leakage	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment-Part1: General requirement GB/T 1962.1-2015 4.2		2024-07-10
		4	Air leak	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment-Part1: General requirement GB/T 1962.1-2015 4.3		2024-07-10
		5	separating force	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment-Part1: General requirement GB/T 1962.1-2015 4.4		2024-07-10
		6	stress cracks	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment-Part1: General requirement GB/T 1962.1-2015 4.5		2024-07-10
		7	All items	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment-Part2: Lock fittings GB/T 1962.2-2001		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	size	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment-Part2: Lock fittings GB/T 1962.2-2001 4.2		2024-07-10
		9	Liquid leakage	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment-Part2: Lock fittings GB/T 1962.2-2001 4.2.1		2024-07-10
		10	Air leak	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment-Part2: Lock fittings GB/T 1962.2-2001 4.2.2		2024-07-10
		11	separating force	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment-Part2: Lock fittings GB/T 1962.2-2001 4.3		2024-07-10
		12	Unscrew torque	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment-Part2: Lock fittings GB/T 1962.2-2001 4.4		2024-07-10
		13	Ease of assembly	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment-Part2: Lock fittings GB/T 1962.2-2001 4.5		2024-07-10
		14	overload resistance	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment-Part2: Lock fittings GB/T 1962.2-2001 4.6		2024-07-10
		15	stress cracks	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment-Part2: Lock fittings GB/T 1962.2-2001 4.7		2024-07-10
75	Medical absorbent cotton	1	All items	Medical absorbent cotton YY/T 0330-2015		2024-07-10
		2	character	Medical absorbent cotton YY/T 0330-2015 3.1		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		3	Identification	Medical absorbent cotton YY/T 0330-2015 3.2		2024-07-10
		4	foreign fiber	Medical absorbent cotton YY/T 0330-2015 3.3		2024-07-10
		5	nep	Medical absorbent cotton YY/T 0330-2015 3.4		2024-07-10
		6	Solubles in Water	Medical absorbent cotton YY/T 0330-2015 3.5		2024-07-10
		7	pH	Medical absorbent cotton YY/T 0330-2015 3.6		2024-07-10
		8	Sedimentation Time	Medical absorbent cotton YY/T 0330-2015 3.7		2024-07-10
		9	Water Absorption	Medical absorbent cotton YY/T 0330-2015 3.8		2024-07-10
		10	Solubles in Ether	Medical absorbent cotton YY/T 0330-2015 3.9		2024-07-10
		11	Fluorescent Substances	Medical absorbent cotton YY/T 0330-2015 3.10		2024-07-10
		12	Loss on Drying	Medical absorbent cotton YY/T 0330-2015 3.11		2024-07-10
		13	Sulfated Ash	Medical absorbent cotton YY/T 0330-2015 3.12		2024-07-10
		14	Surface Active Substances	Medical absorbent cotton YY/T 0330-2015 3.13		2024-07-10
		15	Extractable Colorants	Medical absorbent cotton YY/T 0330-2015 3.14		2024-07-10
		16	Ethylene Oxide Residue	Medical absorbent cotton YY/T 0330-2015 3.15		2024-07-10
		17	Microbial limit	Medical absorbent cotton YY/T 0330-2015 3.16		2024-07-10
76	Medical absorbent	1	All items	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze YY 0331-2006		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	gauze	2	Liquid Permeability	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze YY 0331-2006 3.3	Only used when cited or requested by a customer	2025-07-18
		3	Fiber Identification	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze YY 0331-2006 4.1	Only used when cited or requested by a customer	2025-07-18
		4	pH	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze YY 0331-2006 4.2	Only used when cited or requested by a customer	2025-07-18
		5	Foreign Fibers	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze YY 0331-2006 4.3	Only used when cited or requested by a customer	2025-07-18
		6	Fluorescent Substances	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze YY 0331-2006 4.4	Only used when cited or requested by a customer	2025-07-18



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	number of threads	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze YY 0331-2006 4.5	Only used when cited or requested by a customer	2025-07-18
		8	Mass per square meter	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze YY 0331-2006 4.6	Only used when cited or requested by a customer	2025-07-18
		9	Minimum breaking force	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze YY 0331-2006 4.7	Only used when cited or requested by a customer	2025-07-18
		10	Sinking time	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze YY 0331-2006 4.8	Only used when cited or requested by a customer	2025-07-18
		11	Solubles in Ether	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze YY 0331-2006 4.9	Only used when cited or requested by a customer	2025-07-18



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		12	Surface Active Substances	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze YY 0331-2006 4.10	Only used when cited or requested by a customer	2025-07-18
		13	Solubles in Water	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze YY 0331-2006 4.11	Only used when cited or requested by a customer	2025-07-18
		14	Starch and Dextrin	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze YY 0331-2006 4.12	Only used when cited or requested by a customer	2025-07-18
		15	Extractable Colorants	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze YY 0331-2006 4.13	Only used when cited or requested by a customer	2025-07-18
		16	Loss on Drying	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze YY 0331-2006 4.14	Only used when cited or requested by a customer	2025-07-18



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		17	Sulfated Ash	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze YY 0331-2006 4.15	Only used when cited or requested by a customer	2025-07-18
77	Primary wound dressing	1	All items	Primary wound dressing YY/T 0471.1~6-2004	Use only when quoted or requested by the customer	2024-07-10
		2	free swell absorptive capacity	Test methods for primary wound dressing—Part 1:Aspects of absorbency YY/T 0471.1-2004 3.2		2024-07-10
		3	fluid handling capacity	Test methods for primary wound dressing—Part 1:Aspects of absorbency YY/T 0471.1-2004 3.3		2024-07-10
		4	Liquid Affinity of Amorphous Hydrogels	Test methods for primary wound dressing—Part 1:Aspects of absorbency YY/T 0471.1-2004 3.4		2024-07-10
		5	Gelling Properties	Test methods for primary wound dressing—Part 1:Aspects of absorbency YY/T 0471.1-2004 3.5		2024-07-10
		6	Dispersion Characteristics	Test methods for primary wound dressing—Part 1:Aspects of absorbency YY/T 0471.1-2004 3.6		2024-07-10
		7	Dispersion/Solubility of Hydrogel Additives	Test methods for primary wound dressing—Part 1:Aspects of absorbency YY/T 0471.1-2004 3.7		2024-07-10
		8	Test method for moisture vapor transmission rate	Test methods for primary wound dressings-Part 2: Moisture vapour transmission rate of permeable film dressings YY/T 0471.2-2004 3		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Test method for waterproofness	Test methods for primary wound dressings-Part 3: Waterproofness YY/T 0471.3-2004 3.2		2024-07-10
		10	Comfort test method	Test methods for primary wound dressing-Part 4:Conformability YY/T 0471.4-2004 3.2		2024-07-10
		11	Bacterial barrier properties	Test methods for primary wound dressing-Part 5:Bacterial barrier properties YY/T 0471.5-2004 3		2024-07-10
		12	Odor Transmission Test	Test methods for primary wound dressings-Part 6:Odour control YY/T 0471.6-2004 3		2024-07-10
78	Medical suture needle (without thread)	1	All items	Medical suture needle YY/T 0043-2016		2024-07-10
		2	appearance	Medical suture needle YY/T 0043-2016 4.1		2024-07-10
		3	Hardness	Medical suture needle YY/T 0043-2016 4.2.1		2024-07-10
		4	elasticity	Medical suture needle YY/T 0043-2016 4.2.2		2024-07-10
		5	toughness	Medical suture needle YY/T 0043-2016 4.2.3		2024-07-10
		6	Needle tip strength	Medical suture needle YY/T 0043-2016 4.2.4		2024-07-10
		7	Piercing force	Medical suture needle YY/T 0043-2016 4.3.1		2024-07-10
		8	cutting force	Medical suture needle YY/T 0043-2016 4.3.2		2024-07-10
		9	Initial contamination bacteria	Medical suture needle YY/T 0043-2016 4.4		2024-07-10
		10	corrosion resistance	Medical suture needle YY/T 0043-2016 4.5		2024-07-10
		11	Sterility	Medical suture needle YY/T 0043-2016 4.6		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		12	Ethylene Oxide Residue	Medical suture needle YY/T 0043-2016 4.7		2024-07-10
		13	Cytotoxicity	Medical suture needle YY/T 0043-2016 4.8.1		2024-07-10
		14	Sensitization	Medical suture needle YY/T 0043-2016 4.8.2		2024-07-10
		15	Irritation	Medical suture needle YY/T 0043-2016 4.8.3		2024-07-10
79	Non-absorbable surgical suture	1	All items	Non-absorbable surgical suture YY 0167-2020		2024-07-10
		2	appearance	Non-absorbable surgical suture YY 0167-2020 4.1		2024-07-10
		3	Wire diameter	Non-absorbable surgical suture YY 0167-2020 4.2		2024-07-10
		4	breaking strength	Non-absorbable surgical suture YY 0167-2020 4.3		2024-07-10
		5	Needle and thread connection strength	Non-absorbable surgical suture YY 0167-2020 4.4		2024-07-10
		6	fade	Non-absorbable surgical suture YY 0167-2020 4.5		2024-07-10
		7	length	Non-absorbable surgical suture YY 0167-2020 4.6		2024-07-10
		8	Sterility	Non-absorbable surgical suture YY 0167-2020 4.7		2024-07-10
		9	Ethylene Oxide Residue	Non-absorbable surgical suture YY 0167-2020 4.8		2024-07-10
		10	Biological evaluation	Non-absorbable surgical suture YY 0167-2020 4.9		2024-07-10
		11	identification	Non-absorbable surgical suture YY 0167-2020 4.10		2024-07-10
80	Absorbable surgical suture	1	All items	Absorbable surgical suture YY 1116-2020		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		2	appearance	Absorbable surgical suture YY 1116-2020 4.1		2024-07-10
		3	Wire diameter	Absorbable surgical suture YY 1116-2020 4.2		2024-07-10
		4	breaking strength	Absorbable surgical suture YY 1116-2020 4.3		2024-07-10
		5	Needle and thread connection strength	Absorbable surgical suture YY 1116-2020 4.4		2024-07-10
		6	length	Absorbable surgical suture YY 1116-2020 4.5		2024-07-10
		7	Soluble Chromium Compounds	Absorbable surgical suture YY 1116-2020 4.6.1		2024-07-10
		8	Heavy Metals	Absorbable surgical suture YY 1116-2020 4.6.2		2024-07-10
		9	Moisture Content	Absorbable surgical suture YY 1116-2020 4.6.3		2024-07-10
		10	Fade	Absorbable surgical suture YY 1116-2020 4.6.4		2024-07-10
		11	Ethylene Oxide Residue	Absorbable surgical suture YY 1116-2020 4.6.5		2024-07-10
		12	Sterility	Absorbable surgical suture YY 1116-2020 4.7		2024-07-10
		13	Biological evaluation	Absorbable surgical suture YY 1116-2020 4.8		2024-07-10
		14	identification	Absorbable surgical suture YY 1116-2020 4.9		2024-07-10
81	General specifications for stapler	1	All items	General specifications for stapler YY/T 0245-2008		2024-07-10
		2	Materials for Suture Needles	General specifications for stapler YY/T 0245-2008 4.1		2024-07-10
		3	Usage performance	General specifications for stapler YY/T 0245-2008 4.2		2024-07-10



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		№	Item/ Parameter			
		4	hardness	General specifications for stapler YY/T 0245-2008 4.3		2024-07-10
		5	Surface roughness	General specifications for stapler YY/T 0245-2008 4.4		2024-07-10
		6	Corrosion Resistance	General specifications for stapler YY/T 0245-2008 4.5		2024-07-10
		7	Peel strength of packaging sealing	General specifications for stapler YY/T 0245-2008 4.6		2024-07-10
		8	appearance	General specifications for stapler YY/T 0245-2008 4.7		2024-07-10
		9	size	General specifications for stapler YY/T 0245-2008 4.8		2024-07-10
		10	Sterility	General specifications for stapler YY/T 0245-2008 4.9.1		2024-07-10
		11	Ethylene Oxide Residue	General specifications for stapler YY/T 0245-2008 4.9.2		2024-07-10
		12	Cytotoxicity	General specifications for stapler YY/T 0245-2008 4.10.1		2024-07-10
		13	Sensitization	General specifications for stapler YY/T 0245-2008 4.10.2		2024-07-10
		14	Irritation	General specifications for stapler YY/T 0245-2008 4.10.3		2024-07-10
82	Single-use puncture set local anaesthesia	1	Partial items	Single-use puncture set local anaesthesia YY/T0321.1-2022	Except for radiopacity	2024-07-10
		2	Single-use needle for anaesthesia	Single-use puncture set local anaesthesia YY/T0321.1-2022 5.1		2024-07-10
		3	Single-use filter for anaesthesia	Single-use puncture set local anaesthesia YY/T0321.1-2022 5.2		2024-07-10
		4	Basic dimensions	Single-use puncture set local anaesthesia YY/T0321.1-2022 5.3.1		2024-07-10
		5	Lateral aperture	Single-use puncture set local anaesthesia YY/T0321.1-2022 5.3.3		2024-07-10

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		№	Item/ Parameter			
		6	Tick Labelings	Single-use puncture set local anaesthesia YY/T0321.1-2022 5.3.4		2024-07-10
		7	Flow	Single-use puncture set local anaesthesia YY/T0321.1-2022 5.3.5		2024-07-10
		8	Breaking force	Single-use puncture set local anaesthesia YY/T0321.1-2022 5.3.6		2024-07-10
		9	Joint	Single-use puncture set local anaesthesia YY/T0321.1-2022 5.3.7		2024-07-10
		10	Particle contamination	Single-use puncture set local anaesthesia YY/T0321.1-2022 5.3.8		2024-07-10
		11	Connection firmness	Single-use puncture set local anaesthesia YY/T0321.1-2022 5.3.9		2024-07-10
		12	Tightness	Single-use puncture set local anaesthesia YY/T0321.1-2022 5.3.10		2024-07-10
		13	Bending resistance	Single-use puncture set local anaesthesia YY/T0321.1-2022 5.3.11		2024-07-10
		14	Corrosion resistance of steel wire	Single-use puncture set local anaesthesia YY/T0321.1-2022 5.3.12		2024-07-10
		15	reducing substance (oxidables)	Single-use puncture set local anaesthesia YY/T0321.1-2022 6.2		2024-07-10
		16	metal ions	Single-use puncture set local anaesthesia YY/T0321.1-2022 6.3		2024-07-10
		17	pH	Single-use puncture set local anaesthesia YY/T0321.1-2022 6.4		2024-07-10
		18	evaporation residue	Single-use puncture set local anaesthesia YY/T0321.1-2022 6.5		2024-07-10
		19	ultraviolet absorbancy degree	Single-use puncture set local anaesthesia YY/T0321.1-2022 6.6		2024-07-10
		20	ethylene oxide residue	Single-use puncture set local anaesthesia YY/T0321.1-2022 6.7		2024-07-10



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		№	Item/ Parameter			
83	Single-use needle for anaesthesia	21	sterility	Single-use puncture set local anaesthesia YY/T0321.1-2022 7.2		2024-07-10
		22	bacterial endotoxin	Single-use puncture set local anaesthesia YY/T0321.1-2022 7.3		2024-07-10
		1	All items	Single-use needle for anaesthesia YY/T 0321.2-2021		2024-07-10
		2	Basic dimensions	Single-use needle for anaesthesia YY/T 0321.2-2021 5.1		2024-07-10
		3	Needle tube and needle core seat	Single-use needle for anaesthesia YY/T 0321.2-2021 5.2		2024-07-10
		4	Needle tube	Single-use needle for anaesthesia YY/T 0321.2-2021 5.3		2024-07-10
		5	Lining core	Single-use needle for anaesthesia YY/T 0321.2-2021 5.4		2024-07-10
		6	Needle tip	Single-use needle for anaesthesia YY/T 0321.2-2021 5.5		2024-07-10
		7	Flow	Single-use needle for anaesthesia YY/T 0321.2-2021 5.6		2024-07-10
		8	Connection firmness	Single-use needle for anaesthesia YY/T 0321.2-2021 5.7		2024-07-10
		9	Connection integrity	Single-use needle for anaesthesia YY/T 0321.2-2021 5.8		2024-07-10
		10	Particle contamination	Single-use needle for anaesthesia YY/T 0321.2-2021 5.9		2024-07-10
		11	Color code	Single-use needle for anaesthesia YY/T 0321.2-2021 5.1		2024-07-10
		12	metal ions	Single-use needle for anaesthesia YY/T 0321.2-2021 6.2		2024-07-10
		13	pH	Single-use needle for anaesthesia YY/T 0321.2-2021 6.3		2024-07-10
		14	ethylene oxide residue	Single-use needle for anaesthesia YY/T 0321.2-2021 6.4		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		15	sterility	Single-use needle for anaesthesia YY/T 0321.2-2021 7.2		2024-07-10
		16	bacterial endotoxin	Single-use needle for anaesthesia YY/T 0321.2-2021 7.3		2024-07-10
84	Single-use filter for anaesthesia	1	All items	Single-use filter for anaesthesia YY/T 0321.3-2022		2024-07-10
		2	Joint	Single-use filter for anaesthesia YY/T 0321.3-2022 5.2		2024-07-10
		3	Filtering performance requirements	Single-use filter for anaesthesia YY/T 0321.3-2022 5.3		2024-07-10
		4	Tightness	Single-use filter for anaesthesia YY/T 0321.3-2022 5.4		2024-07-10
		5	Particle contamination	Single-use filter for anaesthesia YY/T 0321.3-2022 5.5		2024-07-10
		6	Fluid flow	Single-use filter for anaesthesia YY/T 0321.3-2022 5.6		2024-07-10
		7	reducing substance (oxidables)	Single-use filter for anaesthesia YY/T 0321.3-2022 6.2		2024-07-10
		8	metal ions	Single-use filter for anaesthesia YY/T 0321.3-2022 6.3		2024-07-10
		9	pH	Single-use filter for anaesthesia YY/T 0321.3-2022 6.4		2024-07-10
		10	ethylene oxide residue	Single-use filter for anaesthesia YY/T 0321.3-2022 6.5		2024-07-10
		11	sterility	Single-use filter for anaesthesia YY/T 0321.3-2022 7.2		2024-07-10
		12	bacterial endotoxin	Single-use filter for anaesthesia YY/T 0321.3-2022 7.3		2024-07-10
85	Intravenous needles for	1	All items	Intravenous needles for single use GB 18671-2009		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
single use		2	Materials	Intravenous needles for single use GB 18671-2009 5		2024-07-10
		3	Color code	Intravenous needles for single use GB 18671-2009 6.1		2024-07-10
		4	Particle contamination	Intravenous needles for single use GB 18671-2009 6.2		2024-07-10
		5	Connection firmness	Intravenous needles for single use GB 18671-2009 6.3		2024-07-10
		6	leakage	Intravenous needles for single use GB 18671-2009 6.4		2024-07-10
		7	Flow	Intravenous needles for single use GB 18671-2009 6.5		2024-07-10
		8	Needle length	Intravenous needles for single use GB 18671-2009 6.6		2024-07-10
		9	Needle tip	Intravenous needles for single use GB 18671-2009 6.7		2024-07-10
		10	lubricant	Intravenous needles for single use GB 18671-2009 6.8		2024-07-10
		11	Pin seat connection	Intravenous needles for single use GB 18671-2009 6.9		2024-07-10
		12	needle handle	Intravenous needles for single use GB 18671-2009 6.10		2024-07-10
		13	flexible pipe	Intravenous needles for single use GB 18671-2009 6.11		2024-07-10
		14	protective sheath and cap	Intravenous needles for single use GB 18671-2009 6.12		2024-07-10
		15	Reducing Substances	Intravenous needles for single use GB 18671-2009 7.1		2024-07-10
		16	Metal Ions	Intravenous needles for single use GB 18671-2009 7.2		2024-07-10
		17	Acid-Base Titration	Intravenous needles for single use GB 18671-2009 7.3		2024-07-10



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		№	Item/ Parameter			
		18	Residue on Evaporation	Intravenous needles for single use GB 18671-2009 7.4		2024-07-10
		19	Ultraviolet Absorbance	Intravenous needles for single use GB 18671-2009 7.5		2024-07-10
		20	Biological evaluation	Intravenous needles for single use GB 18671-2009 8.1		2024-07-10
		21	Sterility	Intravenous needles for single use GB 18671-2009 8.2		2024-07-10
		22	Bacterial endotoxins	Intravenous needles for single use GB 18671-2009 8.3		2024-07-10
86	Sterile hypodermic needles for single use	1	All items	Sterile hypodermic needles for single use GB 15811- 2016		2024-07-10
		2	cleaning	Sterile hypodermic needles for single use GB 15811- 2016 6.1		2024-07-10
		3	Color code	Sterile hypodermic needles for single use GB 15811- 2016 6.2		2024-07-10
		4	honest	Sterile hypodermic needles for single use GB 15811- 2016 6.3		2024-07-10
		5	Connection firmness	Sterile hypodermic needles for single use GB 15811- 2016 6.4		2024-07-10
		6	patency	Sterile hypodermic needles for single use GB 15811- 2016 6.5		2024-07-10
		7	Needle holder and sheath fit	Sterile hypodermic needles for single use GB 15811- 2016 6.6		2024-07-10
		8	Needle tip	Sterile hypodermic needles for single use GB 15811- 2016 6.7		2024-07-10
		9	Needle tube	Sterile hypodermic needles for single use GB 15811- 2016 6.8		2024-07-10
		10	Needle holder	Sterile hypodermic needles for single use GB 15811- 2016 6.9		2024-07-10
		11	pH	Sterile hypodermic needles for single use GB 15811- 2016 7.2		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		12	Total Heavy Metal Content (Metal Ions)	Sterile hypodermic needles for single use GB 15811- 2016 7.3		2024-07-10
		13	Sterility	Sterile hypodermic needles for single use GB 15811- 2016 8.2		2024-07-10
		14	Bacterial endotoxins	Sterile hypodermic needles for single use GB 15811- 2016 8.3		2024-07-10
		15	Hemolysis test	Sterile hypodermic needles for single use GB 15811- 2016 8.4		2024-07-10
		16	Biological evaluation	Sterile hypodermic needles for single use GB 15811- 2016 8.5		2024-07-10
87	Sterile syringes for single use	1	All items	Sterile syringes for single use GB 15810-2019		2024-07-10
		2	appearance	Sterile syringes for single use GB 15810-2019 5.1		2024-07-10
		3	Scale capacity tolerance	Sterile syringes for single use GB 15810-2019 5.2		2024-07-10
		4	Graduated scale	Sterile syringes for single use GB 15810-2019 5.3		2024-07-10
		5	overcoat	Sterile syringes for single use GB 15810-2019 5.4		2024-07-10
		6	Hand spacing	Sterile syringes for single use GB 15810-2019 5.5.1		2024-07-10
		7	Matching between piston and core rod	Sterile syringes for single use GB 15810-2019 5.5.2		2024-07-10
		8	cone tip	Sterile syringes for single use GB 15810-2019 5.6		2024-07-10
		9	residual capacity	Sterile syringes for single use GB 15810-2019 5.7.1		2024-07-10
		10	Body tightness	Sterile syringes for single use GB 15810-2019 5.7.2		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		11	Sliding performance	Sterile syringes for single use GB 15810-2019 5.7.3		2024-07-10
		12	Matching of outer sleeve and piston component	Sterile syringes for single use GB 15810-2019 5.7.4		2024-07-10
		13	pH	Sterile syringes for single use GB 15810-2019 6.1		2024-07-10
		14	Extractable Metal Content	Sterile syringes for single use GB 15810-2019 6.2		2024-07-10
		15	readily oxidation substance	Sterile syringes for single use GB 15810-2019 6.3		2024-07-10
		16	Ethylene Oxide Residue	Sterile syringes for single use GB 15810-2019 6.4		2024-07-10
		17	Sterility	Sterile syringes for single use GB 15810-2019 7.2		2024-07-10
		18	Bacterial endotoxins	Sterile syringes for single use GB 15810-2019 7.3		2024-07-10
88	syringe needle	1	All items	Syringe needle YY/T 0282-2009		2024-07-10
		2	Needle holder	Syringe needle YY/T 0282-2009 5.1		2024-07-10
		3	Needle tube	Syringe needle YY/T 0282-2009 5.2		2024-07-10
		4	Needle tip	Syringe needle YY/T 0282-2009 5.3		2024-07-10
		5	connectivity	Syringe needle YY/T 0282-2009 5.4		2024-07-10
		6	patency	Syringe needle YY/T 0282-2009 5.5		2024-07-10
89	Hydroxyapatite powder for medical	1	All items	Hydroxyapatite powder for medical applications YY 0303-1998	Use only when quoted or	2024-07-10



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		№	Item/ Parameter			
	applications				requested by the customer	
		2	appearance	Hydroxyapatite powder for medical applications YY 0303-1998 4.2		2024-07-10
		3	granularity	Hydroxyapatite powder for medical applications YY 0303-1998 4.3		2024-07-10
		4	Hydroxyapatite Content	Hydroxyapatite powder for medical applications YY 0303-1998 4.4		2024-07-10
		5	Calcium to Phosphorus Atomic Ratio	Hydroxyapatite powder for medical applications YY 0303-1998 4.5		2024-07-10
		6	Infrared Absorption Spectra	Hydroxyapatite powder for medical applications YY 0303-1998 4.6		2024-07-10
		7	Limits for Impurity and Heavy Metal Elements	Hydroxyapatite powder for medical applications YY 0303-1998 4.7		2024-07-10
90	Plasma sprayed hydroxyapatite coated - titanium dental implant	1	All items	Plasma sprayed hydroxyapatite coated - titanium dental implant YY 0304—2009		2024-07-10
		2	appearance	Plasma sprayed hydroxyapatite coated - titanium dental implant YY 0304—2009 4.3.1		2024-07-10
		3	Chemical Composition of HA Coating	Plasma sprayed hydroxyapatite coated - titanium dental implant YY 0304—2009 4.3.2.1		2024-07-10
		4	Chemical Composition and Microstructure of Titanium and Titanium Alloy Materials	Plasma sprayed hydroxyapatite coated - titanium dental implant YY 0304—2009 4.3.2.2		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	Tensile bonding strength between HA coating and titanium substrate	Plasma sprayed hydroxyapatite coated - titanium dental implant YY 0304—2009 4.3.3		2024-07-10
		6	Dynamic fatigue test	Plasma sprayed hydroxyapatite coated - titanium dental implant YY 0304—2009 4.3.4		2024-07-10
		7	Biological evaluation	Plasma sprayed hydroxyapatite coated - titanium dental implant YY 0304—2009 4.4		2024-07-10
		8	Sterility	Plasma sprayed hydroxyapatite coated - titanium dental implant YY 0304—2009 4.5		2024-07-10
91	Wrought titanium and titanium dental implant	1	All items	Wrought titanium and titanium dental implant YY 0315-2016		2024-07-10
		2	Chemical Properties	Wrought titanium and titanium dental implant YY 0315-2016 5.1		2024-07-10
		3	Microstructure	Wrought titanium and titanium dental implant YY 0315-2016 5.2		2024-07-10
		4	size	Wrought titanium and titanium dental implant YY 0315-2016 5.3		2024-07-10
		5	appearance	Wrought titanium and titanium dental implant YY 0315-2016 5.4.1		2024-07-10
		6	Surface defects	Wrought titanium and titanium dental implant YY 0315-2016 5.4.2		2024-07-10
		7	roughness	Wrought titanium and titanium dental implant YY 0315-2016 5.4.3		2024-07-10
		8	cleaning	Wrought titanium and titanium dental implant YY 0315-2016 5.5		2024-07-10
		9	Torsional resistance performance	Wrought titanium and titanium dental implant YY 0315-2016 5.6.1		2024-07-10
		10	Tightening torque	Wrought titanium and titanium dental implant YY 0315-2016 5.6.2		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		11	Fatigue limit	Wrought titanium and titanium dental implant YY 0315-2016 5.6.3		2024-07-10
		12	Sterility	Wrought titanium and titanium dental implant YY 0315-2016 5.7		2024-07-10
		13	Bacterial endotoxins	Wrought titanium and titanium dental implant YY 0315-2016 5.8		2024-07-10
		14	Biological evaluation	Wrought titanium and titanium dental implant YY 0315-2016 5.9		2024-07-10
92	Dental-Orthodontic bracket adhesive materials	1	All items	Dental-Orthodontic bracket adhesive materials YY/T 0269-2009		2024-07-10
		2	appearance	Dental-Orthodontic bracket adhesive materials YY/T 0269-2009 4.1		2024-07-10
		3	working hours	Dental-Orthodontic bracket adhesive materials YY/T 0269-2009 4.2		2024-07-10
		4	Curing Time	Dental-Orthodontic bracket adhesive materials YY/T 0269-2009 4.3		2024-07-10
		5	Sensitivity of materials to environmental light	Dental-Orthodontic bracket adhesive materials YY/T 0269-2009 4.4		2024-07-10
		6	Adhesive Strength	Dental-Orthodontic bracket adhesive materials YY/T 0269-2009 4.5		2024-07-10
		7	Biological evaluation	Dental-Orthodontic bracket adhesive materials YY/T 0269-2009 4.6		2024-07-10
93	Dental-Ceramic	1	Partial items	Dental-Ceramic YY 0716-2009	Except for linear expansion coefficient	2024-07-10
		2	uniformity	Dental-Ceramic YY 0716-2009 5.1		2024-07-10
		3	No foreign objects	Dental-Ceramic YY 0716-2009 5.2		2024-07-10



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		№	Item/ Parameter			
		4	Mixing and compaction properties of Type I ceramics	Dental-Ceramic YY 0716-2009 5.3		2024-07-10
		5	Flexural Strength	Dental-Ceramic YY 0716-2009 5.4.1		2024-07-10
		6	Chemical Solubility	Dental-Ceramic YY 0716-2009 5.4.2		2024-07-10
		7	glass transition temperature	Dental-Ceramic YY 0716-2009 5.4.4		2024-07-10
		8	Biological evaluation	Dental-Ceramic YY 0716-2009 5.5		2024-07-10
94	Artificial teeth for dental prostheses	1	All items	Dentistry-Artificial teeth for dental prostheses YY 0300-2009	Except for radioactive	2024-07-10
		2	Biological evaluation	Dentistry-Artificial teeth for dental prostheses YY 0300-2009 5.1.1		2024-07-10
		3	size	Dentistry-Artificial teeth for dental prostheses YY 0300-2009 5.1.2		2024-07-10
		4	Color and fusion	Dentistry-Artificial teeth for dental prostheses YY 0300-2009 5.1.3		2024-07-10
		5	Surface finish	Dentistry-Artificial teeth for dental prostheses YY 0300-2009 5.1.4		2024-07-10
		6	Pores and other defects	Dentistry-Artificial teeth for dental prostheses YY 0300-2009 5.1.5		2024-07-10
		7	Retaining groove	Dentistry-Artificial teeth for dental prostheses YY 0300-2009 5.2.2		2024-07-10
		8	heat resistance	Dentistry-Artificial teeth for dental prostheses YY 0300-2009 5.2.3		2024-07-10
95	Biological evaluation of	1	Test method-Acute oral toxicity test	Biological evaluation of medical devices used in dentistry-Part2:Test method-Acute oral toxicity test YY/T 0127.14-2009		2024-07-10



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	medical devices used in dentistry	2	Subacute and subchronic systemic toxicity test:oral route	Biological evaluation of medical devices used in dentistry-Part15:Subacute and subchronic systemic toxicity test:oral route YY/T 0127.15-2018		2024-07-10
		3	Mouse lymphoma cells (TK) gene mutation test	Biological evaluation of medical devices used in dentistry-Part17:Mouse lymphoma cells (TK) gene mutation test YY/T 0127.17-2014		2024-07-10
		4	Micronucleus test	Dentistry-Biological evaluation of medical devices used in dentistry Part 2:Test method-Micronucleus test YY/T 0127.12-2008		2024-07-10
		5	Oral mucous irritation test	Biological evaluation of medical devices used in dentistry Part 13:Oral mucous irritation test YY/T 0127.13-2018		2024-07-10
		6	Hemolysis test	Biological testing methods for oral materials Hemolysis test YY/T 0127.1-93		2024-07-10
		7	Acute systemic toxicity : intravenous path	Biological evaluation of medical devices used in dentistry-Part 2: Test method—Acute systemic toxicity : intravenous path YY/T 0127.2-2009		2024-07-10
		8	Subcutaneous implant test	Biological evaluation of dental materials— Part2: Biological evaluation test method of dental materials-Subcutaneous implant test YY/T 0127.8-2001		2024-07-10
		9	Salmonella typhimurium reverse mutation assay(Ames mutagenicity test)	Biological evaluation of medical devices used in dentistry— Part 2:Test method-Salmonella typhimurium reverse mutation assay(Ames mutagenicity test) YY/T 0127.10-2009		2024-07-10
96	Dental elevators	1	All items	Dental elevators YY/T 0170-2011		2024-07-10
		2	size	Dental elevators YY/T 0170-2011 4.1		2024-07-10
		3	hardness	Dental elevators YY/T 0170-2011 4.2		2024-07-10



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		№	Item/ Parameter			
		4	tension	Dental elevators YY/T 0170-2011 4.3.1		2024-07-10
		5	torque	Dental elevators YY/T 0170-2011 4.3.2		2024-07-10
		6	Surface roughness	Dental elevators YY/T 0170-2011 4.4		2024-07-10
		7	Corrosion Resistance	Dental elevators YY/T 0170-2011 4.5		2024-07-10
		8	Pressure resistant steam performance	Dental elevators YY/T 0170-2011 4.6		2024-07-10
		9	heat resistance	Dental elevators YY/T 0170-2011 4.7		2024-07-10
		10	Leakage resistance performance	Dental elevators YY/T 0170-2011 4.8		2024-07-10
		11	appearance	Dental elevators YY/T 0170-2011 4.9		2024-07-10
97	Dental scalers	1	All items	Dental scalers YY/T 0274-2011		2024-07-10
		2	size	Dental scalers YY/T 0274-2011 4.1		2024-07-10
		3	hardness	Dental scalers YY/T 0274-2011 4.2		2024-07-10
		4	sharpness	Dental scalers YY/T 0274-2011 4.3		2024-07-10
		5	tension	Dental scalers YY/T 0274-2011 4.4.1		2024-07-10
		6	torque	Dental scalers YY/T 0274-2011 4.4.2		2024-07-10
		7	Surface roughness	Dental scalers YY/T 0274-2011 4.5		2024-07-10
		8	Corrosion Resistance	Dental-scalers YY/T 0274-2011 4.6		2024-07-10



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		№	Item/ Parameter			
		9	heat resistance	Dental scalers YY/T 0274-2011 4.7		2024-07-10
		10	appearance	Dental scalers YY/T 0274-2011 4.8		2024-07-10
98	Apical elevators	1	All items	Apical elevators YY/T 0277-1995		2024-07-10
		2	size	Apical elevators YY/T 0277-1995 4.1		2024-07-10
		3	material	Apical elevators YY/T 0277-1995 4.2		2024-07-10
		4	hardness	Apical elevators YY/T 0277-1995 4.3		2024-07-10
		5	Corrosion Resistance	Apical elevators YY/T 0277-1995 4.4		2024-07-10
		6	Surface roughness	Apical elevators YY/T 0277-1995 4.5		2024-07-10
		7	cutting edge	Apical elevators YY/T 0277-1995 4.6		2024-07-10
		8	Head strength	Apical elevators YY/T 0277-1995 4.7		2024-07-10
		9	weld	Apical elevators YY/T 0277-1995 4.8		2024-07-10
99	Dental pluggers	1	All items	Dental pluggers YY/T 0275-2011		2024-07-10
		2	size	Dental pluggers YY/T 0275-2011 4.1		2024-07-10
		3	hardness	Dental pluggers YY/T 0275-2011 4.2		2024-07-10
		4	toughness	Dental pluggers YY/T 0275-2011 4.3		2024-07-10
		5	Connection firmness	Dental pluggers YY/T 0275-2011 4.4		2024-07-10



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		№	Item/ Parameter			
		6	Surface roughness	Dental pluggers YY/T 0275-2011 4.5		2024-07-10
		7	Corrosion Resistance	Dental pluggers YY/T0275-2011 4.6		2024-07-10
		8	appearance	Dental pluggers YY/T 0275-2011 4.7		2024-07-10
100	Dental elevators	1	All items	Dental elevators YY/T 0170-2011		2024-07-10
		2	size	Dental elevators YY/T 0170-2011 4.1		2024-07-10
		3	hardness	Dental elevators YY/T 0170-2011 4.2		2024-07-10
		4	tension	Dental elevators YY/T 0170-2011 4.3.1		2024-07-10
		5	torque	Dental elevators YY/T 0170-2011 4.3.2		2024-07-10
		6	Surface roughness	Dental elevators YY/T 0170-2011 4.4		2024-07-10
		7	Corrosion Resistance	Dental elevators YY/T 0170-2011 4.5		2024-07-10
		8	Pressure resistant steam performance	Dental elevators YY/T 0170-2011 4.6		2024-07-10
		9	heat resistance	Dental elevators YY/T 0170-2011 4.7		2024-07-10
		10	Leakage resistance performance	Dental elevators YY/T 0170-2011 4.8		2024-07-10
		11	appearance	Dental elevators YY/T 0170-2011 4.9		2024-07-10
101	Plasmapheresis centrifuge apparatus for single use	1	Partial items	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017	Except for microbial impermeability	2024-07-10



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		2	plasmapheresis centrifuge	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 5.1		2024-07-10
		3	plasma pipeline	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 5.2		2024-07-10
		4	plasma bag	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 5.3		2024-07-10
		5	Reducing Substances	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 6.1.1		2024-07-10
		6	Metal Ions	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 6.1.2		2024-07-10
		7	PH	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 6.1.3		2024-07-10
		8	Residue on Evaporation	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 6.1.4		2024-07-10
		9	Ultraviolet Absorbance	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 6.1.5		2024-07-10
		10	Ethylene Oxide Residue	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 6.1.6		2024-07-10
		11	Reducing Substances	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 6.2.1		2024-07-10
		12	Metal Ions	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 6.2.2		2024-07-10
		13	PH	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 6.2.3		2024-07-10
		14	Residue on Evaporation	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 6.2.4		2024-07-10
		15	Ultraviolet Absorbance	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 6.2.5		2024-07-10
		16	Ethylene Oxide Residue	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 6.2.6		2024-07-10



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		№	Item/ Parameter			
		17	Ethylene Oxide Residue	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 6.3.2		2024-07-10
		18	Biological evaluation	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 7.1.1		2024-07-10
		19	Sterility	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 7.1.2		2024-07-10
		20	Biological evaluation	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 7.2.1		2024-07-10
		21	Sterility	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 7.2.2		2024-07-10
		22	Plasma bag	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 7.3		2024-07-10
		23	Bacterial endotoxins	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 7.4		2024-07-10
102	Leukocyte reduction filters for single use	1	All items	Leukocyte reduction filters for single use YY 0329-2009		2024-07-10
		2	appearance	Leukocyte reduction filters for single use YY 0329-2009 5.1.1		2024-07-10
		3	tightness	Leukocyte reduction filters for single use YY 0329-2009 5.1.2		2024-07-10
		4	connection firmness	Leukocyte reduction filters for single use YY 0329-2009 5.1.3		2024-07-10
		5	particle	Leukocyte reduction filters for single use YY 0329-2009 5.1.4		2024-07-10
		6	flow	Leukocyte reduction filters for single use YY 0329-2009 5.1.5		2024-07-10
		7	protective sheath	Leukocyte reduction filters for single use YY 0329-2009 5.1.6		2024-07-10
		8	Reducing Substances (Easily Oxidizable)	Leukocyte reduction filters for single use YY 0329-2009 5.2.1		2024-07-10



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		№	Item/ Parameter			
			Substances)			
		9	Metal Ions	Leukocyte reduction filters for single use YY 0329-2009 5.2.2		2024-07-10
		10	PH	Leukocyte reduction filters for single use YY 0329-2009 5.2.3		2024-07-10
		11	Residue on Evaporation	Leukocyte reduction filters for single use YY 0329-2009 5.2.4		2024-07-10
		12	Ultraviolet Absorbance	Leukocyte reduction filters for single use YY 0329-2009 5.2.5		2024-07-10
		13	Ethylene Oxide Residue	Leukocyte reduction filters for single use YY 0329-2009 5.2.6		2024-07-10
		14	Sterility	Leukocyte reduction filters for single use YY 0329-2009 5.3.1		2024-07-10
		15	Bacterial endotoxins	Leukocyte reduction filters for single use YY 0329-2009 5.3.2		2024-07-10
		16	Biological evaluation	Leukocyte reduction filters for single use YY 0329-2009 5.5		2024-07-10
103	Disposable hemoperfutor	1	All items	Disposable hemoperfutor YY/T 0464-2019		2024-07-10
		2	appearance	Disposable hemoperfutor YY/T 0464-2019 5.1		2024-07-10
		3	connection between blood inlet and outlet and pipeline	Disposable hemoperfutor YY/T 0464-2019 5.2		2024-07-10
		4	filling adsorbent content	Disposable hemoperfutor YY/T 0464-2019 5.3		2024-07-10
		5	blood volume	Disposable hemoperfutor YY/T 0464-2019 5.4		2024-07-10
		6	particle shedding	Disposable hemoperfutor YY/T 0464-2019 5.5		2024-07-10



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		№	Item/ Parameter			
		7	Reducing Substances (Easily Oxidizable Substances)	Disposable hemoperfutor YY/T0464-2019 5.6.1		2024-07-10
		8	Metal Ions	Disposable hemoperfutor YY/T0464-2019 5.6.2		2024-07-10
		9	PH	Disposable hemoperfutor YY/T0464-2019 5.6.3		2024-07-10
		10	Residue on Evaporation	Disposable hemoperfutor YY/T0464-2019 5.6.4		2024-07-10
		11	Ultraviolet Absorbance	Disposable hemoperfutor YY/T0464-2019 5.6.5		2024-07-10
		12	Biological evaluation	Disposable hemoperfutor YY/T 0464-2019 5.7		2024-07-10
		13	Sterility	Disposable hemoperfutor YY/T 0464-2019 5.8		2024-07-10
		14	Pyrogen	Disposable hemoperfutor YY/T 0464-2019 5.9		2024-07-10
		15	Bacterial endotoxins	Disposable hemoperfutor YY/T 0464-2019 5.10		2024-07-10
		16	sealing performance	Disposable hemoperfutor YY/T 0464-2019 5.11		2024-07-10
		17	Adsorption performance	Disposable hemoperfutor YY/T 0464-2019 5.12		2024-07-10
		18	temperature resistance	Disposable hemoperfutor YY/T 0464-2019 5.13		2024-07-10
		19	period of validity	Disposable hemoperfutor YY/T 0464-2019 5.14		2024-07-10
104	Disposable membrane plasmaseparato	1	All items	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019		2024-07-10



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		№	Item/ Parameter			
	r and plasma component separator	2	appearance	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.1		2024-07-10
		3	Effective membrane area of plasma separator and plasma component separator	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.2		2024-07-10
		4	Plasma separator blood chamber capacity and plasma component separator plasma chamber capacity	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.3		2024-07-10
		5	Basic dimensions of plasma separators and plasma component separators	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.4		2024-07-10
		6	particle shedding	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.5		2024-07-10
		7	Reducing Substances	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.6.1		2024-07-10
		8	Metal Ions	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.6.2		2024-07-10
		9	Acid-Base Titration	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.6.3		2024-07-10
		10	Residue on Evaporation	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.6.4		2024-07-10
		11	Ultraviolet Absorbance	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.6.5		2024-07-10



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		№	Item/ Parameter			
		12	Ethylene Oxide Residue	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.6.6		2024-07-10
		13	Biological evaluation	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.7		2024-07-10
		14	Sterility	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.8		2024-07-10
		15	Pyrogen	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.9		2024-07-10
		16	Bacterial endotoxins	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.10		2024-07-10
		17	Separation of hemoglobin content in plasma by plasma separator	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.11		2024-07-10
		18	sealing performance	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.12		2024-07-10
		19	Plasma filtration rate	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.13.1		2024-07-10
		20	protein screening coefficient	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.13.2		2024-07-10
		21	Plasma component separator plasma component filtration rate	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.13.3		2024-07-10
		22	Screening coefficient of plasma component separator protein	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.13.4		2024-07-10
		23	temperature resistance	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.14		2024-07-10



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		№	Item/ Parameter			
		24	period of validity	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.15		2024-07-10
105	A.V.fistula needle sets for single use	1	All items	A.V.fistula needle sets for single use YY/T 0328-2015		2024-07-10
		2	particle contamination	A.V.fistula needle sets for single use YY/T 0328-2015 5.1		2024-07-10
		3	Sealing performance	A.V.fistula needle sets for single use YY/T 0328-2015 5.2		2024-07-10
		4	connection strength	A.V.fistula needle sets for single use YY/T 0328-2015 5.3		2024-07-10
		5	flow	A.V.fistula needle sets for single use YY/T 0328-2015 5.4		2024-07-10
		6	hose	A.V.fistula needle sets for single use YY/T 0328-2015 5.5		2024-07-10
		7	puncture needle	A.V.fistula needle sets for single use YY/T 0328-2015 5.6		2024-07-10
		8	Stop clamp	A.V.fistula needle sets for single use YY/T 0328-2015 5.7		2024-07-10
		9	Inner cone joint	A.V.fistula needle sets for single use YY/T 0328-2015 5.8		2024-07-10
		10	protective sheath	A.V.fistula needle sets for single use YY/T 0328-2015 5.9		2024-07-10
		11	Anti needle puncture protection device	A.V.fistula needle sets for single use YY/T 0328-2015 5.10		2024-07-10
		12	Reducing Substances	A.V.fistula needle sets for single use YY/T 0328-2015 6.2		2024-07-10
		13	Metal Ions	A.V.fistula needle sets for single use YY/T 0328-2015 6.3		2024-07-10
		14	Acid-Base Titration	A.V.fistula needle sets for single use YY/T 0328-2015 6.4		2024-07-10



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		№	Item/ Parameter			
		15	Residue on Evaporation	A.V.fistula needle sets for single use YY/T 0328-2015 6.5		2024-07-10
		16	Ultraviolet Absorbance	A.V.fistula needle sets for single use YY/T 0328-2015 6.6		2024-07-10
		17	Ethylene Oxide Residue	A.V.fistula needle sets for single use YY/T 0328-2015 6.7		2024-07-10
		18	Biological evaluation	A.V.fistula needle sets for single use YY/T 0328-2015 7.1		2024-07-10
		19	Sterility	A.V.fistula needle sets for single use YY/T 0328-2015 7.2		2024-07-10
		20	Bacterial endotoxins	A.V.fistula needle sets for single use YY/T 0328-2015 7.3		2024-07-10
106	Cardiopulmonary bypass systems—Blood-gas exchangers(oxygenators)	1	All items	Cardiopulmonary bypass systems—Blood-gas exchangers(oxygenators) YY 0604-2016		2024-07-10
		2	Sterility and Pyrogen	Cardiopulmonary bypass systems—Blood-gas exchangers(oxygenators) YY 0604-2016 5.1.1		2024-07-10
		3	Biological evaluation	Cardiopulmonary bypass systems—Blood-gas exchangers(oxygenators) YY 0604-2016 5.1.2		2024-07-10
		4	Tightness of blood channels	Cardiopulmonary bypass systems—Blood-gas exchangers(oxygenators) YY 0604-2016 5.2.1		2024-07-10
		5	Tightness of liquid channels in heat exchangers	Cardiopulmonary bypass systems—Blood-gas exchangers(oxygenators) YY 0604-2016 5.2.2		2024-07-10
		6	Blood volume	Cardiopulmonary bypass systems—Blood-gas exchangers(oxygenators) YY 0604-2016 5.2.3		2024-07-10
		7	joint	Cardiopulmonary bypass systems—Blood-gas exchangers(oxygenators) YY 0604-2016 5.2.4		2024-07-10
		8	Performance characteristics	Cardiopulmonary bypass systems—Blood-gas exchangers(oxygenators) YY 0604-2016 5.3		2024-07-10
		9	Reducing	Cardiopulmonary bypass systems—Blood-gas		2024-07-10

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			Substances	exchangers(oxygenators) YY 0604-2016 5.4.1		
		10	Metal Ions	Cardiopulmonary bypass systems—Blood-gas exchangers(oxygenators) YY 0604-2016 5.4.2		2024-07-10
		11	Acid-Base Titration	Cardiopulmonary bypass systems—Blood-gas exchangers(oxygenators) YY 0604-2016 5.4.3		2024-07-10
		12	Residue on Evaporation	Cardiopulmonary bypass systems—Blood-gas exchangers(oxygenators) YY 0604-2016 5.4.4		2024-07-10
		13	Ultraviolet Absorbance	Cardiopulmonary bypass systems—Blood-gas exchangers(oxygenators) YY 0604-2016 5.4.5		2024-07-10
		14	Color	Cardiopulmonary bypass systems—Blood-gas exchangers(oxygenators) YY 0604-2016 5.4.6		2024-07-10
		15	Ethylene Oxide Residue	Cardiopulmonary bypass systems—Blood-gas exchangers(oxygenators) YY 0604-2016 5.4.7		2024-07-10
107	Cardiopulmonary bypass systems -Water heating/cooling system	1	Partial items	Cardiopulmonary bypass systems -Water heating/cooling system GB 12263-2017	Except for safety requirements and environmental testing	2024-07-10
		2	Appearance and structure	Cardiopulmonary bypass systems -Water heating/cooling system GB 12263-2017 4.2		2024-07-10
		3	Connection firmness	Cardiopulmonary bypass systems -Water heating/cooling system GB 12263-2017 4.3		2024-07-10
		4	capacity	Cardiopulmonary bypass systems -Water heating/cooling system GB 12263-2017 4.4		2024-07-10
		5	flow	Cardiopulmonary bypass systems -Water heating/cooling system GB 12263-2017 4.5		2024-07-10
		6	temperature control	Cardiopulmonary bypass systems -Water heating/cooling system GB 12263-2017 4.6		2024-07-10



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		№	Item/ Parameter			
		7	temperature display	Cardiopulmonary bypass systems -Water heating/cooling system GB 12263-2017 4.7		2024-07-10
		8	Over temperature prompt	Cardiopulmonary bypass systems -Water heating/cooling system GB 12263-2017 4.8		2024-07-10
		9	Prompt for water rise/fall rate	Cardiopulmonary bypass systems -Water heating/cooling system GB 12263-2017 4.9		2024-07-10
		10	noise	Cardiopulmonary bypass systems -Water heating/cooling system GB 12263-2017 4.10		2024-07-10
		11	Prompt sound	Cardiopulmonary bypass systems -Water heating/cooling system GB 12263-2017 4.11		2024-07-10
		12	leakage	Cardiopulmonary bypass systems -Water heating/cooling system GB 12263-2017 4.12		2024-07-10
		13	line pressure	Cardiopulmonary bypass systems -Water heating/cooling system GB 12263-2017 4.13		2024-07-10
108	Haemodialysers, haemodiafilters, haemofilters	1	All items	Hemodialysis and relevant therapies— Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators YY 0053-2016		2024-07-10
		2	Biological evaluation	Hemodialysis and relevant therapies— Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators YY 0053-2016 3.1		2024-07-10
		3	Sterility	Hemodialysis and relevant therapies— Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators YY 0053-2016 3.2		2024-07-10
		4	Pyrogen	Hemodialysis and relevant therapies— Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators YY 0053-2016 3.3		2024-07-10
		5	Mechanical properties	Hemodialysis and relevant therapies— Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators YY 0053-2016 3.4		2024-07-10



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		№	Item/ Parameter			
		6	Usage performance	Hemodialysis and relevant therapies— Haemodialysers,haemodiafilters,haemofilters haemoconcentrators YY 0053-2016 3.5		2024-07-10
		7	Reducing Substances	Hemodialysis and relevant therapies— Haemodialysers,haemodiafilters,haemofilters haemoconcentrators YY 0053-2016 3.6.1		2024-07-10
		8	Metal Ions	Hemodialysis and relevant therapies— Haemodialysers,haemodiafilters,haemofilters haemoconcentrators YY 0053-2016 3.6.2		2024-07-10
		9	PH	Hemodialysis and relevant therapies— Haemodialysers,haemodiafilters,haemofilters haemoconcentrators YY 0053-2016 3.6.3		2024-07-10
		10	Residue on Evaporation	Hemodialysis and relevant therapies— Haemodialysers,haemodiafilters,haemofilters haemoconcentrators YY 0053-2016 3.6.4		2024-07-10
		11	Ultraviolet Absorbance	Hemodialysis and relevant therapies— Haemodialysers,haemodiafilters,haemofilters haemoconcentrators YY 0053-2016 3.6.5		2024-07-10
		12	Ethylene Oxide Residue	Hemodialysis and relevant therapies— Haemodialysers,haemodiafilters,haemofilters haemoconcentrators YY 0053-2016 3.6.6		2024-07-10
109	Extracorporeal blood circuit for blood purification devices	1	All items	Hemodialysis and related therapies—Extracorporeal blood circuit for blood purification devices YY 0267-2016		2024-07-10
		2	Biological evaluation	Hemodialysis and related therapies—Extracorporeal blood circuit for blood purification devices YY 0267-2016 4.1		2024-07-10
		3	Sterility	Hemodialysis and related therapies—Extracorporeal blood circuit for blood purification devices YY 0267-2016 4.2		2024-07-10
		4	Pyrogen	Hemodialysis and related therapies—Extracorporeal blood circuit for blood purification devices YY 0267-2016 4.3		2024-07-10



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		№	Item/ Parameter			
		5	Mechanical properties	Hemodialysis and related therapies—Extracorporeal blood circuit for blood purification devices YY 0267-2016 4.4		2024-07-10
		6	Blood path compliance	Hemodialysis and related therapies—Extracorporeal blood circuit for blood purification devices YY 0267-2016 4.5		2024-07-10
		7	particle contamination	Hemodialysis and related therapies—Extracorporeal blood circuit for blood purification devices YY 0267-2016 4.6		2024-07-10
		8	Reducing Substances	Hemodialysis and related therapies—Extracorporeal blood circuit for blood purification devices YY 0267-2016 4.7.1		2024-07-10
		9	Heavy Metals	Hemodialysis and related therapies—Extracorporeal blood circuit for blood purification devices YY 0267-2016 4.7.2		2024-07-10
		10	Acid-Base Titration	Hemodialysis and related therapies—Extracorporeal blood circuit for blood purification devices YY 0267-2016 4.7.3		2024-07-10
		11	Residue on Evaporation	Hemodialysis and related therapies—Extracorporeal blood circuit for blood purification devices YY 0267-2016 4.7.4		2024-07-10
		12	Ultraviolet Absorbance	Hemodialysis and related therapies—Extracorporeal blood circuit for blood purification devices YY 0267-2016 4.7.5		2024-07-10
		13	Color	Hemodialysis and related therapies—Extracorporeal blood circuit for blood purification devices YY 0267-2016 4.7.6		2024-07-10
		14	Ethylene Oxide Residue	Hemodialysis and related therapies—Extracorporeal blood circuit for blood purification devices YY 0267-2016 4.7.7		2024-07-10
110	haemoconcentrators	1	All items	Hemodialysis and relevant therapies—Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators YY 0053-2016		2024-07-10
		2	Biological evaluation	Hemodialysis and relevant therapies—Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators YY 0053-2016 3.1		2024-07-10
		3	Sterility	Hemodialysis and relevant therapies—Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators YY 0053-2016 3.2		2024-07-10



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		№	Item/ Parameter			
		4	Pyrogen	Hemodialysis and relevant therapies— Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators YY 0053-2016 3.3		2024-07-10
		5	Mechanical properties	Hemodialysis and relevant therapies— Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators YY 0053-2016 3.4		2024-07-10
		6	Usage performance	Hemodialysis and relevant therapies— Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators YY 0053-2016 3.5		2024-07-10
		7	Reducing Substances	Hemodialysis and relevant therapies— Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators YY 0053-2016 3.6.1		2024-07-10
		8	Metal Ions	Hemodialysis and relevant therapies— Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators YY 0053-2016 3.6.2		2024-07-10
		9	PH	Hemodialysis and relevant therapies— Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators YY 0053-2016 3.6.3		2024-07-10
		10	Residue on Evaporation	Hemodialysis and relevant therapies— Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators YY 0053-2016 3.6.4		2024-07-10
		11	Ultraviolet Absorbance	Hemodialysis and relevant therapies— Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators YY 0053-2016 3.6.5		2024-07-10
		12	Ethylene Oxide Residue	Hemodialysis and relevant therapies— Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators YY 0053-2016 3.6.6		2024-07-10
111	Water for haemodialysis and related	1	All items	Water for haemodialysis and related therapies YY 0572-2015		2024-07-10
		2	Microbial	Water for haemodialysis and related therapies YY 0572-2015 4.1		2024-07-10

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		№	Item/ Parameter			
	therapies		requirements			
		3	Chemical Contaminants	Waters for haemodialysis and related therapies YY 0572-2015 4.2		2024-07-10
112	Concentrates for haemodialysis and related therapies	1	All items	Concentrates for haemodialysis and related therapies YY 0598-2015		2024-07-10
		2	character	Concentrates for haemodialysis and related therapies YY 0598-2015 5.1		2024-07-10
		3	Solute Concentration	Concentrates for haemodialysis and related therapies YY 0598-2015 5.2		2024-07-10
		4	Microbial limit	Concentrates for haemodialysis and related therapies YY 0598-2015 5.3		2024-07-10
		5	Bacterial endotoxins	Concentrates for haemodialysis and related therapies YY 0598-2015 5.4		2024-07-10
		6	content	Concentrates for haemodialysis and related therapies YY 0598-2015 5.5		2024-07-10
		7	particle contamination	Concentrates for haemodialysis and related therapies YY 0598-2015 5.6		2024-07-10
113	Surgical instruments-Non-cutting,articulated instruments	1	All items	Surgical instruments-Non-cutting,articulated instruments-General requirements and test methods GB/T 2766-2022		2024-07-10
		2	Heat treatment and hardness of components	Surgical instruments-Non-cutting,articulated instruments-General requirements and test methods GB/T 2766-2022 5.1		2024-07-10
		3	corrosion resistance	Surgical instruments-Non-cutting,articulated instruments-General requirements and test methods GB/T 2766-2022 5.2		2024-07-10
		4	manufacturing process	Surgical instruments-Non-cutting,articulated instruments-General requirements and test methods GB/T 2766-2022 5.3		2024-07-10
		5	Surface Condition	Surgical instruments-Non-cutting,articulated instruments-General requirements and test methods GB/T 2766-2022 5.4		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	elasticity	Surgical instruments-Non-cutting,articulated instruments-General requirements and test methods GB/T 2766-2022 5.5		2024-07-10
		7	Clamping function	Surgical instruments-Non-cutting,articulated instruments-General requirements and test methods GB/T 2766-2022 5.6		2024-07-10
114	Surgical instruments-Non-cutting, articulated instruments-General specifications	1	All items	Surgical instruments-Non-cutting, articulated instruments-General specifications YY/T 0687-2008		2024-07-10
		2	hardness	Surgical instruments-Non-cutting, articulated instruments-General specifications YY/T 0687-2008 4.1		2024-07-10
		3	Manufacturing process and performance	Surgical instruments-Non-cutting, articulated instruments-General specifications YY/T 0687-2008 4.2		2024-07-10
		4	appearance	Surgical instruments-Non-cutting, articulated instruments-General specifications YY/T 0687-2008 4.3.1		2024-07-10
		5	Surface roughness	Surgical instruments-Non-cutting, articulated instruments-General specifications YY/T 0687-2008 4.3.2		2024-07-10
		6	Corrosion Resistance	Surgical instruments-Non-cutting, articulated instruments-General specifications YY/T 0687-2008 4.3.3		2024-07-10
		7	elasticity	Surgical instruments-Non-cutting, articulated instruments-General specifications YY/T 0687-2008 4.4		2024-07-10
		8	Clamping function	Surgical instruments-Non-cutting, articulated instruments-General specifications YY/T 0687-2008 4.5		2024-07-10
		9	strength	Surgical instruments-Non-cutting, articulated instruments-General specifications YY/T 0687-2008 4.6		2024-07-10
115	Scalpel blade	1	All items	Scalpel blade YY 0174-2019		2024-07-10
		2	size	Scalpel blade YY 0174-2019 4.1		2024-07-10
		3	appearance	Scalpel blade YY 0174-2019 4.2		2024-07-10
		4	Blade sharpness	Scalpel blade YY 0174-2019 4.3		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	hardness	Scalpel blade YY 0174-2019 4.4		2024-07-10
		6	elasticity	Scalpel blade YY 0174-2019 4.5		2024-07-10
		7	Rust prevention performance	Scalpel blade YY 0174-2019 4.6		2024-07-10
		8	Sterility	Scalpel blade YY 0174-2019 4.7		2024-07-10
		9	Ethylene Oxide Residue	Scalpel blade YY 0174-2019 4.8		2024-07-10
116	Surgical scissors-General specifications	1	All items	Surgical scissors-General specifications YY/T 0176-2006		2024-07-10
		2	screw	Surgical scissors-General specifications YY/T 0176-2006 4.1		2024-07-10
		3	cutting edge	Surgical scissors-General specifications YY/T 0176-2006 4.2		2024-07-10
		4	Blade contact point	Surgical scissors-General specifications YY/T 0176-2006 4.3		2024-07-10
		5	Shear performance test	Surgical scissors-General specifications YY/T 0176-2006 4.4		2024-07-10
		6	hardness test	Surgical scissors-General specifications YY/T 0176-2006 4.5		2024-07-10
		7	Surface roughness test	Surgical scissors-General specifications YY/T 0176-2006 4.6		2024-07-10
		8	Corrosion resistance test	Surgical scissors-General specifications YY/T 0176-2006 4.7		2024-07-10
		9	appearance	Surgical scissors-General specifications YY/T 0176-2006 4.8		2024-07-10
117	General specification for medical	1	All items	General specification for medical forceps YY/T 0295.1-2005		2024-07-10
		2	size test	General specification for medical forceps YY/T 0295.1-2005 4.1		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	forceps	3	hardness test	General specification for medical forceps YY/T 0295.1-2005 4.2		2024-07-10
		4	appearance test	General specification for medical forceps YY/T 0295.1-2005 4.3		2024-07-10
		5	Elasticity test	General specification for medical forceps YY/T 0295.1-2005 4.4		2024-07-10
		6	Connection firmness test	General specification for medical forceps YY/T 0295.1-2005 4.5		2024-07-10
		7	Labial head teeth	General specification for medical forceps YY/T 0295.1-2005 4.6		2024-07-10
		8	Head contact	General specification for medical forceps YY/T 0295.1-2005 4.7		2024-07-10
		9	Guide pin, positioning pin	General specification for medical forceps YY/T 0295.1-2005 4.8		2024-07-10
		10	Handle pattern	General specification for medical forceps YY/T 0295.1-2005 4.9		2024-07-10
		11	Corrosion resistance test	General specification for medical forceps YY/T 0295.1-2005 4.10		2024-07-10
		12	Surface roughness test	General specification for medical forceps YY/T 0295.1-2005 4.11		2024-07-10
118	Hose biopsy sampling forceps used with endoscope--General specifications	1	All items	Hose biopsy sampling forceps used with endoscope--General specifications YY/T 1076-2004,XG1-2006		2024-07-10
		2	usage performance	Hose biopsy sampling forceps used with endoscope--General specifications YY/T 1076-2004,XG1-2006 4.1		2024-07-10
		3	hardness	Hose biopsy sampling forceps used with endoscope--General specifications YY/T 1076-2004,XG1-2006 4.2		2024-07-10
		4	surface roughness	Hose biopsy sampling forceps used with endoscope--General specifications YY/T 1076-2004,XG1-2006 4.3		2024-07-10
		5	appearance	Hose biopsy sampling forceps used with endoscope--General specifications YY/T 1076-2004,XG1-2006 4.4		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	size	Hose biopsy sampling forceps used with endoscope--General specifications YY/T 1076-2004,XG1-2006 4.5		2024-07-10
		7	Corrosion resistance	Hose biopsy sampling forceps used with endoscope--General specifications YY/T 1076-2004,XG1-2006 4.6		2024-07-10
119	Disposable ECG electrodes	1	Partial items	Disposable ECG electrodes YY/T 0196-2005 4.3.1	Only biological reactions	2024-07-10
120	Medical ultrasonic couplants	1	Partial items	Medical ultrasonic couplants YY/T 0299-2022	Except for sound velocity, acoustic characteristic impedance, and acoustic attenuation parameters	2024-07-10
		2	Sterility	Medical ultrasonic couplants YY/T 0299-2022 5.1.1		2024-07-10
		3	Microbial limit	Medical ultrasonic couplants YY/T 0299-2022 5.1.2		2024-07-10
		4	Biological evaluation	Medical ultrasonic couplants YY/T 0299-2022 5.2		2024-07-10
		5	viscosity	Medical ultrasonic couplants YY/T 0299-2022 5.3		2024-07-10
		6	pH	Medical ultrasonic couplants YY/T 0299-2022 5.3		2024-07-10
		7	appearance	Medical ultrasonic couplants YY/T 0299-2022 5.4		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
121	Hot compress sticker (bag)	1	All items	Hot compress sticker (bag) YY 0060-2018		2024-07-10
		2	size	Hot compress sticker (bag) YY 0060-2018 5.1		2024-07-10
		3	appearance	Hot compress sticker (bag) YY 0060-2018 5.2		2024-07-10
		4	Sealing of outer packaging	Hot compress sticker (bag) YY 0060-2018 5.3		2024-07-10
		5	Inner bag anti drop	Hot compress sticker (bag) YY 0060-2018 5.4		2024-07-10
		6	Tensile strength of packaging bags	Hot compress sticker (bag) YY 0060-2018 5.5		2024-07-10
		7	Moisture permeability of the outer bag	Hot compress sticker (bag) YY 0060-2018 5.6.1		2024-07-10
		8	Oxygen permeability of the outer bag	Hot compress sticker (bag) YY 0060-2018 5.6.2		2024-07-10
		9	Adhesive performance	Hot compress sticker (bag) YY 0060-2018 5.7		2024-07-10
		10	Temperature	Hot compress sticker (bag) YY 0060-2018 5.8		2024-07-10
		11	Biological evaluation	Hot compress sticker (bag) YY 0060-2018 5.9		2024-07-10
122	hazardous substances in electronic information products	1	All items	Testing methods for hazardous substances in electronic information products SJ/T 11365-2006		2024-07-10
		2	Toxic and Hazardous Substances	Testing methods for hazardous substances in electronic information products SJ/T 11365-2006 5		2024-07-10
		3	Polybrominated Biphenyls and	Testing methods for hazardous substances in electronic information products SJ/T 11365-2006 6		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			Polybrominated Diphenyl Ethers			
		4	Lead, cadmium, and mercury	Testing methods for hazardous substances in electronic information products SJ/T 11365-2006 7		2024-07-10
		5	Hexavalent Chromium	Testing methods for hazardous substances in electronic information products SJ/T 11365-2006 8		2024-07-10
123	Ophthalmic optics-Intraocular lenses	1	All items	Ophthalmic optics-Intraocular lenses-Part 1: Terminology YY/T0290.1-2021		2024-07-10
		2	Partial items	Ophthalmic optics-Intraocular lenses-Part2: Optical properties and test methods YY 0290.2-2021	Except for MTF using model	2024-07-10
		3	Optical power	Ophthalmic optics-Intraocular lenses-Part2: Optical properties and test methods YY 0290.2-2021 4.2		2024-07-10
		4	Image quality	Ophthalmic optics-Intraocular lenses-Part2: Optical properties and test methods YY 0290.2-2021 4.3		2024-07-10
		5	Spectral transmittance	Ophthalmic optics-Intraocular lenses-Part2: Optical properties and test methods YY 0290.2-2021 4.4		2024-07-10
		6	Partial items	Ophthalmic optics-Intraocular lenses-Part3: Mechanical properties and test methods YY 0290.3-2018	Except for Gap analysis	2024-07-10
		7	Dimensions and tolerances	Ophthalmic optics-Intraocular lenses-Part3: Mechanical properties and test methods YY 0290.3-2018 4.2		2024-07-10
		8	Compressive force	Ophthalmic optics-Intraocular lenses-Part3: Mechanical properties and test methods YY 0290.3-2018 4.4		2024-07-10
		9	Axial displacement under compressive force	Ophthalmic optics-Intraocular lenses-Part3: Mechanical properties and test methods YY 0290.3-2018 4.5		2024-07-10
		10	Optical eccentricity	Ophthalmic optics-Intraocular lenses-Part3: Mechanical properties and test methods YY 0290.3-2018 4.6		2024-07-10



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		№	Item/ Parameter			
		11	Optical inclination angle	Ophthalmic optics-Intraocular lenses-Part3: Mechanical properties and test methods YY 0290.3-2018 4.7		2024-07-10
		12	contact angle	Ophthalmic optics-Intraocular lenses-Part3: Mechanical properties and test methods YY 0290.3-2018 4.8		2024-07-10
		13	Compression force attenuation	Ophthalmic optics-Intraocular lenses-Part3: Mechanical properties and test methods YY 0290.3-2018 4.9		2024-07-10
		14	Dynamic fatigue durability	Ophthalmic optics-Intraocular lenses-Part3: Mechanical properties and test methods YY 0290.3-2018 4.10		2024-07-10
		15	Surgical procedures	Ophthalmic optics-Intraocular lenses-Part3: Mechanical properties and test methods YY 0290.3-2018 4.11		2024-07-10
		16	Surface and material uniformity	Ophthalmic optics-Intraocular lenses-Part3: Mechanical properties and test methods YY 0290.3-2018 4.12		2024-07-10
		17	Performance recovery of simulated surgical procedures	Ophthalmic optics-Intraocular lenses-Part3: Mechanical properties and test methods YY 0290.3-2018 5		2024-07-10
		18	All items	Ophthalmic optics-Intraocular lenses-Part 4: Labeling and information YY/T 0290.4-2022		2024-07-10
		19	Partial items	Ophthalmic implants-Intraocular lenses-Part 5: Biocompatibility YY 0290.5-2008	Except for intraocular implantation test	2024-07-10
		20	Total Extraction Test	Ophthalmic implants-Intraocular lenses-Part 5: Biocompatibility YY 0290.5-2008 5.2		2024-07-10
		21	Leachability Test	Ophthalmic implants-Intraocular lenses-Part 5: Biocompatibility YY 0290.5-2008 5.3		2024-07-10
		22	Hydrolysis stability	Ophthalmic implants-Intraocular lenses-Part 5: Biocompatibility YY/T 0290.5-2008 5.4		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		23	Light stability	Ophthalmic implants-Intraocular lenses-Part 5: Biocompatibility YY/T 0290.5-2008 5.5		2024-07-10
		24	laser stability	Ophthalmic implants-Intraocular lenses-Part 5: Biocompatibility YY/T 0290.5-2008 5.6		2024-07-10
		25	Insoluble inorganic substances	Ophthalmic implants-Intraocular lenses-Part 5: Biocompatibility YY/T 0290.5-2008 5.7		2024-07-10
		26	biological test	Ophthalmic implants-Intraocular lenses-Part 5: Biocompatibility YY/T 0290.5-2008 6		2024-07-10
		27	All items	Ophthalmic optics-Intraocular lenses-Part 6: Shelf-life and transport stability YY/T0290.6-2021		2024-07-10
		28	All items	Ophthalmic optics-Intraocular lenses-Part 8: Fundamental requirement YY0290.8-2022		2024-07-10
		29	Optical and mechanical properties	Ophthalmic optics-Intraocular lenses-Part 8: Fundamental requirement YY0290.8-2022 5		2024-07-10
		30	Biocompatibility	Ophthalmic optics-Intraocular lenses-Part 8: Fundamental requirement YY0290.8-2022 6		2024-07-10
		31	Sterilization	Ophthalmic optics-Intraocular lenses-Part 8: Fundamental requirement YY0290.8-2022 9		2024-07-10
		32	All items	Ophthalmic implants-Intraocular lenses-Part 9: Multifocal intraocular lenses YY 0290.9-2010		2024-07-10
		33	general requirements	Ophthalmic implants-Intraocular lenses-Part 9: Multifocal intraocular lenses YY0290.9-2010 4.1		2024-07-10
		34	Dimensions and tolerances	Ophthalmic implants-Intraocular lenses-Part 9: Multifocal intraocular lenses YY 0290.9-2010 4.2		2024-07-10
		35	general requirements	Ophthalmic implants-Intraocular lenses-Part 9: Multifocal intraocular lenses YY 0290.9-2010 5.1		2024-07-10
		36	Optical power	Ophthalmic implants-Intraocular lenses-Part 9: Multifocal intraocular lenses YY 0290.9-2010 5.2		2024-07-10



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		№	Item/ Parameter			
		37	Image quality	Ophthalmic implants-Intraocular lenses-Part 9: Multifocal intraocular lenses YY 0290.9-2010 5.3		2024-07-10
		38	Optical Design	Ophthalmic implants-Intraocular lenses-Part 9: Multifocal intraocular lenses YY 0290.9-2010 5.4.1		2024-07-10
		39	Spectral transmission characteristics	Ophthalmic implants-Intraocular lenses-Part 9: Multifocal intraocular lenses YY 0290.9-2010 5.4.2		2024-07-10
124	Ophthalmic optics-Contact lenses Rigid contact lenses specification	1	Partial items	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012	Except for rabbit eye compatibility experiment	2024-07-10
		2	Rear vertex power, column mirror power, and column mirror axis position	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.2.2		2024-07-10
		3	Prismatic degree	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.2.3		2024-07-10
		4	Maximum deviation of optical center	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.2.4		2024-07-10
		5	Transmittance performance	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.2.5		2024-07-10
		6	Geometric dimension requirements	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.3		2024-07-10
		7	refractivity	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.4.2.1		2024-07-10
		8	oxygen permeability	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.4.2.2		2024-07-10



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		№	Item/ Parameter			
		9	hardness	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.4.2.3		2024-07-10
		10	contact angle	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.4.2.4		2024-07-10
		11	Mechanical	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.4.2.5		2024-07-10
		12	Extraction Experiment	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.4.3.1		2024-07-10
		13	Ingestion and release of preservatives	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.4.3.2		2024-07-10
		14	Fading Test	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.4.3.3		2024-07-10
		15	Biocompatibility evaluation	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.5		2024-07-10
		16	Acute systemic toxicity	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.5.2		2024-07-10
		17	Eye irritation test	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.5.3		2024-07-10
		18	Cytotoxicity	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.5.4		2024-07-10
		19	Sensitization	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.5.5		2024-07-10
		20	Microbial limit	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.6		2024-07-10
		21		Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.7		2024-07-10
		22		Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.8		2024-07-10



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		№	Item/ Parameter			
125	Ophthalmic optics — Contact lenses Soft contact lenses	1	Partial items	Ophthalmic optics-Contact lenses-Part 3:Soft contact lenses GB 11417.3-2012	Except for rabbit eye compatibility experiment	2024-07-10
		2	Rear vertex power, column mirror power, and column mirror axis position	Ophthalmic optics-Contact lenses-Part3:Soft contact lenses GB 11417.3-2012 4.2.2		2024-07-10
		3	Prismatic degree	Ophthalmic optics-Contact lenses-Part3:Soft contact lenses GB 11417.3-2012 4.2.3		2024-07-10
		4	Transmittance performance	Ophthalmic optics-Contact lenses-Part3:Soft contact lenses GB 11417.3-2012 4.2.4		2024-07-10
		5	Geometric dimension requirements	Ophthalmic optics-Contact lenses-Part3:Soft contact lenses GB 11417.3-2012 4.3		2024-07-10
		6	Geometric dimension requirements	Ophthalmic optics-Contact lenses-Part3:Soft contact lenses GB 11417.3-2012 4.4.2.1		2024-07-10
		7	water content	Ophthalmic optics-Contact lenses-Part3:Soft contact lenses GB 11417.3-2012 4.4.2.2		2024-07-10
		8	Oxygen permeability	Ophthalmic optics-Contact lenses-Part3:Soft contact lenses GB 11417.3-2012 4.4.2.3		2024-07-10
		9	fading test	Ophthalmic optics-Contact lenses-Part3:Soft contact lenses GB 11417.3-2012 4.4.2.4		2024-07-10
		10	extraction test	Ophthalmic optics-Contact lenses-Part3:Soft contact lenses GB 11417.3-2012 4.4.3.1		2024-07-10
		11	Ingestion and release of preservatives	Ophthalmic optics-Contact lenses-Part3:Soft contact lenses GB 11417.3-2012 4.4.3.2		2024-07-10



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		№	Item/ Parameter			
		12	Acute systemic toxicity	Ophthalmic optics-Contact lenses-Part3:Soft contact lenses GB 11417.3-2012 4.5.2		2024-07-10
		13	Acute eye irritation test	Ophthalmic optics-Contact lenses-Part3:Soft contact lenses GB 11417.3-2012 4.5.3		2024-07-10
		14	Cytotoxicity	Ophthalmic optics-Contact lenses-Part3:Soft contact lenses GB 11417.3-2012 4.5.4		2024-07-10
		15	Sensitization	Ophthalmic optics-Contact lenses-Part3:Soft contact lenses GB 11417.3-2012 4.5.5		2024-07-10
		16	Microbial requirements	Ophthalmic optics-Contact lenses-Part3:Soft contact lenses GB 11417.3-2012 4.6		2024-07-10
		17	stability	Ophthalmic optics-Contact lenses-Part3:Soft contact lenses GB 11417.3-2012 4.7		2024-07-10
		18	Internal quality and surface defects	Ophthalmic optics-Contact lenses-Part3:Soft contact lenses GB 11417.3-2012 4.8		2024-07-10
126	Medical sodium hyaluronate gel	1	All items	Medical sodium hyaluronate gel YY/T 0308-2015		2024-07-10
		2	appearance	Medical sodium hyaluronate gel YY/T 0308-2015 5.1		2024-07-10
		3	Effective usage	Medical sodium hyaluronate gel YY/T 0308-2015 5.2		2024-07-10
		4	Identification	Medical sodium hyaluronate gel YY/T0308-2015 5.3		2024-07-10
		5	Content	Medical sodium hyaluronate gel YY/T0308-2015 5.4		2024-07-10
		6	transmittance	Medical sodium hyaluronate gel YY/T0308-2015 5.5		2024-07-10
		7	pH	Medical sodium hyaluronate gel YY/T0308-2015 5.6		2024-07-10
		8	Osmotic Pressure	Medical sodium hyaluronate gel YY/T0308-2015 5.7		2024-07-10



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		№	Item/ Parameter			
		9	Shear viscosity	Medical sodium hyaluronate gel YY/T 0308-2015 5.8		2024-07-10
		10	elasticity	Medical sodium hyaluronate gel YY/T 0308-2015 5.9		2024-07-10
		11	Inherent Viscosity	Medical sodium hyaluronate gel YY/T0308-2015 5.10.1		2024-07-10
		12	Average molecular weight and molecular weight distribution coefficient	Medical sodium hyaluronate gel YY/T 0308-2015 5.10.2		2024-07-10
		13	Protein Content	Medical sodium hyaluronate gel YY/T0308-2015 5.11		2024-07-10
		14	Ultraviolet Absorbance	Medical sodium hyaluronate gel YY/T0308-2015 5.12		2024-07-10
		15	Refractive index	Medical sodium hyaluronate gel YY/T0308-2015 5.13		2024-07-10
		16	Heavy Metal Content	Medical sodium hyaluronate gel YY/T0308-2015 5.14		2024-07-10
		17	Ethanol Residue	Medical sodium hyaluronate gel YY/T0308-2015 5.15		2024-07-10
		18	Sterility	Medical sodium hyaluronate gel YY/T 0308-2015 5.16		2024-07-10
		19	Bacterial endotoxins	Medical sodium hyaluronate gel YY/T 0308-2015 5.17		2024-07-10
		20	Hemolysis test	Medical sodium hyaluronate gel YY/T 0308-2015 5.18		2024-07-10
		21	Biological evaluation	Medical sodium hyaluronate gel YY/T 0308-2015 5.19		2024-07-10
127	General specification	1	Partial items	General specification for medical oxygen generator with molecular sieve YY/T 0298-1998	Except for air	2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	for medical oxygen generator with molecular sieve				tightness, noise, moisture content, oxygen output, environmental testing, indicator lights; Use only when quoted or requested by the customer	
		2	appearance	General specification for medical oxygen generator with molecular sieve YY/T 0298-1998 5.1		2024-07-10
		3	Oxygen Concentration	General specification for medical oxygen generator with molecular sieve YY/T0298-1998 5.2.1		2024-07-10
		4	Carbon Dioxide Content	General specification for medical oxygen generator with molecular sieve YY/T0298-1998 5.2.3		2024-07-10
		5	Carbon Monoxide Content	General specification for medical oxygen generator with molecular sieve YY/T0298-1998 5.2.4		2024-07-10
		6	Gaseous Acid and Alkali Content	General specification for medical oxygen generator with molecular sieve YY/T0298-1998 5.2.5		2024-07-10
		7	Ozone and Other Gaseous Oxidants Content	General specification for medical oxygen generator with molecular sieve YY/T0298-1998 5.2.6		2024-07-10
		8	smell	General specification for medical oxygen generator with molecular sieve YY/T0298-1998 5.2.7		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
128	Capsular tension ring	9	Solid particle size	General specification for medical oxygen generator with molecular sieve YY/T0298-1998 5.2.8		2024-07-10
		10	Solid Matter Content	General specification for medical oxygen generator with molecular sieve YY/T0298-1998 5.2.9		2024-07-10
		1	All items	Ophthalmic optical-Capsular tension ring YY 0762-2017		2024-07-10
		2	Functional elasticity	Ophthalmic optical-Capsular tension ring YY 0762-2017 4.1.1		2024-07-10
		3	Deformation and stress	Ophthalmic optical-Capsular tension ring YY 0762-2017 4.1.2		2024-07-10
		4	Uniformity	Ophthalmic optical-Capsular tension ring YY 0762-2017 4.1.3		2024-07-10
		5	Dynamic fatigue durability	Ophthalmic optical-Capsular tension ring YY 0762-2017 4.1.4		2024-07-10
		6	size	Ophthalmic optical-Capsular tension ring YY 0762-2017 4.2		2024-07-10
		7	surface quality	Ophthalmic optical-Capsular tension ring YY 0762-2017 4.3		2024-07-10
		8	Extraction	Ophthalmic optical-Capsular tension ring YY0762-2017 4.4		2024-07-10
		9	Cytotoxicity	Ophthalmic optical-Capsular tension ring YY 0762-20171 4.5.2		2024-07-10
		10	Eye irritation test	Ophthalmic optical-Capsular tension ring YY 0762-20171 4.5.3		2024-07-10
		11	Sensitization	Ophthalmic optical-Capsular tension ring YY 0762-20171 4.5.4		2024-07-10
		12	local effects of eye after Implantation	Ophthalmic optical-Capsular tension ring YY 0762-20171 4.5.5		2024-07-10
		13	Sterility	Ophthalmic optical-Capsular tension ring YY 0762-20171 4.6		2024-07-10
		14	Ethylene Oxide Residue	Ophthalmic optical-Capsular tension ring YY0762-2017 4.7		2024-07-10

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
129	Endovascular prostheses	1	Partial items	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014	Use only when quoted or requested by the customer.Except for visibility and MRI compatibility	2024-07-10
		2	Bond strength	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.1.2		2024-07-10
		3	Component compatibility	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.1.3		2024-07-10
		4	Size	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.1.4		2024-07-10
		5	Bending/Discounting	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.1.5		2024-07-10
		6	Profile	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.1.6		2024-07-10
		7	Pushability	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.1.7		2024-07-10
		8	simulated use	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.1.9		2024-07-10
		9	Torsion	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.1.10		2024-07-10
		10	Torsional bonding strength	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.1.11		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		11	traceability	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.1.12		2024-07-10
		12	Bond strength	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.2.2		2024-07-10
		13	Balloon inflation time	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.2.3		2024-07-10
		14	Balloon decompression time	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.2.4		2024-07-10
		15	Mean Burst Pressure of Balloon	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.2.5		2024-07-10
		16	Rated burst pressure of balloon	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.2.6		2024-07-10
		17	Balloon rated fatigue	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.2.7		2024-07-10
		18	Component size compatibility	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.2.8		2024-07-10
		19	Dimensional verification	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.2.9		2024-07-10
		20	release force	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.2.10		2024-07-10
		21	simulated use	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.2.12		2024-07-10
		22	Torsional bonding strength	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.2.13		2024-07-10
		23	Tensile strength of pipes	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.2.14		2024-07-10
		24	Bond strength	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.3.2		2024-07-10
		25	Component size compatibility	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.3.3		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		26	Dimensional verification	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.3.4		2024-07-10
		27	Bending/Discounting	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.3.5		2024-07-10
		28	simulated use	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.3.7		2024-07-10
		29	Torsional bonding strength	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.3.8		2024-07-10
		30	Tensile strength of pipes	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.3.9		2024-07-10
		31	Biological evaluation	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.4		2024-07-10
		32	hemostatic	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.5		2024-07-10
		33	The relationship between implant length and diameter	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.1.2		2024-07-10
		34	simulated use	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.1.4		2024-07-10
		35	Wall adhesion	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.2.2		2024-07-10
		36	Anti extrusion performance	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.2.3		2024-07-10
		37	Local compression	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.2.4		2024-07-10
		38	Anti displacement performance	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.2.5		2024-07-10
		39	Radial support force	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.2.6		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		40	Retract	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.2.7		2024-07-10
		41	simulated use	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.2.8		2024-07-10
		42	Rupture/circumferential strength	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.3.2		2024-07-10
		43	corrosion	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.3.3		2024-07-10
		44	Processing fit strength	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.3.4		2024-07-10
		45	durability	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.3.5		2024-07-10
		46	Axial tensile strength	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.3.6		2024-07-10
		47	Strength after repeated puncture	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.3.7		2024-07-10
		48	bonding strength	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.3.8		2024-07-10
		49	Pores, water permeability, and water osmotic pressure	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.4.2		2024-07-10
		50	Overall water permeability/leakage rate	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.4.3		2024-07-10
		51	Dimensional verification	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.5.2		2024-07-10
		52	Bending/Discounting	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.5.3		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		53	Anti displacement performance	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.5.4		2024-07-10
		54	Tensile testing of module components	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.5.5		2024-07-10
		55	The relationship between implant length and diameter in size selection	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.6.2		2024-07-10
		56	Size	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.6.3		2024-07-10
		57	Retract	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.6.4		2024-07-10
		58	simulated use	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.6.5		2024-07-10
		59	Implant diameter and balloon filling pressure	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.6.6		2024-07-10
		60	Radial support force	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.7.2		2024-07-10
		61	Anti extrusion performance	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.7.3		2024-07-10
		62	simulated use	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.7.4		2024-07-10
		63	Blank surface area of bracket	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.7.5		2024-07-10
		64	Local compression	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.7.6		2024-07-10
		65	Bending/Discountin g	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.7.7		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
130	Vena cava filters	1	All items	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016	Except for MRI and visibility	2024-07-10
		2	Size	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 4.2		2024-07-10
		3	Catheter rupture	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.1.2		2024-07-10
		4	Dimensional verification and component dimensional compatibility	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.1.3		2024-07-10
		5	Pressurized injection	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.1.4		2024-07-10
		6	simulated use	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.1.5		2024-07-10
		7	tensile strength	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.1.6		2024-07-10
		8	Torsional bonding performance	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.1.7		2024-07-10
		9	Dimensional verification and component dimensional	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.2.2		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			compatibility			
		10	release force	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.2.3		2024-07-10
		11	simulated use	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.2.4		2024-07-10
		12	tensile strength	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.2.5		2024-07-10
		13	Torsional bonding strength	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.2.6		2024-07-10
		14	corrosion	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.3.3		2024-07-10
		15	durability	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.3.4		2024-07-10
		16	Filter size verification	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.3.5		2024-07-10
		17	Filter tensile strength	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.3.6		2024-07-10
		18	Anti displacement performance	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.3.7		2024-07-10
		19	Radial support force	Cardiovascular implants-Endovascular devices- Part 3: Vena cava		2024-07-10

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				filters YY/T 0663.3-2016 8.5.3.9		
		20	Visual inspection	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.3.10		2024-07-10
		21	Filter tensile strength	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.4.2		2024-07-10
		22	Recycling/conversion force	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.4.3		2024-07-10
		23	matching performance	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.4.4.2		2024-07-10
		24	Recycling performance	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.4.4.3		2024-07-10
		25	Conversion performance	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.4.4.4		2024-07-10
		26	Catheter rupture	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.5.2		2024-07-10
		27	Dimensional verification and component dimensional compatibility	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.5.3		2024-07-10
		28	Pressurized injection	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016		2024-07-10



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		№	Item/ Parameter			
				8.5.5.4		
		29	simulated use	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 8.5.5.5		2024-07-10
		30	tensile strength	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.5.6		2024-07-10
		31	Torsional bonding performance	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.5.7		2024-07-10
		32	Dimensional verification and component dimensional compatibility	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.6.2		2024-07-10
		33	Recycling/conversion force	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.6.3		2024-07-10
		34	simulated use	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.6.4		2024-07-10
		35	Torsional bonding strength	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.6.5		2024-07-10
		36	tensile strength	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.6.6		2024-07-10
		37	biocompatibility	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.7.2		2024-07-10



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		№	Item/ Parameter			
131	Cardiovascular implants-Cardiac occluder	1	Partial items	Cardiovascular implants-Cardiac occluder YY/T 1553-2017	Except for MRI and visibility	2024-07-10
		2	Size	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 4.2		2024-07-10
		3	appearance	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.2.2		2024-07-10
		4	particle contamination	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.2.3		2024-07-10
		5	size	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.2.4		2024-07-10
		6	corrosion	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.2.5		2024-07-10
		7	Tensile strength of cardiac occluder	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.2.6		2024-07-10
		8	stability	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.2.7		2024-07-10
		9	Pore or flow resistance	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.2.8		2024-07-10
		10	durability	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.2.11		2024-07-10
		11	Chemical Properties	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.2.12		2024-07-10
		12	appearance	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.3.2		2024-07-10
		13	size	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.3.3		2024-07-10
		14	tensile strength	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.3.4		2024-07-10
		15	Torsional bonding strength	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.3.5		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		16	Bending/Discounting	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.3.6		2024-07-10
		17	hemostatic	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.3.7		2024-07-10
		18	Corrosion Resistance	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.3.8		2024-07-10
		19	Chemical Properties	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.3.10		2024-07-10
		20	bonding strength	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.4.2		2024-07-10
		21	Bending	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.4.3		2024-07-10
		22	simulated use	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.4.4		2024-07-10
		23	Sterility	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 11.1		2024-07-10
		24	Microbial limit	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 11.2		2024-07-10
		25	Residual Sterilants	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 11.3		2024-07-10
		26	bacterial endotoxin/pyrogen	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 11.4		2024-07-10
132	Cross-linked sodium hyaluronate gel for plastic surgery	1	All items	Cross-linked sodium hyaluronate gel for plastic surgery YY/T 0962-2021		2024-07-10
		2	appearance	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.1		2024-07-10
		3	Effective usage	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.2		2024-07-10
		4	Particle size distribution	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.3		2024-07-10



№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	Pushing force	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.4		2024-07-10
		6	Infrared identification	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.5		2024-07-10
		7	Swelling	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.6		2024-07-10
		8	osmotic pressure	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.7		2024-07-10
		9	pH value	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.8		2024-07-10
		10	Sodium hyaluronate content	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.9		2024-07-10
		11	protein	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.10		2024-07-10
		12	Total heavy metals	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.11		2024-07-10
		13	Residual amount of crosslinking agent	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.12		2024-07-10
		14	Free Sodium hyaluronate content	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.13		2024-07-10
		15	other additives	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.14		2024-07-10
		16	Sterility	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.15		2024-07-10
		17	bacterial endotoxin	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.16		2024-07-10
		18	Hemolytic Streptolysin	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.17		2024-07-10
		19	biological evaluation	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.18		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		20	biodegradability	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.19		2024-07-10
133	Medical devices for human in vitro assisted reproductive technology-In vitro mouse embryo assay	1	All items	Medical devices for human in vitro assisted reproductive technology-In vitro mouse embryo assay YY/T 1434-2016		2024-07-10
134	Rigid gas permeable contact lenses for orthokeratology	1	All items	Rigid gas permeable contact lenses for orthokeratology YY 0477-2016		2024-07-10
		2	Rear vertex power, column mirror power, and column mirror axis position	Rigid gas permeable contact lenses for orthokeratology YY 0477-2016 4.2.1		2024-07-10
		3	Transmittance performance	Rigid gas permeable contact lenses for orthokeratology YY 0477-2016 4.2.2		2024-07-10
		4	size	Rigid gas permeable contact lenses for orthokeratology YY 0477-2016 4.3		2024-07-10
		5	refractivity	Rigid gas permeable contact lenses for orthokeratology YY 0477-2016 4.4.2.1		2024-07-10
		6	oxygen permeability	Rigid gas permeable contact lenses for orthokeratology YY 0477-2016 4.4.2.2		2024-07-10
		7	hardness	Rigid gas permeable contact lenses for orthokeratology YY 0477-2016 4.4.2.3		2024-07-10
		8	contact angle	Rigid gas permeable contact lenses for orthokeratology YY 0477-2016 4.4.2.4		2024-07-10
		9	Mechanical	Rigid gas permeable contact lenses for orthokeratology YY 0477-2016 4.4.2.5		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		10	Chemical Properties	Rigid gas permeable contact lenses for orthokeratology YY 0477-2016 4.4.3		2024-07-10
		11	Biological evaluation	Rigid gas permeable contact lenses for orthokeratology YY 0477-2016 4.5		2024-07-10
		12	Microbial limit	Rigid gas permeable contact lenses for orthokeratology YY 0477-2016 4.6		2024-07-10
		13	stability	Rigid gas permeable contact lenses for orthokeratology YY 0477-2016 4.7		2024-07-10
		14	Internal quality and surface defects	Rigid gas permeable contact lenses for orthokeratology YY 0477-2016 4.8		2024-07-10
135	Phagocytosis of mouse peritoneal macrophages on chicken erythrocytes-Ex-vivo method	1	All items	Immunogenic evaluation method of medical devices-Part 4:Phagocytosis of mouse peritoneal macrophages on chicken erythrocytes-Ex-vivo method YY/T 1465.4-2017		2024-07-10
136	A method for blastocyst cell staining and counting	1	All items	Medical devices for human assisted reproductive technology-A method for blastocyst cell staining and counting YY/T 1688-2021		2024-07-10
137	Prenatal developmental toxicity test	1	All items	Test for reproductive and developmental toxicity of medical devices-Part2: Prenatal developmental toxicity test YY/T 1292.2-2015		2024-07-10
138	Cardiovascular implants— Cardiac valve repair devices and delivery	1	All items	Cardiovascular implants— Cardiac valve repair devices and delivery system YY/T 1787-2021		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	system					
139	Medical devices for human assisted reproductive technology—Determination of amino acids in human assisted reproductive media	1	All items	Medical devices for human assisted reproductive technology—Determination of amino acids in human assisted reproductive media YY/T 1695-2020		2024-07-10
140	Additive manufacturing medical product—3D printing titanium alloy implant metal ion precipitation evaluation method	1	All items	Additive manufacturing medical product—3D printing titanium alloy implant metal ion precipitation evaluation method YY/T 1802-2021		2024-07-10
141	Sterilization of medical devices—Microbiological methods—Part 1: Determination	1	All items	Sterilization of medical devices—Microbiological methods—Part 1: Determination of a population of microorganisms on products GB/T 19973.1-2015		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	of a population of microorganisms on products					
142	Tissue engineering medical device	1	Characterization of type I collagen	Tissue engineering medical device products-Methods for determination of type I collagen YY/T 1453-2016		2024-07-10
		2	Remnant α -Gal antigen determination	Tissue engineering medical device products-Remnant α -Gal antigen determination in scaffold materials utilizing animal tissues and their derivatives YY/T 1561-2017		2024-07-10
		3	Quantification of remnant DNA(Fluorescence method)	Tissue engineered medical product-Part 25:Quantification of remnant DNA in biological materials utilizing animal tissues and their derivatives:Fluorescence method YY/T 0606.25-2014		2024-07-10
143	Tissue engineering medical device	1	determination of type I collagen	Tissue engineering medical device products-Methods for determination of type I collagen YY/T 1453-2016		2024-07-10
		2	Identification	Tissue engineering medical device products-Methods for determination of type I collagen YY/T 1453-2016 4.1		2024-07-10
		3	Purity of Type I Collagen	Tissue engineering medical device products-Methods for determination of type I collagen YY/T 1453-2016 4.2		2024-07-10
		4	Collagen Content	Tissue engineering medical device products-Methods for determination of type I collagen YY/T 1453-2016 4.3		2024-07-10
		5	Hydroxyproline Content	Tissue engineering medical device products-Methods for determination of type I collagen YY/T 1453-2016 4.4		2024-07-10
		6	Peptide Profile	Tissue engineering medical device products-Methods for determination of type I collagen YY/T 1453-2016 4.5		2024-07-10
		7	Melting Point	Tissue engineering medical device products-Methods for determination of type I collagen YY/T 1453-2016 4.6		2024-07-10
		8	Ignition Residue	Tissue engineering medical device products-Methods for determination of type I collagen YY/T 1453-2016 4.7		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Total Heavy Metals and Trace Elements	Tissue engineering medical device products-Methods for determination of type I collagen YY/T 1453-2016 4.8		2024-07-10
		10	Acid Hydrolysis Products	Tissue engineering medical device products-Methods for determination of type I collagen YY/T 1453-2016 4.9		2024-07-10
		11	Total Sugar Content (Calculated as Glucose)	Tissue engineering medical device products-Methods for determination of type I collagen YY/T 1453-2016 4.10		2024-07-10
		12	Fat Content	Tissue engineering medical device products-Methods for determination of type I collagen YY/T 1453-2016 4.11		2024-07-10
		13	Sterility, microbial limits	Tissue engineering medical device products-Methods for determination of type I collagen YY/T 1453-2016 4.12.1		2024-07-10
		14	Bacterial endotoxins	Tissue engineering medical device products-Methods for determination of type I collagen YY/T 1453-2016 4.12.2		2024-07-10
		15	Biological evaluation	Tissue engineering medical device products-Methods for determination of type I collagen YY/T 1453-2016 4.12.3		2024-07-10
		16	Remnant α -Gal antigen determination	Tissue engineering medical device products-Remnant α -Gal antigen determination in scaffold materials utilizing animal tissues and their derivatives YY/T 1561-2017		2024-07-10
		17	Quantification of remnant DNA in biological materials utilizing animal tissues and their derivatives:Fluorescence method	Tissue engineered medical product-Part 25:Quantification of remnant DNA in biological materials utilizing animal tissues and their derivatives:Fluorescence method YY/T 0606.25-2014		2024-07-10
144	Medical device utilizing animal tissues and their derivatives	1	immunological evaluation	Immunological evaluation of medical device utilizing animal tissues and their derivatives in GGTA1 KO mice 非标方法 non		2024-07-10
		2	immunogen	Quantification of remnant α -Gal antigen and determination of α -Gal antigen clearance in Medical devices utilizing animal tissues and their derivatives YY/T 1561-2017		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
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		3	Material specific antibody detection	Material specific antibody detection for medical devices utilizing animal tissues and their derivatives Non-standard method non		2024-07-10
145	Medical devices utilizing animal tissues and their derivatives or allogeneic medical device	1	Titer of inactivated virus	Medical devices utilizing animal tissues and their derivatives – Part 3: Validation of the elimination and/or inactivation of viruses and Transmissible Spongiform Encephalopathy(TSE) agents; YY/T 0771.3-2009		2024-07-10
				2020 Revision		2024-07-10
				1. Medical devices utilizing animal tissues and their derivatives – Part 3: Validation of the elimination and/or inactivation of viruses and Transmissible Spongiform Encephalopathy(TSE) agents; 2017 revision		2024-07-10
		2	Kinetics of virus inactivated	Medical devices utilizing animal tissues and their derivatives – Part 3: Validation of the elimination and/or inactivation of viruses and Transmissible Spongiform Encephalopathy(TSE) agents; YY/T 0771.3-2009		2024-07-10
				2020 Revision		2024-07-10
				1. Medical devices utilizing animal tissues and their derivatives – Part 3: Validation of the elimination and/or inactivation of viruses and Transmissible Spongiform Encephalopathy(TSE) agents; 2017 revision		2024-07-10
		3	Serum immunoglobulin and complement componen	Immunogenic evaluation method of medical devices—Part 2:Serum immunoglobulin and complement component detection(enzyme-linked immunoabsorbent assay) YY/T 1465.2-2016		2024-07-10
		4	Serum immunoglobulin and complement componen	Immunogenic evaluation method of medical devices—Part 2:Serum immunoglobulin and complement component detection(enzyme-linked immunoabsorbent assay) YY/T 1465.2-2016		2024-07-10



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		5	biomaterial-specific antibody	Tissue engineered medical products—Part 14:Standard practice for evaluation of immune responses of substrate and scaffolds products:ELISA tests YY/T 0606.14 -2014		2024-07-10
146	medical devices	1	molecular weight of collagen	Tissue engineering medical device products—Collagen protein—Part 2:Determination of molecular weight of type I collagen—Sodium dodecyl sulfate polyacrylamide gel electrophoresis YY/T 1805.2-2021		2024-07-10
		2	Quantification of collagen based on marker peptide	Tissue engineering medical device products—Collagen protein—Part 3:quantification of collagen based on marker peptide detection-liquid chromatography-mass spectrometry YY/T 1805.3-2022		2024-07-10
		3	Quantification of remnant DNA	Tissue engineered medical products-Quantification of remnant DNA in biological materials utilizing animal tissues and their derivatives: Fluorescence method YY/T 1876-2023		2024-07-10
		4	lymphocyte proliferation	Tissue engineered medical products—Part 15:Standard practice for evaluation of immune responses of substrate and scaffolds products:Lymphocyte proliferation tests YY/T 0606.15-2014		2024-07-10
147	Biological for nanomaterial medical devices—Testing and characterization methods for silver nanoparticles and ions released from silver nanoparticle	1	silver nanoparticles and ions released	Biological for nanomaterial medical devices—Testing and characterization methods for silver nanoparticles and ions released from silver nanoparticle containing dressing YY/T 1863-2023		2025-07-18



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		№	Item/ Parameter			
	containing dressing					
Active medical device						
1		1	All items	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020		2024-07-10
		2	General requirements	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 4.1		2024-07-10
		3	secondary tip vibration excursion	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 4.2		2024-07-10
		4	drive frequency	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 4.3		2024-07-10
		5	drived output acoustic power	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 4.4		2024-07-10
		6	quiescent electrical power	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 4.5		2024-07-10
		7	maximum electrical power	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 4.6		2024-07-10
		8	clamping force	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 4.7		2024-07-10
		9	grasping force	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 4.8		2024-07-10
		10	Appearance and structure	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 4.9		2024-07-10
		11	power supply	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 4.10		2024-07-10
		12	power input	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 4.11		2024-07-10
		13	type tests	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 5.1		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		14	ambient temperature,humidity,atmospheric pressure	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 5.3		2024-07-10
		15	supply voltage,type of current,nature of supply,frequency	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 5.5		2024-07-10
		16	humidity preconditioning treatment	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 5.7		2024-07-10
		17	determination of applied parts and accessible parts	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 5.9		2024-07-10
		18	protection against electric shock	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 6.2		2024-07-10
		19	protection against harmful ingress of water or particulate matter	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 6.3		2024-07-10
		20	methods of sterilization	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 6.4		2024-07-10
		21	suitability for use in oxygen rich environment	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 6.5		2024-07-10
		22	mode of operation	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 6.6		2024-07-10
		23	General	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 7.1		2024-07-10
		24	marking on the outside of ME	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 7.2		2024-07-10



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			EQUITMENT or ME EQUITMENT parts			
		25	marking on the inside of ME EQUITMENT or ME EQUITMENT parts	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 7.3		2024-07-10
		26	markings of controls and instruments	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 7.4		2024-07-10
		27	safety signs	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 7.5		2024-07-10
		28	symbols	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 7.6		2024-07-10
		29	colours of the insulation of conductors	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 7.7		2024-07-10
		30	indicator lights and controls	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 7.8		2024-07-10
		31	accompanying documents	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 7.9		2024-07-10
		32	Fundamental rule of protection against electric shock	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 8.1		2024-07-10
		33	Requirements related to power sources	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 8.2		2024-07-10
		34	Classification of APPLIED PARTS	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 8.3		2024-07-10



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		35	Limitation of voltage, current or energy	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 8.4		2024-07-10
		36	Separation of parts	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 8.5		2024-07-10
		37	Protective earthing, functional earthing and potential equalization of ME EQUIPMENT	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 8.6		2024-07-10
		38	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 8.7		2024-07-10
		39	Insulation	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 8.8		2024-07-10
		40	CREEPAGE DISTANCES and AIR CLEARANCES	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 8.9		2024-07-10
		41	Components and wiring	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 8.10		2024-07-10
		42	MAINS PARTS, components and layout	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 8.11		2024-07-10
		43	HAZARDS associated with moving parts	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 9.2		2024-07-10



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		44	HAZARD associated with surfaces, corners and edges	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 9.3		2024-07-10
		45	Instability HAZARDS	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 9.4		2024-07-10
		46	Expelled parts HAZARD	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 9.5		2024-07-10
		47	Acoustic energy (including infra- and ultrasound) and vibration	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 9.6		2024-07-10
		48	Pressure vessels and parts subject to pneumatic and hydraulic pressure..... 285	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 9.7		2024-07-10
		49	HAZARDS associated with support systems	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 9.8		2024-07-10
		50	X-Radiation	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 10.1		2024-07-10
		51	Alpha, beta, gamma, neutron and other particle radiation	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 10.2		2024-07-10
		52	Microwave radiation	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 10.3		2024-07-10
		53	Lasers	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 10.4		2024-07-10



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		54	Other visible electromagnetic radiation	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 10.5		2024-07-10
		55	Infrared radiation	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 10.6		2024-07-10
		56	Ultraviolet radiation	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 10.7		2024-07-10
		57	Excessive temperatures in ME EQUIPMENT.	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 11.1		2024-07-10
		58	Fire prevention	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 11.2		2024-07-10
		59	Constructional requirements for fire ENCLOSURES of ME EQUIPMENT .	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 11.3		2024-07-10
		60	ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics.	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 11.4		2024-07-10
		61	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 11.5		2024-07-10
		62	Overflow, spillage, leakage, ingress of water or particulate matter,	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 11.6		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT			
		63	Interruption of the power supply SUPPLY MAINS to ME EQUIPMENT	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 11.8		2024-07-10
		64	Accuracy of controls and instruments	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 12.1		2024-07-10
		65	USABILITY	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 12.2		2024-07-10
		66	Alarm systems	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 12.3		2024-07-10
		67	Protection against hazardous output....	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 12.4		2024-07-10
		68	Specific HAZARDOUS SITUATIONS	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 13.1		2024-07-10
		69	SINGLE FAULT CONDITIONS	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 13.2		2024-07-10
		70	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 14		2024-07-10
		71	Arrangements of controls and	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 15.1		2024-07-10



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			indicators of ME EQUIPMENT			
		72	Serviceability	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 15.2		2024-07-10
		73	Mechanical strength	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 15.3		2024-07-10
		74	ME EQUIPMENT components and general assembly	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 15.4		2024-07-10
		75	MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 15.5		2024-07-10
		76	General requirements for the ME SYSTEMS	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 16.1		2024-07-10
		77	ACCOMPANYING DOCUMENTS of an ME SYSTEM	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 16.2		2024-07-10
		78	Power supply .	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 16.3		2024-07-10
		79	ENCLOSURES	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 16.4		2024-07-10
		80	SEPARATION DEVICES.....	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 16.5		2024-07-10



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		81	LEAKAGE CURRENTS.	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 16.6		2024-07-10
		82	Protection against MECHANICAL HAZARDS	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 16.7		2024-07-10
		83	Interruption of the power supply to parts of an ME SYSTEM	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 16.8		2024-07-10
		84	ME SYSTEM connections and wiring	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 16.9		2024-07-10
		85	All items	Medical electrical equipment-Part1-8: General equipments for basic safety and essential performance-Collateral standard: General requirement, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY/T 9706.108-2021		2024-07-10
		86	General equipment	Medical electrical equipment-Part1-8: General equipments for basic safety and essential performance-Collateral standard: General requirement, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY/T 9706.108-2021 4		2024-07-10
		87	ME EQUIPMENT indentionation marking and documents	Medical electrical equipment-Part1-8: General equipments for basic safety and essential performance-Collateral standard: General requirement, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY/T 9706.108-2021 5		2024-07-10
		88		Medical electrical equipment-Part1-8: General equipments for basic safety and essential performance-Collateral standard:		2024-07-10



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				General requirement, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY/T 9706.108-2021 5.1		
		89	ACCOMPANYING DOCUMENTS	Medical electrical equipment-Part1-8: General equipments for basic safety and essential performance-Collateral standard: General requirement, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY/T 9706.108-2021 5.2		2024-07-10
		90	ALARM CONTION	Medical electrical equipment-Part1-8: General equipments for basic safety and essential performance-Collateral standard: General requirement, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY/T 9706.108-2021 6.1		2024-07-10
		91	Disclosures for INTELLIGENT ALARM SYSTEM	Medical electrical equipment-Part1-8: General equipments for basic safety and essential performance-Collateral standard: General requirement, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY/T 9706.108-2021 6.2		2024-07-10
		92	Generation of ALARM SIGNALS	Medical electrical equipment-Part1-8: General equipments for basic safety and essential performance-Collateral standard: General requirement, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY/T 9706.108-2021 6.3		2024-07-10
		93	Disclosure of delays	Medical electrical equipment-Part1-8: General equipments for basic safety and essential performance-Collateral standard: General requirement, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY/T 9706.108-2021 6.4		2024-07-10



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		94	ALARM PRESETS	Medical electrical equipment-Part1-8: General equipments for basic safety and essential performance-Collateral standard: General requirement, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY/T 9706.108-2021 6.5		2024-07-10
		95	ALARM LIMIT	Medical electrical equipment-Part1-8: General equipments for basic safety and essential performance-Collateral standard: General requirement, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY/T 9706.108-2021 6.6		2024-07-10
		96	ALARM SYSTEM security	Medical electrical equipment-Part1-8: General equipments for basic safety and essential performance-Collateral standard: General requirement, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY/T 9706.108-2021 6.7		2024-07-10
		97	ALARM SIGNAL inactivation states	Medical electrical equipment-Part1-8: General equipments for basic safety and essential performance-Collateral standard: General requirement, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY/T 9706.108-2021 6.8		2024-07-10
		98	ALARM RESET	Medical electrical equipment-Part1-8: General equipments for basic safety and essential performance-Collateral standard: General requirement, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY/T 9706.108-2021 6.9		2024-07-10
		99	NON-LATCHING and LATCHING ALARM SIGNALS	Medical electrical equipment-Part1-8: General equipments for basic safety and essential performance-Collateral standard: General requirement, tests and guidance for alarm systems in		2024-07-10



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				medical electrical equipment and medical electrical systems YY/T 9706.108-2021 6.10		
		100	DISTRIBUTED ALARM SYSTEM	Medical electrical equipment-Part1-8: General equipments for basic safety and essential performance-Collateral standard: General requirement, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY/T 9706.108-2021 6.11		2024-07-10
		101	ALARM SYSTEM logging	Medical electrical equipment-Part1-8: General equipments for basic safety and essential performance-Collateral standard: General requirement, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY/T 9706.108-2021 6.12		2024-07-10
		102	All items	Measurement method for energy consumption of medical electrical equipment YY/T 1738-2020		2025-07-18
		103	environmental requirement	Measurement method for energy consumption of medical electrical equipment YY/T 1738-2020 4.1		2025-07-18
		104	Testing equipment requirements	Measurement method for energy consumption of medical electrical equipment YY/T 1738-2020 4.2		2025-07-18
		105	Preparation requirements before testing	Measurement method for energy consumption of medical electrical equipment YY/T 1738-2020 4.3		2025-07-18
		106	shutdown mode	Measurement method for energy consumption of medical electrical equipment YY/T 1738-2020 5.1		2025-07-18
		107	standby mode	Measurement method for energy consumption of medical electrical equipment YY/T 1738-2020 5.2		2025-07-18
		108	Operating mode	Measurement method for energy consumption of medical electrical equipment YY/T 1738-2020 5.3		2025-07-18
		109	low power mode	Measurement method for energy consumption of medical electrical equipment YY/T 1738-2020 5.4		2025-07-18



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2	Medical electrical equipment intended for use in the emergency medical services environment	110	charge mode	Measurement method for energy consumption of medical electrical equipment YY/T 1738-2020 5.5		2025-07-18
		111	energy consumption calculation	Measurement method for energy consumption of medical electrical equipment YY/T 1738-2020 6		2025-07-18
		1	All items	Medical electrical equipment-Part 1-12:General requirements for basic safety and essential performance-Collateral Standard:Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services envi YY 9706.112-2021		2024-07-10
		2	Additional requirements for ME equipment and the power grid of ME systems	Medical electrical equipment-Part 1-12:General requirements for basic safety and essential performance-Collateral Standard:Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services envi YY 9706.112-2021 4.1		2024-07-10
		3	Environmental conditions of ME equipment	Medical electrical equipment-Part 1-12:General requirements for basic safety and essential performance-Collateral Standard:Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services envi YY 9706.112-2021 4.2		2024-07-10
		4	Classification of ME equipment and ME systems	Medical electrical equipment-Part 1-12:General requirements for basic safety and essential performance-Collateral Standard:Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services envi YY 9706.112-2021 5		2024-07-10
		5	Additional requirements for legibility of marks	Medical electrical equipment-Part 1-12:General requirements for basic safety and essential performance-Collateral Standard:Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services envi YY 9706.112-2021 6.1		2024-07-10
		6	Additional	Medical electrical equipment-Part 1-12:General requirements for		2024-07-10



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			requirements for IP classification marking	basic safety and essential performance-Collateral Standard:Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services envi YY 9706.112-2021 6.2		
		7	Operating manual	Medical electrical equipment-Part 1-12:General requirements for basic safety and essential performance-Collateral Standard:Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services envi YY 9706.112-2021 6.3		2024-07-10
		8	Technical manual: Fixed or permanently installed class I ME equipment	Medical electrical equipment-Part 1-12:General requirements for basic safety and essential performance-Collateral Standard:Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services envi YY 9706.112-2021 6.4		2024-07-10
		9	Protection of electrical hazard (source) of ME equipment	Medical electrical equipment-Part 1-12:General requirements for basic safety and essential performance-Collateral Standard:Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services envi YY 9706.112-2021 7		2024-07-10
		10	Additional requirements for water or particulate matter intrusion into ME equipment and ME systems	Medical electrical equipment-Part 1-12:General requirements for basic safety and essential performance-Collateral Standard:Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services envi YY 9706.112-2021 8.1		2024-07-10
		11	Additional requirements for power supply/grid interruptions for ME equipment and ME	Medical electrical equipment-Part 1-12:General requirements for basic safety and essential performance-Collateral Standard:Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services envi YY 9706.112-2021 8.2		2024-07-10



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			systems			
		12	Additional requirements for internal power supply of ME equipment	Medical electrical equipment-Part 1-12:General requirements for basic safety and essential performance-Collateral Standard:Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services envi YY 9706.112-2021 8.3		2024-07-10
		13	Controller and meter accuracy and hazard output protection	Medical electrical equipment-Part 1-12:General requirements for basic safety and essential performance-Collateral Standard:Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services envi YY 9706.112-2021 9		2024-07-10
		14	Additional mechanical strength requirements for ME equipment intended for use in EMS environments	Medical electrical equipment-Part 1-12:General requirements for basic safety and essential performance-Collateral Standard:Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services envi YY 9706.112-2021 10.1		2024-07-10
		15	Requirements for installation of ME equipment	Medical electrical equipment-Part 1-12:General requirements for basic safety and essential performance-Collateral Standard:Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services envi YY 9706.112-2021 10.2		2024-07-10
		16	Additional requirements for EMC of ME equipment and ME systems	Medical electrical equipment-Part 1-12:General requirements for basic safety and essential performance-Collateral Standard:Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services envi YY 9706.112-2021 11		2024-07-10
		17	Partial items	Medical electrical equipment Part1:General requirements for safety GB 9706.1-2007	Except for 39-41	2024-07-10



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		18	All items	Medical electrical equipment Part1:General requirements for safety IEC 60601-1: 2012	Except for AP APG	2024-07-10
				Medical electrical equipment Part1:General requirements for safety IEC 60601-1:1988	Except for 39-41	2024-07-10
				Medical electrical equipment Part1:General requirements for safety-1.Collateral standard:Safety requirements for medical electrical systems GB 9706.15-2008		2024-07-10
				Medical electrical equipment Part1:General requirements for safety-1.Collateral standard:Safety requirements for medical electrical systems IEC 60601-1-1:2000		2024-07-10
		19	All items	The environmental requirements and test methods for medical electrical equipment GB/T 14710-2009		2024-07-10
		20	All items	Medical electrical equipment-Recurrent test and test after repair of medical electrical equipment YY/T 0841-2023		2025-07-18
		21	All items	Medical electrical equipment-Part 1-8:General requirements for safety-Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY 0709-2009		2024-07-10
				Medical electrical equipment-Part 1-9:General requirements for safety-Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems IEC 60601-1-8:2003		2024-07-10
		22	General requirements	Medical electrical equipment-Recurrent test and test after repair of medical electrical equipment YY/T 0841-2023 4.1		2025-07-18
		23	All items	Electric apparatus for gastric lavage YY 1105-2008		2024-07-10
		24	Testing before delivery, after modification, and after repair	Medical electrical equipment-Recurrent test and test after repair of medical electrical equipment YY/T 0841-2023 4.2		2025-07-18



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		25	All items	General Specifications for medical foot switch YY/T 1057-2016		2024-07-10
		26	periodic testing	Medical electrical equipment-Recurrent test and test after repair of medical electrical equipment YY/T 0841-2023 4.3		2025-07-18
		27	All items	fire hazard testing for electric and electronic products-part21:abnormal heat-ball pressure test GB/T 5169.21-2017		2024-07-10
		28	overview	Medical electrical equipment-Recurrent test and test after repair of medical electrical equipment YY/T 0841-2023 5.1		2025-07-18
		29	All items	Flammability of solid non-metallic materials when exposed to flame sources-list of test methods GB/T 11020-2005		2024-07-10
		30	visual inspection	Medical electrical equipment-Recurrent test and test after repair of medical electrical equipment YY/T 0841-2023 5.2		2025-07-18
		31	All items	Method for determining the comparative and the proof trackin indices of solid insulating materials under moist conditionis GB/T 4207-2022		2024-07-10
		32	measure	Medical electrical equipment-Recurrent test and test after repair of medical electrical equipumt YY/T 0841-2023 5.3		2025-07-18
		33	All items	fire hazard testing for electric and electronic products—part16:test flames—50W horizontal and vertical flame test methods GB/T 5169.16-2017		2024-07-10
		34	functional testing	Medical electrical equipment-Recurrent test and test after repair of medical electrical equipment YY/T 0841-2023 5.4		2025-07-18
		35	All items	Medical electrical equipment—Part 1-10: General requirements for basic safety and essential performance-Collateral Standard: Requirements for the development of physiologic closed-loop controllllers YY/T 9706.110-2021		2024-07-10
		36	test report	Medical electrical equipment-Recurrent test and test after repair of medical electrical equipumt YY/T 0841-2023 6.1		2025-07-18
		37	All items	Medical electrical equipment-Part 2: Padicular requirements for the safet y ofexternal cardiac pacemakers with internal power		2024-07-10



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				source YY 0945.2- 2015		
		38	energy consumption calculation	Medical electrical equipment-Recurrent test and test after repair of medical electrical equipment YY/T 0841-2023 6.2		2025-07-18
3	Medical electrical equipment used in the home healthcare environment	1	All items	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021		2024-07-10
		2	Additional requirements for supply mains for ME equipment and ME systems	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 4.1		2024-07-10
		3	Environmental conditions for transport and storage between uses	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 4.2.2		2024-07-10
		4	Environmental operating conditions	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 4.2.3.1		2024-07-10
		5	Environmental shock to Transit-operable ME equipment	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 4.2.3.2		2024-07-10
		6	General requirments for testing ME	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral		2024-07-10

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			equipment	standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 5		
		7	classification of ME equipment and ME systems	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 6		2024-07-10
		8	usability of the accompanying documents	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 7.1		2024-07-10
		9	additional requirements for marking of IP classification	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 7.2		2024-07-10
		10	accompanying documents	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 7.3		2024-07-10
		11	instructions for use	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 7.4		2024-07-10
		12	technical description	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral		2024-07-10



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				standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 7.5		
		13	additional requirements for cleaning ,disinfection of ME equipment and ME systems	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 8.1		2024-07-10
		14	additional requirements for sterilization of ME equipment and ME systems	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 8.2		2024-07-10
		15	additional requirements for ingress of water or particulate matter into ME equipment and ME systems	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 8.3		2024-07-10
		16	additional requirements for interruption of the power supply/supply mains to ME equipment and ME systems	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 8.4		2024-07-10
		17	Status indication	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and		2024-07-10



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				medical electrical systems used in the home healthcare environment YY 9706.111-2021 8.5.1		
		18	Accessibility of small internal power supply	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 8.5.2		2024-07-10
		19	accuracy of controls and instruments and protection against hazardous outputs	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 9		2024-07-10
		20	requirements for mechanical strength for non-transit-operable ME equipment	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 10.1.2		2024-07-10
		21	requirements for mechanical strength for transit-operable ME equipment	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 10.1.3		2024-07-10
		22	additional requirements for actuating parts of controls of ME equipment	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 10.2		2024-07-10
		23	protection against strangulation or asphyxiation	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and		2024-07-10



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				medical electrical systems used in the home healthcare environment YY 9706.111-2021 11		
		24	additional requirements for electromagnetic compatibility of ME equipment and ME systems	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 12		2024-07-10
		25	additional requirements for generation of alarm signals	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 13.1		2024-07-10
		26	additional requirements for alarm signal volume	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 13.2		2024-07-10
4	Monitoring equipment	1	All items	Medical electrical equipment part2:particular requirements for the safety of electrocardiographic monitoring equipment GB 9706.25-2005		2024-07-10
				Medical electrical equipment part2:particular requirements for the safety of electrocardiographic monitoring equipment IEC 60601-2-27:1994		2024-07-10
		2	All items	Medical electrical equipment-Particular requirements for basic safety and essential performance of respiratory gas monitors YY0601-2010		2024-07-10
		3	All items	Medical electrical equipment—part2-49:Particular requirement for the safety of multifunction patient monitoring equipment YY 0668-2008		2024-07-10



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5	Physiological parameters analysis and measurement equipment	4	All items	ECG cables and leadwires YY 0828-2011		2024-07-10
		5	All items	Medical electrical equipment- Part 2-27 :Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment GB 9706.227-2021		2024-07-10
		1	All items	Non-invasive Automatic measurement Blood Pressure Monitor YY 0670-2008		2024-07-10
		2	All items	Medical electrical equipment— Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipments YY 0783-2010		2024-07-10
		3	All items	Medical electrical equipment—part2-30:particular requirements for the safety,including essential performance,of automatic cycling non-invasive blood pressure monitoring equipment YY 0667-2008		2024-07-10
		4	All items	Clinical electronic thermometer GB/T 21416-2008 /XG1-2008		2024-07-10
		5	All items	Clinical thermometers—Performance of electrical thermometers for continuous measurement YY 0785-2010		2024-07-10
		6	Partial items	Clinical infrared thermometers— Part 1 :Ear GB/T 21417.1-2008	except for 4.4.4	2024-07-10
		7	All items	Temperature biofeedback equipment YY/T 1096-2007		2024-07-10
		8	All items	Bridge type impedance blood flow recorder YY/T 1143-2008		2024-07-10
		9	All items	Direct impedance blood flow recorder YY/T 1078-2008		2024-07-10
		10	All items	Myoelectric biofeedback equipment YY/T 1095-2015		2024-07-10
		11	All items	Electroencephalographic biofeedback equipment YY/T 0903-2013		2024-07-10



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		12	All items	Medical Electrical equipment—Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY 0784-2011		2024-07-10
		13	All items	Medical electrical equipment - Part 2-26: Particular requirements for the safety of electroencephalographs GB 9706.26-2005		2024-07-10
				Medical electrical equipment - Part 2-26: Particular requirements for the safety of electroencephalographs IEC 60601-2-26: 2003		2024-07-10
		14	All items	Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs GB 9706.226-2021		2024-07-10
		15	All items	Medical Electrical Equipment – Part 2-40: Particular Requirements For The Basic Safety And Essential Performance Of Electromyographs And Evoked Response Equipment YY 9706.240-2021		2024-07-10
		16	All items	Medical electrical equipment - Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment YY 9706.234-2021		2024-07-10
		17	All items	Medical electrical equipment—part2-30:particular requirements for the basic safety and essential performanceof automated non-invasive sphygmomanometers YY9706.230-2023		2024-07-10
		18	All items	Medical Electrical equipment—Part 2-61:Particular requirements for the basic safety and essential performance of pulse oximeter equipment YY 9706.261-2023		2024-07-10
		19	All items	Medical electrical equipment-Part2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors YY 9706.249-2023		2024-07-10
		20	All items	Electrophysiology catheter YY/T 1519-2017		2024-07-10



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		21	All items	Multi-channels electrophysiology recording system YY/T 1635-2018		2024-07-10
		22	All items	Electrical pneumatic tourniquet equipment YY/T 1830-2022		2024-07-10
		23	All items	Stethoscope YY/T 1035-2021		2025-07-18
		24	Appearance and structural requirements	Stethoscope YY/T 1035-2021 4.1		2025-07-18
		25	stethoscopesound transmission performance	Stethoscope YY/T 1035-2021 4.2		2025-07-18
		26	Requirements for stethoscope earrings	Stethoscope YY/T 1035-2021 4.3		2025-07-18
		27	Requirements for sound transmission connection conduit	Stethoscope YY/T 1035-2021 4.4		2025-07-18
6	electrocardiograph	1	All items	single and multichannel electrocardiograph YY 1139-2013		2024-07-10
		2	All items	Medical electrical equipment-part 2: Particular requirements for the safety,including essential performance of ambulatory electrocardiographic systems YY 0885-2013		2024-07-10
		3	All items	Disposable ECG electrodes YY/T 0196-2005		2024-07-10
		4	All items	Medical electrical equipment-Part 2-47:Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems YY 9706.247-2021		2024-07-10
		5	All items	Medical electrical equipment-Part 2-25:Particular requirements for the basic safety and essential performance of electrocardiographs GB 9706.225-2021		2024-07-10



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7	Optical equipment and appliances	1	All items	ophthalmic instruments-Trial case lenses GB/T 17342-2009		2024-07-10
		2	All items	Ophthalmic instruments-Perimeters YY/T 0676-2008/XGI-2021		2024-07-10
		3	All items	ophthalmic instruments-Refractor heads YY 0674-2008		2024-07-10
		4	All items	Ophthalmic instruments-Fundus camera YY/T 0634-2022		2024-07-10
				Ophthalmic instruments-Fundus camera ISO 10940:2009		2024-07-10
		5	All items	Ophthalmic instruments-Endoilluminators-Part 1: Requirements and test methods YY 0792.1-2016		2024-07-10
		6	All items	Ophthalmic instruments-Endoilluminators-Part 2: Fundamental requirements and test methods for optical radiation safety YY 0792.2-2010		2024-07-10
		7	All items	Ophthalmic optics and instruments-Optical devices for enhancing low vision GB 23719-2009		2024-07-10
		8	All items	Ophthalmic instruments—Synoptophores YY/T 0675-2023		2024-09-13
				Ophthalmic instruments—Synoptophores ISO 10944:1998		2024-07-10
				Ophthalmic instruments—Synoptophores ISO 10944:2009		2024-07-10
		9	All items	Ophthalmic instruments-Eye refractometers YY 0673-2008		2024-07-10
		10	All items	Ophthalmic instruments — Fundamental requirements and test methods —Part 1: General requirements applicable to all ophthalmic instruments ISO 15004-1: 2020		2024-07-10
		11	All items	Ophthalmic instruments-Fundamental requirements and test methods-Part 2: Light hazard protection ISO 15004-2: 2007		2024-07-10



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		12	All items	Ophthalmic instruments-Microkeratome YY 0788-2010		2024-07-10
		13	All items	standard for logarithmic visual acuity charts GB/T 11533-2011		2024-07-10
		14	All items	Measurement methods of illuminance for medical optical instruments YY/T 1146-2016		2024-07-10
		15	All items	pupil distance meters JIG 952-2014		2024-07-10
		16	Partial items	assembled spectacles-Part 1: single-vision and multifocal GB 13511.1-2011	except 5.4	2024-07-10
		17	All items	Optics and optical instruments—Focimeters GB /T 17341-1998		2024-07-10
		18	All items	Ophthalmometers GB 38455-2019		2024-07-10
				Ophthalmometers ISO 10343:2014		2024-07-10
		19	All items	Ophthalmic instruments-Fundamental requirements and test methods-Part 2: Light hazard protection ISO 15004-2: 2024		2025-07-18
		20	General	Ophthalmic instruments-Fundamental requirements and test methods-Part 3: Light hazard protection ISO 15004-2: 2024 4.1		2025-07-18
		21	Group 1 instruments	Ophthalmic instruments-Fundamental requirements and test methods-Part 4: Light hazard protection ISO 15004-2: 2024 4.2		2025-07-18
		22	Group 2 instruments	Ophthalmic instruments-Fundamental requirements and test methods-Part 5: Light hazard protection ISO 15004-2: 2024 4.3		2025-07-18
		23	General	Ophthalmic instruments-Fundamental requirements and test methods-Part 6: Light hazard protection ISO 15004-2: 2024 5.1		2025-07-18
		24	Requirements for classification as a Group 1 instrument	Ophthalmic instruments-Fundamental requirements and test methods-Part 7: Light hazard protection ISO 15004-2: 2024 5.2		2025-07-18



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		25	Requirements for classification as a Group 2 instrument	Ophthalmic instruments-Fundamental requirements and test methods-Part 8: Light hazard protection ISO 15004-2: 2024 5.3		2025-07-18
		26	Exposure limits for Group 1 classification	Ophthalmic instruments-Fundamental requirements and test methods-Part 9: Light hazard protection ISO 15004-2: 2024 5.4		2025-07-18
		27	Recommended maximum exposure (RME) values for Group 2 instruments	Ophthalmic instruments-Fundamental requirements and test methods-Part 10: Light hazard protection ISO 15004-2: 2024 5.5		2025-07-18
		28	Exposure limits and maximum recommended exposure values	Ophthalmic instruments-Fundamental requirements and test methods-Part 11: Light hazard protection ISO 15004-2: 2024 5.6		2025-07-18
		29	Group 2 instruments: determination of time and number of pulses to reach recommended maximum exposure	Ophthalmic instruments-Fundamental requirements and test methods-Part 12: Light hazard protection ISO 15004-2: 2024 6.4		2025-07-18
		30	Information supplied by the manufacturer	Ophthalmic instruments-Fundamental requirements and test methods-Part 13: Light hazard protection ISO 15004-2: 2024 7		2025-07-18
8	Ophthalmic measurement diagnostic equipment and apparatus	1	All items	Ophthalmic instruments-Retinoscopes YY/T 0718-2009		2024-07-10
		2	All items	Ophthalmic instruments-Direct ophthalmoscopes YY/T 1080-2009		2024-07-10
		3	All items	Ophthalmic instruments- Indirect ophthalmoscope YY/T 0633-2022		2024-07-10



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				Ophthalmic instruments- Indirect ophthalmoscope ISO 10943:2011		2024-07-10
		4	All items	Ophthalmic instruments—Corneal topographers YY/T 0787-2024		2025-07-18
		5	All items	ophthalmic instruments-slit-lamp microscopes YY/T 0065-2016		2024-07-10
		6	All items	ophthalmic instruments-Chart projectors YY/T 0764-2009		2024-07-10
				ophthalmic instruments-Chart projectors ISO 10938: 1998		2024-07-10
		7	Area measured	Ophthalmic instruments—Corneal topographers YY/T 0787-2024 4.1		2025-07-18
		8	All items	Ophthalmic instruments -Instrumentsto measure axial distance in the eye YY/T 1484-2016		2024-07-10
		9	Measurement sample density	Ophthalmic instruments—Corneal topographers YY/T 0787-2024 4.2		2025-07-18
		10	All items	Lens ultrasonic removal and vitrectomy devices for ophthalmic surgery YY/T 0766-2009		2024-07-10
		11	Measurement and report of performance	Ophthalmic instruments—Corneal topographers YY/T 0787-2024 4.3		2025-07-18
		12	All items	Medical electrical equipment-Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and virectomy devices for ophthalmic surgery YY 9706.258-2022		2024-07-10
		13	Colour presentation of results	Ophthalmic instruments—Corneal topographers YY/T 0787-2024 4.4		2025-07-18
9	Diagnostic X-ray generators	1	All items	Medical electrical equipment-Part 2-43:Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures GB 9706.243-2021		2024-07-10



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		2	All items	Medical electrical equipment—Part 2-43:Particular requirements for the safety of X-ray equipment for interventional procedures GB 9706.23-2005		2024-07-10
				Medical electrical equipment Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures IEC 60601-2-43:2000		2024-07-10
		3	All items	Medical electrical equipment-Part 2-45:Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices GB 9706.245-2020		2024-07-10
		4	All items	Medical electrical equipment--Part 2-45:Particular requirements for the safety of mammographic X-ray equipment and mammographic sterotactic devices GB 9706.24-2005		2024-07-10
				Medical electrical equipment--Part 2-45:Particular requirements for the safety of mammographic X-ray equipment and mammographic sterotactic devices IEC 60601-2-45:2001		2024-07-10
		5	All items	Medical electrical equipment-Part 2-54:Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy GB 9706.254-2020		2024-07-10
		6	All items	Particular specifications for mammographic X-ray equipment YY/T 0706-2017		2024-07-10
		7	All items	Particular specifications for medical X-ray angiography equipment YY/T 0740-2022		2024-07-10
		8	All items	Particular specifications for mini medical diagnostic X-ray equipment YY/T 0347-2009		2024-07-10
		9	All items	Particular specifications for gastrointestinal diagnostic X-ray equipment YY/T 0742-2021		2024-07-10
		10	All items	Particular specifications for mobile C-arm X-ray equipment YY/T 0744-2018		2024-07-10



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		11	All items	Particular specifications for mobile radiography X-ray equipment YY/T 0707-2020		2024-07-10
		12	All items	Particular specifications for X-ray equipment installed on the vehicle YY/T 0746-2021		2024-07-10
		13	All items	Particular specifications for X-ray unit for oral cavity YY/T 0010-2020		2024-07-10
		14	All items	Particular specification for oral cavity X-ray equipment for digital tomography YY/T 0795-2022		2024-07-10
		15	All items	General specifications for medical diagnostic X-ray equipment YY/T 0106-2021		2024-07-10
		16	All items	General specifications for digital medical X-ray radiography system YY/T 0741-2018		2024-07-10
		17	All items	Environmental requirements and test methods for medical X-ray equipment YY/T 0291-2016		2024-07-10
10	X-ray subsidiary and ancillary equipment	1	All items	Medical electrical equipment Part 2: particular requirements for the safety of associated equipment of X-ray equipment GB 9706.14-1997		2024-07-10
				Medical electrical equipment Part 2: particular requirements for the safety of associated equipment of X-ray equipment IEC 60601-2-32:1994		2024-07-10
		2	All items	Particular specifications for medical X-ray radiographic table YY/T 0737-2009		2024-07-10
		3	All items	Particular specifications for angiographic injector YY/T 0891-2013		2024-07-10
		4	All items	Particular specifications for X-ray gastrointestinal diagnostic table YY/T 0743-2009		2024-07-10
		5	All items	Particular specifications for cardiovascular table YY/T 0738-2009		2024-07-10
		6	All items	Particular specifications for wall stand of medical X-ray equipment YY/T 0739-2009		2024-07-10



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		7	All items	General specifications for X-ray image intensifier TV system for medical diagnosis YY/T 0608-2013		2024-07-10
		8	All items	General specification for medical diagnostic X-ray adjustable beam limiting devices YY/T 0129-2007		2024-07-10
		9	Size and type of plug and socket	specification for high voltage cable assemblies and sockets of Mammographic X-ray equipment YY/T 1541-2017		2024-07-10
		10	Image noise	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018		2024-07-10
		11	Compatibility	Basic requirements of communication and conformance for medical diagnostic X-ray image equipment Part1: general requirements YY/T 1708.1-2020		2024-07-10
11	X-ray equipment for computed tomography	1	All items	Medical electrical equipment-Part 2-44:Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography GB 9706.244-2020		2024-07-10
		2	All items	Medical electrical equipment-Part 2:Particular requirements for the safety of X-ray equipment for computed tomography GB 9706.18-2006		2024-07-10
				Medical electrical equipment-Part 2:Particular requirements for the safety of X-ray equipment for computed tomography IEC 60601-2-44:2002		2024-07-10
		3	All items	specifications of X-ray equipment for 64 slice helical computed tomography YY/T 1417-2016		2024-07-10
		4	All items	General specifications of X-ray equipment for computed tomography YY/T 0310-2015		2024-07-10
12	X-ray generation and limiting device	1	All items	Medical electrical equipment-Part 2:Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators GB 9706.3-2000		2024-07-10
				Medical electrical equipment-Part 2:Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators IEC 60601-2-7-1998		2024-07-10



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		2	All items	Medical electrical equipment Part 2:Particular requirements for the safety ofX-ray source assemblies and X-ray tube assembliesfor medical diagnosis GB 9706.228-2020		2024-07-10
13	Diagnostic X-ray generators	1	All items	Medical electrical equipment-Part 1-3:General requirements for basic safety and essential performance-Collateral Standard:Radiation protection in diagnostic X-ray equipment GB 9706.103-2020		2024-07-10
14	Medical radiological protection equipmen	1	All items	Medical electrical equipment Part1:General requirements for safety3. Collaterals tandard:requirements for radiation protectionin diagnostic X-ray equipment GB 9706.12-1997		2024-07-10
				Medical electrical equipment –Part 1-3: General requirements for basic safety and essential performance –Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:1994		2024-07-10
15	phototherapy equipment	1	All items	Medical electrical equipment-Part 2-50:Particular requirements for the basic safety and essential performance of infant phototherapy equipment GB 9706.250-2021		2024-07-10
				Medical electrical equipment-Part 2:Particular requirements for the safety of infant phototherapy equipment IEC 60601-2-50:2005		2024-07-10
		2	All items	Red light therapy equipment YY/T 1496-2016		2024-07-10
		3	All items	Ultraviolet therapy equipment YY/T 0901-2013		2024-07-10
		4	All items	Medical electrical equipment--Part 2-83:Particular requirements for the basicsafety and essential performance of home light therapy equipment GB 9706.283-2022		2024-07-10
		5	All items	infrared ray cauterization therapy equipment YY/T 0323-2024		2025-07-18
		6	All items	Medical electrical equipment--Part 2-75:Particular requirements for the basicsafety and essential performance of photodynamic		2024-07-10



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				therapy and photodynamicdiagnosis equipment GB 9706.275-2022		
		7	Output Optical Power	infrared ray cauterization therapy equipment YY/T 0323-2024 4.1		2025-07-18
		8	output control	infrared ray cauterization therapy equipment YY/T 0323-2024 4.2		2025-07-18
		9	Timing device	infrared ray cauterization therapy equipment YY/T 0323-2024 4.3		2025-07-18
		10	mark	infrared ray cauterization therapy equipment YY/T 0323-2024 4.4		2025-07-18
		11	accompanying document	infrared ray cauterization therapy equipment YY/T 0323-2024 4.5		2025-07-18
		12	Electrical safety	infrared ray cauterization therapy equipment YY/T 0323-2024 4.6		2025-07-18
		13	environmental test	infrared ray cauterization therapy equipment YY/T 0323-2024 4.7		2025-07-18
		14	electromagnetic compatibility	infrared ray cauterization therapy equipment YY/T 0323-2024 4.8		2025-07-18
		15	Requirements for LS equipment	infrared ray cauterization therapy equipment YY/T 0323-2024 4.9		2025-07-18
16	Laser products	1	All items	Medical electrical equipment--Part 2:Particular requirements for the safety of diagnostic and therapeutic laser equipment GB 9706.222-2022		2024-07-10
		2	All items	Medical electrical equipment--Part 2:Particular requirements for the safety of diagnostic and therapeutic laser equipment GB 9706.20-2000		2024-07-10
				Medical electrical equipment--Part 2:Particular requirements for the safety of diagnostic and therapeutic laser equipment IEC 60601-2-22: 1995		2024-07-10



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		3	All items	Test methods for laser beam widths,divergence angle and transverse mode GB/T 13739-2011		2024-07-10
		4	All items	Safety of laser products Part1: Equipment classification and requirements GB/T 7247.1-2024		2025-07-18
		5	All items	Test methods for laser radiation power and its instability GB/T 13863-2011		2024-07-10
		6	Principle of classification	Safety of laser products Part1: Equipment classification and requirements GB/T 7247.1-2024 4		2025-07-18
		7	All items	Evaluation and test for beam quality of high energy laser GB/T 32831-2016		2024-07-10
		8	Determination of attainable emission levels and product classification	Safety of laser products Part1: Equipment classification and requirements GB/T 7247.1-2024 5		2025-07-18
		9	All items	Laser therapeutic equipment—He-Ne laser equipment GB/T 12257-2023		2024-07-10
		10	Engineering protection requirements	Safety of laser products Part1: Equipment classification and requirements GB/T 7247.1-2024 6		2025-07-18
		11	Therapeutic laser	Laser therapeutic equipment—He-Ne laser equipment GB/T 12257-2023		2024-07-10
		12	Markers	Safety of laser products Part1: Equipment classification and requirements GB/T 7247.1-2024 7		2025-07-18
		13	Aiming system	Laser therapeutic equipment—He-Ne laser equipment GB/T 12257-2023		2024-07-10
		14	Other information requirements	Safety of laser products Part1: Equipment classification and requirements GB/T 7247.1-2024 8		2025-07-18
		15	Transfer system	Laser therapeutic equipment—He-Ne laser equipment GB/T 12257-2023		2024-07-10



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		16	Other parts of dedicated laser products	Safety of laser products Part1: Equipment classification and requirements GB/T 7247.1-2024 9		2025-07-18
		17	Timing apparatus	Laser therapeutic equipment—He-Ne laser equipment GB/T 12257-2023		2024-07-10
		18	Laser goggle	Laser therapeutic equipment—He-Ne laser equipment GB/T 12257-2023		2024-07-10
		19	Therapeutic laser	Laser therapeutic equipment—Carbon dioxide laser equipment GB/T 11748-2023		2024-07-10
		20	Aiming system	Laser therapeutic equipment—Carbon dioxide laser equipment GB/T 11748-2023		2024-07-10
		21	Transfer system	Laser therapeutic equipment—Carbon dioxide laser equipment GB/T 11748-2023		2024-07-10
		22	Cooling system	Laser therapeutic equipment—Carbon dioxide laser equipment GB/T 11748-2023		2024-07-10
		23	Laser goggle	Laser therapeutic equipment—Carbon dioxide laser equipment GB/T 11748-2023		2024-07-10
		24	All items	Laser confocal scanner YY/T 1154-2009		2024-07-10
		25	All items	Therapeutic Laser Equipment—Pulsed Nd:YAG LaserEquipment for Therapy YY 1300-2016		2024-07-10
		26	All items	Therapeutic Laser Equipment—RubyLaserEquipment for Therapy YY 0983-2016		2024-07-10
		27	All items	Therapeutic laser equipment—Ho:YAG laser equipment YY 0846-2011/XGI-2021		2024-07-10
		28	All items	Laser therapeutic equipment-Pulsed carbon dioxide laser treating instrument YY/T 0844-2011		2024-07-10
		29	All items	Laser therapeutic equipment—Diode laser equipment for photodynamic therapy YY 0845-2011		2024-07-10



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		№	Item/ Parameter			
		30	All items	Laser therapeutic equipment Q-Switched Nd:YAG laser equipment YY 1475-2016		2024-07-10
		31	All items	Treating laser equipment Excimer laser cornea ametropia cure system YY 0599-2015		2024-07-10
		32	All items	Q-Switched Nd:YAG Laser Ophthalmic System YY 0789-2010/XGI-2021		2024-07-10
		33	All items	General requirements for therapeutic laser fiber YY/T 0758-2021		2024-07-10
		34	All items	Laser treating equipment—Ophthalmic semiconductor laser photocoagulators YY 1289-2022		2025-07-18
		35	Peak Wavelength	Laser treating equipment—Ophthalmic semiconductor laser photocoagulators YY 1289-2022 5.1.1		2025-07-18
		36	All items	Therapeutic laser equipment-Laser diode irradiation therapeutic equipment for nasal cavity YY/T 1751-2020		2024-07-10
		37	Beam Quality	Laser treating equipment—Ophthalmic semiconductor laser photocoagulators YY 1289-2022 5.1.2		2025-07-18
		38	Laser output performance of therapeutic equipment	Therapeutic laser equipment-Laser diode irradiation therapeutic equipment for nasal cavity YY/T 1751-2020 4.2		2024-07-10
		39	Beam Convergence Angle or Divergence Angle	Laser treating equipment—Ophthalmic semiconductor laser photocoagulators YY 1289-2022 5.1.3		2025-07-18
		40	Light guide parts	Therapeutic laser equipment-Laser diode irradiation therapeutic equipment for nasal cavity YY/T 1751-2020 4.3		2024-07-10
		41	Spot Diameter at Treatment Position	Laser treating equipment—Ophthalmic semiconductor laser photocoagulators YY 1289-2022 5.1.4		2025-07-18
		42	Over voltage indication performance	Therapeutic laser equipment-Laser diode irradiation therapeutic equipment for nasal cavity YY/T 1751-2020 4.4		2024-07-10



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		43	Pulse Characteristics	Laser treating equipment—Ophthalmic semiconductor laser photocoagulators YY 1289-2022 5.1.5		2025-07-18
		44	appearance	Therapeutic laser equipment-Laser diode irradiation therapeutic equipment for nasal cavity YY/T 1751-2020 4.6		2024-07-10
		45	Terminal Output Power (or Energy) Range	Laser treating equipment—Ophthalmic semiconductor laser photocoagulators YY 1289-2022 5.1.6		2025-07-18
		46	All items	Therapeutic laser equipment-Er:YAG laser equipment for therapy YY 1301-2016		2024-07-10
		47	Terminal Output Power (or Energy) Instability	Laser treating equipment-Ophthalmic laser photocoagulators YY 1289-2022 5.1.7		2025-07-18
		48	laser wavelength	Therapeutic laser equipment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.1		2024-07-10
		49	Reproducibility of Terminal Output Power (or Energy)	Laser treating equipment-Ophthalmic laser photocoagulators YY 1289-2022 5.1.8		2025-07-18
		50	laser mode	Therapeutic laser equipment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.2		2024-07-10
		51	Multi-point Scanning Output Mode	Laser treating equipment-Ophthalmic laser photocoagulators YY 1289-2022 5.1.9		2025-07-18
		52	laser pulse duration	Therapeutic laser equipment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.3		2024-07-10
		53	Targeting Light Wavelength	Laser treating equipment-Ophthalmic laser photocoagulators YY 1289-2022 5.2.1		2025-07-18
		54	laser pulse train duration	Therapeutic laser equipment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.4		2024-07-10
		55	Targeting Light Power	Laser treating equipment-Ophthalmic laser photocoagulators YY 1289-2022 5.2.2		2025-07-18



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		56	maximum laser pulse power	Therapeutic laser equipment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.5		2024-07-10
		57	Transmission and/or Observation System Performance	Laser treating equipment-Ophthalmic laser photocoagulators YY 1289-2022 5.3		2025-07-18
		58	maximum average power	Therapeutic laser equipment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.6		2024-07-10
		59	maximum single pulse energy and duration	Therapeutic laser equipment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.7		2024-07-10
		60	All items	Laser therapeutic equipment —— Nd: YAG Laser Equipment YY 0307-2022		2025-07-18
		61	laser pulse energy	Therapeutic laser equipment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.8		2024-07-10
		62	Therapeutic beam	Laser therapeutic equipment —— Nd: YAG Laser Equipment YY 0307-2022 5.1		2025-07-18
		63	laser treatment area size	Therapeutic laser equipment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.9		2024-07-10
		64	Aiming beam	Laser therapeutic equipment —— Nd: YAG Laser Equipment YY 0307-2022 5.2		2025-07-18
		65	laser treatment speckle energypower density	Therapeutic laser equipment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.10		2024-07-10
		66	Fiber transfer system	Laser therapeutic equipment —— Nd: YAG Laser Equipment YY 0307-2022 5.3		2025-07-18
		67	laser divergence angle	Therapeutic laser equipment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.11		2024-07-10
		68	Cooling system	Laser therapeutic equipment —— Nd: YAG Laser Equipment YY 0307-2022 5.4		2025-07-18



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		69	laser energy instability	Therapeutic laser equipment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.12		2024-07-10
		70	Shield goggle	Laser therapeutic equipment —— Nd: YAG Laser Equipment YY 0307-2022 5.5		2025-07-18
		71	laser energy repeatability	Therapeutic laser equipment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.13		2024-07-10
		72	Foot pedal switch	Laser therapeutic equipment —— Nd: YAG Laser Equipment YY 0307-2022 5.6		2025-07-18
		73	aiming beam wavelength	Therapeutic laser equipment-Er:YAG laser equipment for therapy YY 1301-2016 5.3.1		2024-07-10
		74	Safety	Laser therapeutic equipment —— Nd: YAG Laser Equipment YY 0307-2022 5.7		2025-07-18
		75	aiming beam power	Therapeutic laser equipment-Er:YAG laser equipment for therapy YY 1301-2016 5.3.2		2024-07-10
		76	Environmental test	Laser therapeutic equipment —— Nd: YAG Laser Equipment YY 0307-2022 5.8		2025-07-18
		77	laser goggle	Therapeutic laser equipment-Er:YAG laser equipment for therapy YY 1301-2016 5.6		2024-07-10
		78	All items	Laser treating equipment—Ophthalmic semiconductor laser photocoagulators YY/T 0486-2024		2025-07-18
		79	The use of symbols	Laser treating equipment—Ophthalmic semiconductor laser photocoagulators YY/T 0486-2024 4.1		2025-07-18
		80	Marking	Laser treating equipment—Ophthalmic semiconductor laser photocoagulators YY/T 0486-2024 4.2		2025-07-18
		81	Packaging Label	Laser treating equipment—Ophthalmic semiconductor laser photocoagulators YY/T 0486-2024 4.3		2025-07-18
		82	Shelf Packaging or Multi-unit Packaging Label	Laser treating equipment—Ophthalmic semiconductor laser photocoagulators YY/T 0486-2024 4.4		2025-07-18



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		83	Manufacturer-provided Information	Laser treating equipment—Ophthalmic semiconductor laser photocoagulators YY/T 0486-2024 5		2025-07-18
17	Optical imaging diagnostic equipment	1	All items	Operation microscopes-Part 1:Requirements and test methods GB 11239.1-2005		2024-07-10
		2	All items	Stereomicroscopes-Part 1:Stereomicroscopes for general use GB/T 19864.1-2013		2024-07-10
				Stereomicroscopes-Part 2:High performance stereomicroscope GB/T 19864.2-2013		2024-07-10
				Testing of stereomicroscope GB/T 19863-2005		2024-07-10
		3	All items	Biological microscope GB/T 2985-2008		2024-07-10
		4	All items	Micro-circulation microscopes YY/T 0067-2007		2024-07-10
		5	All items	Microscope-Objectives GB/T 2609-2015		2024-07-10
		6	All items	Microscope-Oculars(eyepieces) GB/T 9246-2008		2024-07-10
		7	All items	Microscopes-Condensers GB/T 9247-2008		2024-07-10
		8	All items	Microscopes-Marking of objectives and eyepieces GB/T 22056-2018		2024-07-10
		9	All items	Microscopes-Imaging distances related to mechanical reference planes—Part 1:Tube length 160mm GB/T 22055-2022		2024-07-10
		10	All items	Microscopes-Dimensions and positions of holes for stage clips and attachable mechanical stage on microscope stage JB/T 8230.7-1999		2024-07-10
		11	All items	Microscopes-connecting dimensions of dismountable condenser and colour filter JB/T 8230.8-1999		2024-07-10



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18	Lung ventilator	12	All items	Medical luminaires—Medical head-mounted luminaires YY/T 0932-2014		2024-07-10
		13	All items	Infrared examining equipment for mammary gland YY/T 0324-2019		2024-07-10
		14	All items	Medical electrical equipment—Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use IEC60601-2-57: 2011		2024-07-10
		1	All items	Medical electrical equipment—Part 2-90: Particular requirements for the basic safety and essential performance of respiratory high flow therapy equipment GB 9706.290-2022		2024-07-10
		2	All items	Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors GB 9706.255-2022		2024-07-10
		3	All items	Medical electrical equipment — Part 2-79: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment YY 9706.279-2023		2024-07-10
		4	All items	Medical electrical equipment — Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency YY 9706.280-2023		2024-07-10
		5	All items	Medical electrical equipment—Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services equipment YY 9706.284-2023		2024-07-10
		6	All items	Medical electrical equipment—Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients YY 9706.272-2021		2024-07-10



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19	ventilators	1	All items	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011		2024-07-10
20	ventilators	1	Additional requirements for ESSENTIAL PERFORMANCE	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.4.3.101		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.4.3.101		2024-07-10
		2	ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.4.6		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.4.6		2024-07-10
		3	Overpressure requirement	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.4.11.101		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.4.11.101		2024-07-10
		4	Additional requirements for general requirements for testing of ME EQUIPMENT	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.5.101		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.5.101		2024-07-10
		5	Consult ACCOMPANYING DOCUMENTS	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.7.2.3		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.7.2.3		2024-07-10
		6	Additional requirements for	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.7.2.101		2024-07-10

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			marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts	Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.7.2.101		2024-07-10
		7	Additional requirements for ACCESSORIES	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.7.2.4.101		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.7.2.4.101		2024-07-10
		8	Additional requirements for physiological effects	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.7.2.13.101		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.7.2.13.101		2024-07-10
		9	Additional requirements for protective packaging	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.7.2.17.101		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.7.2.17.101		2024-07-10
		10	Unit of measure	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.7.4.3		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.7.4.3		2024-07-10
		11	Additional general requirements	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.7.9.1		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.7.9.1		2024-07-10
		12	Additional requirements for	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.9.6.2.1.101		2024-07-10

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			warnings and safety notices	Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.9.6.2.1.101		2024-07-10
		13	Additional requirements for suction procedures	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.9.101		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.9.101		2024-07-10
		14	Leakage	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.11.6.4		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.11.6.4		2024-07-10
		15	Additional requirements for ingress of water or particulate matter into ME EQUIPMENT or ME SYSTEM	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.11.6.5.101		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.11.6.5.101		2024-07-10
		16	Cleaning and disinfection of ME EQUIPMENT or ME SYSTEM	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.11.6.6		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.11.6.6		2024-07-10
		17	Additional requirements for interruption of the powersupplySUPPLY MAINS to ME EQUIPMENT	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.11.8.101		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.11.8.101		2024-07-10



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		18	Volume-controlled breath type	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.12.1.101		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.12.1.101		2024-07-10
		19	Pressure-controlled breath type	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.12.1.102		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.12.1.102		2024-07-10
		20	DELIVERED VOLUME MONITORING	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.12.1.103		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.12.1.103		2024-07-10
		21	Response of the VENTILATOR to an increase in O2 concentration	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.12.1.104		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.12.1.104		2024-07-10
		22	Protection against hazardous output	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.12.4		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.12.4		2024-07-10
		23	Protection against accidental adjustments	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.12.101		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.12.101		2024-07-10



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		24	HAZARDOUS SITUATIONS and fault conditions	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.13		2024-07-10
		25	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.13		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.14		2024-07-10
		26	Construction of ME EQUIPMENT	Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.14		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.15		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.15		2024-07-10
		27	ME SYSTEMS	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.16		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.16		2024-07-10
		28	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.17		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.17		2024-07-10
		29	Gas connections	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.101		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.101		2024-07-10
		30	Requirements for the VBS and ACCESSORIES	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.102		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.102		2024-07-10



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		31	Spontaneous breathing during loss of power supply	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.103		2024-07-10
		32	Training	Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.103		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.104		2024-07-10
		33	Indication of duration of operation	Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.104		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.105		2024-07-10
		34	SIGNAL INPUT/OUTPUT PART	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.105		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.105		2024-07-10
		35	Display loops	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.106		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.106		2024-07-10
		36	Timed ventilatory pause	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.107		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.107		2024-07-10
		37	Medical electrical equipment – Part 1-6: General requirements for basic safety and	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.108		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.108		2024-07-10
		37	Medical electrical equipment – Part 1-6: General requirements for basic safety and	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 206		2024-07-10
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 206		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			essential performance – Collateral Standard: Usability			
		38	Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 208 Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 208		2024-07-10
		39	All items	Medical electrical equipment-Part 2:Particular requirements for the safety of lung ventilator GB9706.28-2006 Medical electrical equipment-Part 3:Particular requirements for the safety of lung ventilator IEC 60601-2-12:2001		2024-07-10
		40	All items	Lung ventilators for medical use-Particular requirements for basic safety and essential performance-Part 1:Home-care ventilatory support devices YY 0600.1-2007		2024-07-10
		41	All items	Lung ventilators for medical use-Particular requirements for basic safety and essential performance-Part 2:Home-care ventilatory for ventilator-dependent patients YY 0600.2-2007		2024-07-10



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		42	All items	Lung ventilators for medical use-Particular requirements for basic safety and essential performance-Part 3:Emergency and transports ventilators YY 0600.3-2007		2024-07-10
		43	All items	Medical suture needle YY 0042-2018		2024-07-10
		44	All items	Breathing tubes intended for use with anaesthetic apparatus and ventilators YY/T 0461-2003		2024-07-10
21	anaesthetic system	1	All items	Medical electrical equipment-Part 2-13:Particular requirements for the basic safety and essential performance of an anaesthetic workstation GB 9706.213-2021		2024-07-10
		2	All items	Medical electrical equipment-Part2:Particular requirements for the safety and essential performance of anaesthetic systems GB 9706.29-2006		2024-07-10
				Medical electrical equipment-Part3:Particular requirements for the safety and essential performance of anaesthetic systems IEC 60601-2-13:2003		2024-07-10
		3	All items	Inhalational anaesthesia system-Part 1:Anaesthetic breathing system for adults YY 0635.1-2013		2024-07-10
		4	All items	Inhalational anaesthesia system-Part 2:Anaesthetic gas scavenging systems transfer and receiving systems YY 0635.2-2009		2024-07-10
		5	All items	Inhalational anaesthesia system-Part 3:Anaesthetic vapour delivery devices YY 0635.3-2009		2024-07-10
		6	All items	Inhalational anaesthesia system-Part 4:Requirements for anaesthetic ventilators YY 0635.4-2009		2024-07-10
22	ventilators、anaesthetic、Emergency equipment 、	1	All items	Medical electrical equipment-Part 2-70:Particular requirements for the basic safety and essential performance of sleep apnoea breathing therapy equipment YY 9706.270-2021		2024-07-10
		2	All items	Sleep apnoea breathing therapy-Part 1: Sleep apnoea breathing therapy devices YY 0671.1-2009		2024-07-10



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	auxiliary device	3	All items	Sleep apnoea breathing therapy-Part 1: Sleep apnoea breathing therapy devices YY/T 0671-2021		2024-07-10
		4	All items	Medical suction equipment-Part1: Electrically powered suction equipment-Safety requirements YY/T 0636.1-2021		2024-07-10
		5	All items	Medical suction equipment-Part2: Manually powered suction equipment YY/T 0636.2-2021		2024-07-10
		6	All items	Medical suction equipment—Part3:Suction equipment powered a vacuum or pressure source YY/T 0636.3-2021		2024-07-10
		7	All items	Medical electrical equipment-Part 2-74:Particular requirements for basic safety and essential performance of respiratory humidifying equipment YY 9706.274-2022		2024-07-10
		8	All items	Anaesthetic reservoir bags YY/T 0978-2016		2024-07-10
		9	All items	Gas mixers for medical use-Standalone gas mixers YY/T0893-2023		2024-07-10
		10	basic performance requirements	Gas mixers for medical use-Standalone gas mixers YY/T0893-2023 4		2024-07-10
		11	general requirement	Anaesthetic and respiratory equipment- Medical endoscopes-Video endoscopes YY/T0893-2023 5		2024-07-10
		12	materials	Anaesthetic and respiratory equipment- Medical endoscopes-Video endoscopes YY/T0893-2023 6		2024-07-10
		13	normal operative condition	Anaesthetic and respiratory equipment- Medical endoscopes-Video endoscopes YY/T0893-2023 7		2024-07-10
		14	air intake pressure requirements	Anaesthetic and respiratory equipment- Medical endoscopes-Video endoscopes YY/T0893-2023 8		2024-07-10
		15	back-draft	Anaesthetic and respiratory equipment- Medical endoscopes-Video endoscopes YY/T0893-2023 9		2024-07-10
		16	leak	Anaesthetic and respiratory equipment- Medical endoscopes-Video endoscopes YY/T0893-2023 10		2024-07-10



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		17	alarm system	Anaesthetic and respiratory equipment- Medical endoscopes- Video endoscopes YY/T0893-2023 11		2024-07-10
		18	oxygen concentration indicator accuracy	Anaesthetic and respiratory equipment- Medical endoscopes- Video endoscopes YY/T0893-2023 12		2024-07-10
		19	air failure	Anaesthetic and respiratory equipment- Spirometers intended for the measurement of time forced expired volumes in humans YY/T0893-2023 13		2024-07-10
		20	gas connection	Anaesthetic and respiratory equipment- Spirometers intended for the measurement of time forced expired volumes in humans YY/T0893-2023 14		2024-07-10
		21	air intake filter	Anaesthetic and respiratory equipment- Spirometers intended for the measurement of time forced expired volumes in humans YY/T0893-2023 15		2024-07-10
		22	flow controller	Anaesthetic and respiratory equipment- Spirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 16		2024-07-10
		23	Low pressure hose assembly	Anaesthetic and respiratory equipment- Spirometers intended for the measurement of time forced expired volumes in humans YY/T0893-2023 17		2024-07-10
		24	electric safety	Anaesthetic and respiratory equipment- Spirometers intended for the measurement of time forced expired volumes in humans YY/T0893-2023 18		2024-07-10
		25	label	Anaesthetic and respiratory equipment- Spirometers intended for the measurement of time forced expired volumes in humans YY/T0893-2023 19		2024-07-10
		26	attached documents	Anaesthetic and respiratory equipment- Spirometers intended for the measurement of time forced expired volumes in humans YY/T0893-2023 20		2024-07-10



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		27	All items	Medical electrical equipment-Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators GB 9706.204-2022		2024-07-10
		28	All items	Suction catheters for use in the respiratory tract YY/T 0339—2024		2025-07-18
		29	All items	Semi-Automatic External Defibrillator GB9706.8-2009		2024-07-10
				Semi-Automatic External Defibrillator IEC 60601-2-4:2002		2024-07-10
				Semi-Automatic External Defibrillator IEC 60601-2-4:2003		2024-07-10
		30	material	Suction catheters for use in the respiratory tract YY/T 0339—2024 5		2025-07-18
		31	Partial items	Oxygen concentrators for medical use-Safety requirements YY 9706.269-2021	except 50.4,50.5	2024-07-10
		32	Design requirements	Suction catheters for use in the respiratory tract YY/T 0339—2024 6		2025-07-18
		33	All items	Respiratory tract humidifiers for medical use-Particular requirements for respiratory humidification systems YY0786-2010		2024-07-10
		34	the requirements for Suction catheters for use in the respiratory tract by sterile	Suction catheters for use in the respiratory tract YY/T 0339—2024 7		2025-07-18
		35	All items	Buoy type oxygen inhalator YY 1107-2003		2024-07-10
		36	Package	Suction catheters for use in the respiratory tract YY/T 0339—2024 8		2025-07-18
		37	product information	Suction catheters for use in the respiratory tract YY/T 0339—2024 9		2025-07-18

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23	Anaesthetic equipment	1	All items	Breathing tubes intended for use with anaesthetic apparatus and ventilators YY/T 1040.1-2015		2024-07-10
		2	All items	Anaesthetic and respiratory equipment—Conical connectors—Part 2:Screw-threaded weight-bearing connectors YY/T 1040.2-2008		2024-07-10
		3	All items	Anaesthetic and respiratory equipment-Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans YY/T 1438-2016		2024-07-10
		4	All items	Anaesthetic and respiratory equipment —— User-applied labels for syringes containing drugs used during anaesthesia —— Colours, design and performance YY/T 0975-2016		2024-07-10
		5	All items	Anaesthetic vaporizers—Agent-specific filling systems YY/T 0755-2009		2024-07-10
		6	All items	Breathing system filters for anaesthetic and respiratory use—Part2:Non-filtration aspects YY/T 0753.2-2009		2024-07-10
		7	All items	Anaesthetic and respiratory equipment-Supralaryngeal airways and connectors YY/T 0985-2016		2024-07-10
24	Medical oxygen production equipment	1	All items	Oxygen concentrator supply systems for use with medical gas pipeline systems YY/T 1468-2016		2024-07-10
		2	All items	Oxygen supplies for medicine and aircraft breathing GB/T 8982-2009		2024-07-10
25	Surgical Instruments	1	All items	Surgical Instruments—Gill shaft,Bolt and Rivet YY/T 0173-2010		2024-07-10
		2	All items	Rectosigmoid biopsy forceps YY/T 0178-2010		2024-07-10
		3	All items	Naso-pharyngeal biopsy forceps YY/T 0246-2010		2024-07-10
		4	All items	Ophthalmic scissors YY/T 0176.9-2011		2024-07-10
		5	All items	General specification for ophthalmic knives YY/T 0072-2010		2024-07-10



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		6	All items	Ophthalmic Forceps YY/T 0819-2010		2024-07-10
		7	All items	Electric surgical equipment for osseous tissue YY/T 0752-2016		2024-07-10
		8	All items	Battery power supply surgical equipment for osseous tissue YY/T 0904-2013		2024-07-10
		9	All items	Abdominal suction tube YY/T 0191-2011		2024-07-10
		10	All items	Plasma surgical equipment YY/T 1409—2016		2024-07-10
		11	All items	Cardiopulmonary bypass systems—Centrifugal pump YY 1412-2016		2024-07-10
		12	All items	Metal plating classification technology condition of parts YY/T 0076-1992		2024-07-10
		13	All items	Cutting tools for electric osseous tissue surgical equipment--Part 4: Milling cutter YY/T 1629.4-2020		2024-07-10
		14	All items	Cutting tools for electric osseous tissue surgical equipment--Part 5: Saw blade YY/T 1629.5-2020		2024-07-10
		15	All items	Cutting tools for electric osseous tissue surgical equipment--Part 6: Rasp YY/T 1629.6-2021		2024-07-10
		16	All items	Disposable abdominal trocars YY/T 1710-2020		2024-07-10
		17	All items	Cutting tools for electric osseous tissue surgical equipment-Part 2: Cranial perforator YY/T 1629.2-2018		2024-07-10
		18	Structure and size	Cutting tools for electric osseous tissue surgical equipment-Part 2: Cranial perforator YY/T 1629.2-2018		2024-07-10
		19	Appearance	Cutting tools for electric osseous tissue surgical equipment-Part 2: Cranial perforator YY/T 1629.2-2018		2024-07-10
		20	Requirement	Cutting tools for electric osseous tissue surgical equipment-Part 2: Cranial perforator YY/T 1629.2-2018		2024-07-10



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		№	Item/ Parameter			
		21	Surface roughness	Cutting tools for electric osseous tissue surgical equipment-Part 2:Cranial perforator YY/T 1629.2-2018		2024-07-10
		22	Hardness	Cutting tools for electric osseous tissue surgical equipment-Part 2:Cranial perforator YY/T 1629.2-2018		2024-07-10
		23	Interface strength	Cutting tools for electric osseous tissue surgical equipment-Part 2:Cranial perforator YY/T 1629.2-2018		2024-07-10
		24	Adaptability	Cutting tools for electric osseous tissue surgical equipment-Part 2:Cranial perforator YY/T 1629.2-2018		2024-07-10
		25	Corrosion resistance	Cutting tools for electric osseous tissue surgical equipment-Part 2:Cranial perforator YY/T 1629.2-2018		2024-07-10
		26	Cleaning, disinfection or sterilization	Cutting tools for electric osseous tissue surgical equipment-Part 2:Cranial perforator YY/T 1629.2-2018		2024-07-10
		27	Sterile products should be sterile	Cutting tools for electric osseous tissue surgical equipment-Part 2:Cranial perforator YY/T 1629.2-2018		2024-07-10
		28	All items	Cutting tools for electric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2024-07-10
		29	Structure and size	Cutting tools for electric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2024-07-10
		30	Edge size	Cutting tools for electric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2024-07-10
		31	Surface roughness	Cutting tools for electric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2024-07-10
		32	Rod straightness	Cutting tools for electric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2024-07-10
		33	Radial circular runout of edge	Cutting tools for electric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2024-07-10
		34	Hardness	Cutting tools for electric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2024-07-10



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		35	Connecting Strength	Cutting tools for electric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2024-07-10
		36	Edge strength	Cutting tools for electric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2024-07-10
		37	Permanent deformation	Cutting tools for electric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2024-07-10
		38	Corrosion resistance	Cutting tools for electric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2024-07-10
		39	Tolerance to disinfection or sterilization	Cutting tools for electric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2024-07-10
		40	Aseptic requirements	Cutting tools for electric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2024-07-10
		41	Ethylene oxide residue	Cutting tools for electric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2024-07-10
		42	Adaptability	Cutting tools for electric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2024-07-10
		43	All items	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2024-07-10
		44	Appearance and structure	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2024-07-10
		45	Display and Control	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2024-07-10
		46	Tip main amplitude	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2024-07-10
		47	Tip transverse amplitude	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2024-07-10
		48	Excitation frequency	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2024-07-10



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		49	Tip vibration frequency	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2024-07-10
		50	Derived Output Sound Power	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2024-07-10
		51	Duty cycle	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2024-07-10
		52	Static (no-load) power	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2024-07-10
		53	Maximum electric power	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2024-07-10
		54	Power reserve index	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2024-07-10
		55	Main Sound Output Area	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2024-07-10
		56	Acoustic output area of secondary transverse vibration	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2024-07-10
		57	Liquid flow rate	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2024-07-10
		58	Noise	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2024-07-10
		59	Characteristics to be published in the specification	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2024-07-10
26	Electrical acoustic measurement and analysis equipment	1	All items	Audiometers Part2:Equipment for speech audiometry GB/T 7341.2-1999		2024-07-10
		2	All items	Audiometers Part4:Equipment for extended high-frequency audiometry GB/T 7341.4-1999		2024-07-10
		3	All items	Electroacoustics-Audiological equipment-Part 1:Pure-tone audiometers GB/T 7341.1-2010		2024-07-10



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		4	All items	Instruments for the measurement of aural acoustic impedance/admittance GB/T 7341.5-2018		2024-07-10
27	Hearing Aids	1	All items	Measurement of performance characteristics of hearing aids for quality inspection for delivery purposes SJ 10862-1996 SJ 10862-1996		2024-07-10
		2	All items	Electroacoustics-General specification for hearing aids GB/T 14199-2010		2024-07-10
		3	All items	Electroacoustics-Hearing aids-Part1:Hearing aids with induction pick-up coil input GB/T 25102.1-2010		2024-07-10
				Electroacoustics-Hearing aids-Part1:Hearing aids with induction pick-up coil input IEC 60118-1:1999		2024-07-10
		4	All items	Electroacoustics-hearing aids-Part 2:Hearing aids with automatic gain control circuits GB/T 25102.2-2010		2024-07-10
				Electroacoustics-hearing aids-Part 2:Hearing aids with automatic gain control circuits IEC60118-2:1983		2024-07-10
		5	All items	Electroacoustics-Hearing aids-Part 0:Measurement of electroacoustical characteristics GB/T 25102.100-2010		2024-07-10
				Electroacoustics-Hearing aids-Part 0:Measurement of electroacoustical characteristics IEC 60118-0:1983		2024-07-10
		6	All items	Electroacoustics - Hearing aids - Part13:Electromagnetic compatibility(EMC) GB/T 25102.13 -2010		2024-07-10
				Electroacoustics - Hearing aids - Part13:Electromagnetic compatibility(EMC) IEC60118-13:2016		2024-07-10
28	Medical endoscope	1	All items	Medical electrical equipment-Part 2-18:Particular requirements for the basic safety and essential performance of endoscopic equipment GB 9706.218-2021		2024-07-10
		2	All items	Medical electrical equipment- Part2 :Particular requirements for the safety of endoscopic equipment GB 9706.19-2000		2024-07-10
				Medical electrical equipment- Part3 :Particular requirements for the safety of endoscopic equipment IEC 60601-2-18: 1996		2024-07-10



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		3	All items	Medical endoscopes Fiber optical cable for lighting YY/T 0763-2009/XGI-2023		2024-07-10
		4	All items	Endoscopic washing station YY/T 0992-2023		2024-07-10
		5	Partial items	Medical Endoscopes—Capsule Endoscopes YY/T 1298-2016/XGI-2019	except 4.5.1、4.5.2	2024-07-10
		6	All items	Medical Endoscopes-Rigid Endoscope-Part 1:Optical properties and test methods YY 0068.1-2008		2024-07-10
		7	All items	Medical endoscopes-Rigid endoscope-Part 2:Mechanical properties and test methods YY/T 0068.2-2008		2024-07-10
		8	All items	Medical endoscopes-Rigid endoscope-Part 3:Marking and instruction manual YY/T 0068.3-2008		2024-07-10
		9	All items	Medical Endoscopes —Rigid endoscope —part 4:Fundamental requirement YY 0068.4-2009 YY 0068.4-2023		2024-07-10
		10	All items	Medical endoscopes—Rigid resectoscope YY/T 0619—2017		2024-07-10
		11	All items	General specification of medical rigid trachea endoscope YY/T 0069-2009		2024-07-10
		12	All items	Esophagoscope YY/T 0070-2018		2024-07-10
		13	All items	Sigmoidos-copy and rectoscope set YY/T 0071-2018		2024-07-10
		14	All items	Large intestine fiber endoscope YY/T 0283-2007		2024-07-10
		15	All items	Anoscope YY/T 0190-2008		2024-07-10
		16	All items	Upper gastro intestinal fiberscope YY/T 1028-2023		2024-09-13
		17	All items	General specification for anaesthetic laryngoscope YY 0499-2004		2024-07-10



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		18	All items	Nasal specula YY/T 0189-2008		2024-07-10
		19	All items	Robotically-assisted laparoscopic surgical system YY/T 1941-2024		2025-07-18
		20	Master tool manipulator workspace	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.1.1		2025-07-18
		21	Master-slave clutch control	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.1.2		2025-07-18
		22	End effector effective workspace	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.2.1		2025-07-18
		23	Remote center of motion accuracy	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.2.2		2025-07-18
		24	Effective operating force of instrument arm	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.2.3		2025-07-18
		25	Jaw Opening/Closing Force	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.2.4		2025-07-18
		26	Motion control of endoscope	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.3.1		2025-07-18
		27	Remote center of motion adjustment function	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.3.2		2025-07-18
		28	Master-slave operation distance accuracy	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.3.3.1		2025-07-18
		29	Master-slave operation distance repeatability	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.3.3.2		2025-07-18



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		№	Item/ Parameter			
		30	Master-slave operation posture accuracy	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.3.4.1		2025-07-18
		31	Master-slave operation posture repeatability	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.3.4.2		2025-07-18
		32	Master-slave control delay	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.3.5		2025-07-18
		33	System display delay	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.3.6		2025-07-18
		34	Master-slave distance scaling ratio	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.3.7		2025-07-18
		35	Braking distance	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.4.1		2025-07-18
		36	Slip distance	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.4.2		2025-07-18
		37	Speed limitation	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.4.3		2025-07-18
		38	Collision protection	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.4.4		2025-07-18
		39	Safety interlock	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.4.5		2025-07-18
		40	Patient release	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.4.6		2025-07-18
		41	Mechanical interface requirements	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.5.1		2025-07-18
		42	Communication and identification of	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.5.2		2025-07-18



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			robotic surgical instruments with RALS			
		43	Degrees of freedom of robotic surgical instruments	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.5.3		2025-07-18
		44	Compatibility between robotic surgical instruments and trocar sleeves	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.5.4		2025-07-18
		45	Sealing performance of robotic surgical instruments	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.5.5		2025-07-18
		46	Requirements for reusable robotic surgical instruments	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.5.6		2025-07-18
		47	Sterility	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.5.7.1		2025-07-18
		48	Ethylene oxide residue	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.5.7.2		2025-07-18
		49	Appearance	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.5.8		2025-07-18
		50	Dimensions	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.5.9		2025-07-18
		51	Hardness	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.5.10		2025-07-18
		52	Corrosion resistance	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.5.11		2025-07-18
		53	Surface roughness	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.5.12		2025-07-18



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		54	Self-test function	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.6.1		2025-07-18
		55	Prompt information	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.6.2		2025-07-18
29	Medical endoscope	1	All items	Medical endoscopes-Video endoscopes YY/T 1587-2018		2024-07-10
		2	Contact materials with patient	Medical endoscopes-Video endoscopes YY/T 1587-2018		2024-07-10
		3	Field angle	Medical endoscopes-Video endoscopes YY/T 1587-2018		2024-07-10
		4	Relative self-effect of illumination light luminosity	Medical endoscopes-Video endoscopes YY/T 1587-2018		2024-07-10
		5	Brightness response characteristics	Medical endoscopes-Video endoscopes YY/T 1587-2018		2024-07-10
		6	SNR	Medical endoscopes-Video endoscopes YY/T 1587-2018		2024-07-10
		7	SFR	Medical endoscopes-Video endoscopes YY/T 1587-2018		2024-07-10
		8	Static image tolerance	Medical endoscopes-Video endoscopes YY/T 1587-2018		2024-07-10
		9	mechanical character	Medical endoscopes-Video endoscopes YY/T 1587-2018		2024-07-10
30	Ultrasound endoscope	1	All items	ultrasound endoscope YY/T 1676-2020		2024-07-10
		2	acoustic working frequency	ultrasound endoscope YY/T 1676-2020 4.1		2024-07-10
		3	depth of penetration	ultrasound endoscope YY/T 1676-2020 4.2		2024-07-10
		4	lateral resolution	ultrasound endoscope YY/T 1676-2020 4.3		2024-07-10



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		5	axial resolution	ultrasound endoscope YY/T 1676-2020 4.4		2024-07-10
		6	dead zone	ultrasound endoscope YY/T 1676-2020 4.5		2024-07-10
		7	slice thickness	ultrasound endoscope YY/T 1676-2020 4.6		2024-07-10
		8	Horizontal geometric position accuracy	ultrasound endoscope YY/T 1676-2020 4.7		2024-07-10
		9	Longitudinal geometric position accuracy	ultrasound endoscope YY/T 1676-2020 4.8		2024-07-10
		10	Measurement deviation of perimeter and area	ultrasound endoscope YY/T 1676-2020 4.9		2024-07-10
		11	M-mode performance index	ultrasound endoscope YY/T 1676-2020 4.10		2024-07-10
		12	three-dimensional ultrasonography	ultrasound endoscope YY/T 1676-2020 4.11		2024-07-10
		13	Geometric position accuracy of retraction direction	ultrasound endoscope YY/T 1676-2020 4.12		2024-07-10
		14	Image geometric distortion	ultrasound endoscope YY/T 1676-2020 4.13		2024-07-10
		15	ultrasonic colour flow imaging performance	ultrasound endoscope YY/T 1676-2020 4.14		2024-07-10
		16	angle of ultrasound visual field	ultrasound endoscope YY/T 1676-2020 4.15		2024-07-10
31	Roller irrigation and	1	All items	Medical endoscopes--Endoscope functional supply units--Roller irrigation and suction equipment YY/T 0863-2011		2024-07-10



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	suction equipment	2	All items	Medical endoscopes--Endoscope functional supply units--Irrigation pump YY/T 0864-2011		2024-07-10
		3	All items	Medical Endoscopes-Endoscope supply units-insufflators YY 0843-2011		2024-07-10
		4	All items	Medical Endoscopes—Endoscope supply units—cold light sources YY/T 1081-2011		2024-07-10
		5	All items	Medical endoscopes- Endoscope supply units-Video camera system YY/T 1603-2018		2024-07-10
		6	MTF	Medical endoscopes- Endoscope supply units-Video camera system YY/T 1603-2018		2024-07-10
		7	focal length	Medical endoscopes- Endoscope supply units-Video camera system YY/T 1603-2018		2024-07-10
		8	Brightness response characteristics	Medical endoscopes- Endoscope supply units-Video camera system YY/T 1603-2018		2024-07-10
		9	SNR	Medical endoscopes- Endoscope supply units-Video camera system YY/T 1603-2018		2024-07-10
		10	SFR	Medical endoscopes- Endoscope supply units-Video camera system YY/T 1603-2018		2024-07-10
		11	Static image tolerance	Medical endoscopes- Endoscope supply units-Video camera system YY/T 1603-2018		2024-07-10
		12	All items	Endoscopic surgical instruments-Reusable abdominal suction and irrigation tubes YY/T 1846-2022		2024-07-10
		13	All items	Medical endoscopes--Endoscope surgical equipment--Shaver YY/T 0955-2014		2024-07-10
32	Medical Endoscope endoscope accessories	1	All items	Medical Endoscope endoscope accessories cytology brush YY/T 0930-2014		2024-07-10
		2	All items	Medical Endoscopes — Endotherapy Device — Palmate Retractor YY/T 1446—2016		2024-07-10
		3	All items	Medical endoscopes-Endoscope device-Curette YY/T 1297—2015		2024-07-10



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		4	All items	Medical endoscopes -Endotherapy device -Needle forceps YY/T 0943-2014		2024-07-10
		5	All items	Medical endoscopes — Endotherapy device —Grasping forceps YY/T 0940-2014		2024-07-10
		6	All items	Medical endoscopes — Endotherapy device —Separating forceps YY/T 0944-2014		2024-07-10
		7	All items	Medical endoscopes — Endotherapy device —Punch forceps YY/T 0941-2014		2024-07-10
		8	All items	Medical Endoscope endoscope device loop ligature YY/T 0931-2014/XGI-2020		2024-07-10
		9	All items	Medical Endoscopes — endotherapy device — stone retrieval forceps YY/T 0847-2011		2024-07-10
		10	All items	Madical endoscopes--endoscope accessories--bridges YY/T 0922-2014		2024-07-10
		11	All items	Medical endoscopes--Endoscope accessories--Sheaths YY/T 0842-2011		2024-07-10
		12	All items	Hose biopsy sampling forceps used with endoscope-General specifications YY/T 1076-2004		2024-07-10
		13	All items	Endoscopic instruments-Part1:Trocars for laparoscope use YY/T 1783-2021		2024-07-10
		14	All items	Endoscopy instruments--Part 2: Laparoscopy scissors YY/T 0672.2-2011		2024-07-10
		15	All items	Laryngoscopic fittings-Part 1:Conventional hook-on type handle-blade fittings YY 0498.1-2004		2024-07-10
		16	All items	Laryngoscopic fittings-Part 2:Miniature electric lamps-Screw threads and sockets for conventional blades YY 0498.2-2004		2024-07-10
33	Ultrasonic physiological parameters measurement	1	All items	Medical electrical equipment Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment GB 9706.237-2020		2024-07-10



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	and analysis equipment	2	General requirements	Medical electrical equipment Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment GB 9706.237-2020 201.4		2024-07-10
		3	ME equipment identification, marking and documentation	Medical electrical equipment Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment GB 9706.237-2020 201.7		2024-07-10
		4	Protection of ME equipment against electric shock hazard	Medical electrical equipment Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment GB 9706.237-2020 201.8		2024-07-10
		5	Protection against unnecessary or excessive radiation hazards (sources)	Medical electrical equipment Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment GB 9706.237-2020 201.10		2024-07-10
		6	Protection against extreme temperature and other hazards (sources)	Medical electrical equipment Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment GB 9706.237-2020 201.11		2024-07-10
		7	Accuracy of controller and instrument and protection of dangerous output	Medical electrical equipment Part 2-38: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment GB 9706.237-2020 201.12		2024-07-10
		8	Dangerous situation and fault status of ME equipment	Medical electrical equipment Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment GB 9706.237-2020 201.13		2024-07-10
		9	All items	Medical electrical equipment Part 2-37: Particular requirements		2024-07-10



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				for the safety of ultrasonic medical diagnostic and monitoring equipment GB 9706.9-2009		
				Medical electrical equipment Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment IEC 60601-2-37:2001 + Am1:2004 + Am2:2005		2024-07-10
		10	All items	Ultrasonics-Hand-held probe Doppler foetal heartbeat detectors-Performance requirements and methods of measurement and reporting YY/T 0749-2009		2024-07-10
		11	All items	Ultrasonic Doppler fetal monitor YY/T 0449-2018		2024-07-10
		12	All items	Ultrasonic Doppler foetal heartbeat detector YY/T 0448-2019		2024-07-10
		13	All items	Ultrasound Bone Sonometers YY/T 0774-2019		2024-07-10
		14	All items	Ultrasound transcranial Doppler system YY/T 0593-2022		2024-07-10
		15	All items	Methods of measuring the frequency of medical diagnostic and monitoring ultrasonic equipment YY/T 1142-2013		2024-07-10
		16	All items	Requirement for the declaration of the acoustic output of medical diagnostic ultrasonic equipment GB/T 16846-2008		2024-07-10
		17	All items	Testing methods for M-mode of ultrasonic diagnostic equipment YY/T 0108-2008		2024-07-10
		18	All items	Measurement methods of output power for medical diagnostic ultrasonic equipments YY/T 1084-2015		2024-07-10
		19	All items	Ultrasonics - Field characterization -Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields YY/T 0642-2022		2024-09-13
		20	Part of Items	Measuring methods for beam area of medical ultrasound equipment transducer YY/T 1278-2015	Except for 4.3	2024-07-10
		21	All items	Ultrasound - Test methods of performance for quasi-static strain sonoelasticity YY/T 1419-2016		2024-07-10



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		№	Item/ Parameter			
		22	All items	Environmental requirement and test methods for medical ultrasonic equipment YY/T 1420-2016		2024-07-10
		23	All items	B mode ultrasonic diagnostic equipment GB 10152-2009		2024-07-10
		24	All items	Medical ultrasound equipment class series-Part 1: B mode ultrasound diagnostic equipment YY/T 0162.1-2009		2024-07-10
		25	All items	General technical requirements for intravascular ultrasound (IVUS) diagnostic equipment YY/T 1659-2019		2024-07-10
		26	acoustic working frequency	General technical requirements for intravascular ultrasound (IVUS) diagnostic equipment YY/T 1659-2019 4.1		2024-07-10
		27	radius of imaging	General technical requirements for intravascular ultrasound (IVUS) diagnostic equipment YY/T 1659-2019 4.2		2024-07-10
		28	axial resolution	General technical requirements for intravascular ultrasound (IVUS) diagnostic equipment YY/T 1659-2019 4.3		2024-07-10
		29	lateral resolution	General technical requirements for intravascular ultrasound (IVUS) diagnostic equipment YY/T 1659-2019 4.4		2024-07-10
		30	pullback resolution	General technical requirements for intravascular ultrasound (IVUS) diagnostic equipment YY/T 1659-2019 4.5		2024-07-10
		31	Longitudinal geometric position accuracy	General technical requirements for intravascular ultrasound (IVUS) diagnostic equipment YY/T 1659-2019 4.6		2024-07-10
		32	Horizontal geometric position accuracy	General technical requirements for intravascular ultrasound (IVUS) diagnostic equipment YY/T 1659-2019 4.7		2024-07-10
		33	Geometric position accuracy of retraction direction	General technical requirements for intravascular ultrasound (IVUS) diagnostic equipment YY/T 1659-2019 4.8		2024-07-10
		34	Image geometric distortion	General technical requirements for intravascular ultrasound (IVUS) diagnostic equipment YY/T 1659-2019 4.9		2024-07-10



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		35	Appearance and structure	General technical requirements for intravascular ultrasound (IVUS) diagnostic equipment YY/T 1659-2019 4.10		2024-07-10
		36	Use function	General technical requirements for intravascular ultrasound (IVUS) diagnostic equipment YY/T 1659-2019 4.11		2024-07-10
34	Ultrasonic imaging diagnostic equipment	1	All items	Test method for performance of three-dimensional ultrasonography YY/T 1279-2015		2024-07-10
		2	All items	Ultrasonic colour flow imaging systems YY/T 0767-2023		2024-09-13
35	Ultrasonic physiotherapy equipment	1	All items	Medical electrical equipment Part 2-5: Particular requirements for the basic safety and essential performance of Ultrasonic physiotherapy equipment GB 9706.205-2020		2024-07-10
		2	General requirements	Medical electrical equipment Part 2-5: Particular requirements for the basic safety and essential performance of Ultrasonic physiotherapy equipment GB 9706.205-2020 201.4		2024-07-10
		3	secondary tip vibration excursion	Medical electrical equipment Part 2-5: Particular requirements for the basic safety and essential performance of Ultrasonic physiotherapy equipment GB 9706.205-2020 201.7		2024-07-10
		4	drive frequency	Medical electrical equipment Part 2-5: Particular requirements for the basic safety and essential performance of Ultrasonic physiotherapy equipment GB 9706.205-2020 201.8		2024-07-10
		5	drived output acoustic power	Medical electrical equipment Part 2-5: Particular requirements for the basic safety and essential performance of Ultrasonic physiotherapy equipment GB 9706.205-2020 201.10		2024-07-10
		6	quiescent electrical power	Medical electrical equipment Part 2-5: Particular requirements for the basic safety and essential performance of Ultrasonic physiotherapy equipment GB 9706.205-2020 201.11		2024-07-10
		7	maximum electrical power	Medical electrical equipment Part 2-5: Particular requirements for the basic safety and essential performance of Ultrasonic physiotherapy equipment GB 9706.205-2020 201.12		2024-07-10



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		8	clamping force	Medical electrical equipment Part 2-5: Particular requirements for the basic safety and essential performance of Ultrasonic physiotherapy equipment GB 9706.205-2020 201.13		2024-07-10
		9	grasping force	Medical electrical equipment Part 2-5: Particular requirements for the basic safety and essential performance of Ultrasonic physiotherapy equipment GB 9706.205-2020 201.15		2024-07-10
		10	All items	Medical electrical equipment Part 2-5: GB Particular requirements for the safety of ultrasonic physiotherapy equipmen GB 9706.7-2008		2024-07-10
				Medical electrical equipment Part 2-5: GB Particular requirements for the safety of ultrasonic physiotherapy equipmen IEC 60601-2-5:2000		2024-07-10
		11	All items	Ultrasonic Therapy Equipment for Superficial Tissue YY 0830-2011		2024-07-10
		12	Part of Items	Ultrasonics-surgical systems-Measurement and declaration of the basic output characteristics YY/T 0644-2008	Except for 6.5、6.6	2024-07-10
		13	All items	Ultrasonic physiotherapy equipment YY /T 1090-2018		2024-07-10
		14	All items	Ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T 1750-2020		2024-07-10
		15	primary tip vibration excursion	Ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T 1750-2020 4.1		2024-07-10
		16	secondary tip vibration excursion	Ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T 1750-2020 4.2		2024-07-10
		17	drive frequency	Ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T 1750-2020 4.3		2024-07-10
		18	drived output acoustic power	Ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T 1750-2020 4.4		2024-07-10
		19	quiescent electrical power	Ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T 1750-2020 4.5		2024-07-10



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		20	maximum electrical power	Ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T 1750-2020 4.6		2024-07-10
		21	clamping force	Ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T 1750-2020 4.7		2024-07-10
		22	grasping force	Ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T 1750-2020 4.8		2024-07-10
		23	Appearance and structure	Ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T 1750-2020 4.9		2024-07-10
		24	Use function	Ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T 1750-2020 4.10		2024-07-10
36	Ultrasonic biometer for ophthalmology	1	All items	A mode ultrasonic biometer for ophthalmology YY/T 0107-2015		2024-07-10
		2	All items	Ophthalmic high frequency ultrasound scanner YY/T 0849-2011		2024-07-10
		3	All items	A mode ultrasonic biometer for ophthalmology scanner YY/T 0107-2024		2025-07-18
		4	All items	General technical requirements for ophthalmic ultrasound B-mode scan YY/T 0773-2023		2024-09-13
		5	Measurement range	A mode ultrasonic biometer for ophthalmology scanner YY/T 0107-2024 4.1		2025-07-18
		6	measurement error	A mode ultrasonic biometer for ophthalmology scanner YY/T 0107-2024 4.2		2025-07-18
		7	Effective display digits	A mode ultrasonic biometer for ophthalmology scanner YY/T 0107-2024 4.3		2025-07-18
		8	additional function	A mode ultrasonic biometer for ophthalmology scanner YY/T 0107-2024 4.4		2025-07-18
		9	Internal power supply working time	A mode ultrasonic biometer for ophthalmology scanner YY/T 0107-2024 4.5		2025-07-18
		10	Appearance and Structure	A mode ultrasonic biometer for ophthalmology scanner YY/T 0107-2024 4.6		2025-07-18



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37	Ultrasonic imaging diagnostic accessory equipment	1	All items	Test methods for B mode ultrasonic diagnostic equipment :connect the Intracavity probe YY/T 0906-2013		2024-07-10
		2	All items	Medical ultrasonic couplant YY 0299-2022		2024-07-10
		3	All items	Medicalultrasonicnebulizer YY/T 0109-2024		2025-07-18
		4	Ultrasonic oscillation frequency deviation	Medicalultrasonicnebulizer YY/T 0109-2024 4.1		2025-07-18
		5	Total amount of ultrasonic atomization	Medicalultrasonicnebulizer YY/T 0109-2024 4.2		2025-07-18
		6	Maximum ultrasonic atomization rate	Medicalultrasonicnebulizer YY/T 0109-2024 4.3		2025-07-18
		7	water temperature	Medicalultrasonicnebulizer YY/T 0109-2024 4.4		2025-07-18
		8	noise	Medicalultrasonicnebulizer YY/T 0109-2024 4.5		2025-07-18
		9	Distribution characteristics of atomized particles	Medicalultrasonicnebulizer YY/T 0109-2024 4.6		2025-07-18
		10	Maximum liquid capacity warning	Medicalultrasonicnebulizer YY/T 0109-2024 4.7		2025-07-18
		11	control function	Medicalultrasonicnebulizer YY/T 0109-2024 4.8		2025-07-18
		12	Appearance and Structure	Medicalultrasonicnebulizer YY/T 0109-2024 4.9		2025-07-18
		13	accompanying document	Medicalultrasonicnebulizer YY/T 0109-2024 4.10		2025-07-18



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38	high frequency surgical equipment	1	All items	Medical electrical equipment—Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories GB 9706.202-2021		2024-07-10
		2	Part of Items	Medical electrical equipment Part2-2:Particular requirements for the safety of high frequency surgical equipment GB 9706.4—2009	Except for 39	2024-07-10
				Medical electrical equipment Part2-3:Particular requirements for the safety of high frequency surgical equipment IEC 60601-2-2:2007	Except for 39	2024-07-10
		3	All items	Medical electrical equipment-Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment GB 9706.203-2020		2025-07-18
		4	All items	High frequency electrocautery therapy equipmen YY/T 0322-2018/XGI-2023		2024-07-10
		5	Genral Requirement	Medical electrical equipment-Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment GB 9706.203-2020 201.4		2025-07-18
		6	All items	Millimeter wave therapy equipment YY/T 0898-2013		2024-07-10
		7	Genral Equipments for Testing ME Equipment	Medical electrical equipment-Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment GB 9706.203-2020 201.5		2025-07-18
		8	All items	Specified electromagnetic wave therapy equipment YY/T 0061-2021		2024-07-10
		9	Classification of ME Equipment and ME Systems	Medical electrical equipment-Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment GB 9706.203-2020 201.6		2025-07-18
		10	ME Equipment Identification,	Medical electrical equipment-Part 2-3: Particular requirements for the basic safety and essential performance of short-wave		2025-07-18

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			Marking, and Documents	therapy equipment GB 9706.203-2020 201.7		
		11	Protection Against Electrical Hazards From ME Equipment	Medical electrical equipment-Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment GB 9706.203-2020 201.8		2025-07-18
		12	Protection Against Mechanical Hazards of ME Equipment and ME Systems	Medical electrical equipment-Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment GB 9706.203-2020 201.9		2025-07-18
		13	Protection Against Unwanted and Excessive Radiation Hazards	Medical electrical equipment-Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment GB 9706.203-2020 201.10		2025-07-18
		14	Protection Against Excessive Temperatures and Other Hazards	Medical electrical equipment-Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment GB 9706.203-2020 201.11		2025-07-18
		15	Accuracy of Controls and Instruments and Protection Against Hazardous Outputs	Medical electrical equipment-Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment GB 9706.203-2020 201.12		2025-07-18
		16	Hazardous Situations and Fault Conditions	Medical electrical equipment-Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment GB 9706.203-2020 201.13		2025-07-18
		17	Programmable Electrical Medical Systems (PEMS)	Medical electrical equipment-Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment GB 9706.203-2020 201.14		2025-07-18



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		№	Item/ Parameter			
		18	Construction of ME Equipment	Medical electrical equipment-Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment GB 9706.203-2020 201.15		2025-07-18
		19	ME Systems	Medical electrical equipment-Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment GB 9706.203-2020 201.16		2025-07-18
		20	Electromagnetic Compatibility of ME Equipment and ME Systems	Medical electrical equipment-Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment GB 9706.203-2020 201.17		2025-07-18
39	Radio-frequency ablation equipment	1	All items	Radio-frequency ablation equipment for ear, nose and throat YY 0897-2013		2024-07-10
		2	All items	Radio frequency ablation catheter YY/T 0778-2018		2024-07-10
		3	All items	Radio frequency hyperthermia equipment YY 0777-2010		2024-07-10
		4	All items	radio frequency ablation equipment for liver YY/T 0776-2023		2025-07-18
		5	Operating Frequency	radio frequency ablation equipment for liver YY/T 0776-2023 4.1		2025-07-18
		6	Operating Frequency	radio frequency ablation equipment for liver YY/T 0776-2023 4.2		2025-07-18
		7	RF Output Power	radio frequency ablation equipment for liver YY/T 0776-2023 4.3		2025-07-18
		8	High current mode	radio frequency ablation equipment for liver YY/T 0776-2023 4.4		2025-07-18
		9	Impedance display function	radio frequency ablation equipment for liver YY/T 0776-2023 4.5		2025-07-18
		10	Temperature display function	radio frequency ablation equipment for liver YY/T 0776-2023 4.6		2025-07-18



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		№	Item/ Parameter			
		11	Protection function	radio frequency ablation equipment for liver 4.7 YY/T 0776-2023		2025-07-18
		12	Timing	radio frequency ablation equipment for liver 4.8 YY/T 0776-2023		2025-07-18
		13	priming pump	radio frequency ablation equipment for liver 4.9 YY/T 0776-2023		2025-07-18
		14	Liver radiofrequency ablation electrode, auxiliary (remote) temperature probe	radio frequency ablation equipment for liver 4.11 YY/T 0776-2023		2025-07-18
		15	Neutral electrode	radio frequency ablation equipment for liver 4.12 YY/T 0776-2023		2025-07-18
		16	All items	Radiofrequencyablationinstrumentforcardiapplication 0860-2024 YY/T		2025-07-18
		17	Operating Frequency	Radiofrequencyablationinstrumentforcardiapplication 0860-2024 5.1.1 YY/T		2025-07-18
		18	RF Output Power	Radiofrequencyablationinstrumentforcardiapplication 0860-2024 5.1.2 YY/T		2025-07-18
		19	Impedance display function	Radiofrequencyablationinstrumentforcardiapplication 0860-2024 5.1.3 YY/T		2025-07-18
		20	Temperature display function	Radiofrequencyablationinstrumentforcardiapplication 0860-2024 5.1.4 YY/T		2025-07-18
		21	Timing	Radiofrequencyablationinstrumentforcardiapplication 0860-2024 5.1.5 YY/T		2025-07-18
		22	Protection function	Radiofrequencyablationinstrumentforcardiapplication 0860-2024 5.1.6 YY/T		2025-07-18
		23	Equipment appearance	Radiofrequencyablationinstrumentforcardiapplication 0860-2024 5.1.7 YY/T		2025-07-18



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		24	Manual stop function	Radiofrequencyablationinstrumentforcardiapplication YY/T 0860-2024 5.1.8		2025-07-18
		25	priming pump	Radiofrequencyablationinstrumentforcardiapplication YY/T 0860-2024 5.2		2025-07-18
		26	Cardiac radiofrequency ablation catheter	Radiofrequencyablationinstrumentforcardiapplication YY/T 0860-2024 5.3		2025-07-18
		27	Cardiac Surgery Radiofrequency Ablation Surgical Accessories	Radiofrequencyablationinstrumentforcardiapplication YY/T 0860-2024 5.4		2025-07-18
		28	All items	General technical requirements for radio frequency ablation equipment YY 0650-2022		2025-07-18
		29	Output waveform parameters	General technical requirements for radio frequency ablation equipment YY 0650-2022 4.2		2025-07-18
		30	RF Output Power	General technical requirements for radio frequency ablation equipment YY 0650-2022 4.3		2025-07-18
		31	Temperature control mode	General technical requirements for radio frequency ablation equipment YY 0650-2022 4.4		2025-07-18
		32	Protection function	General technical requirements for radio frequency ablation equipment YY 0650-2022 4.5		2025-07-18
		33	Other functions	General technical requirements for radio frequency ablation equipment YY 0650-2022 4.6		2025-07-18
40	Oral treatment equipment	1	All items	Ultrasonics dental descaler equipment YY/T 0460-2009		2024-07-10
		2	All items	Ultrasonics—Dental descaler systems—Measurement and declaration of the output characteristics YY/T 0751-2009		2024-07-10
		3	All items	dentistry—powered polymerization activators—part 1:quartz tungsten halogen lamps YY 0055-2018		2024-07-10



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		4	All items	Dentistry—Stationary dental units and dental patient chairs—Part 1:General requirements YY/T 1043.1-2022		2024-07-10
		5	Basic safety and basic performance	Dentistry—Stationary dental units and dental patient chairs—Part 1:General requirements YY/T 1043.1-2022 5.1.1		2024-07-10
		6	Controllers and Indicators	Dentistry—Stationary dental units and dental patient chairs—Part 2:General requirements YY/T 1043.1-2022 5.1.2		2024-07-10
		7	Function stop system	Dentistry—Stationary dental units and dental patient chairs—Part 3:General requirements YY/T 1043.1-2022 5.1.3		2024-07-10
		8	usability	Dentistry—Stationary dental units and dental patient chairs—Part 4:General requirements YY/T 1043.1-2022 5.1.4		2024-07-10
		9	Cleaning and disinfection	Dentistry—Stationary dental units and dental patient chairs—Part 5:General requirements YY/T 1043.1-2022 5.1.5		2024-07-10
		10	OVERHEAT	Dentistry—Stationary dental units and dental patient chairs—Part 6:General requirements YY/T 1043.1-2022 5.1.6		2024-07-10
		11	Solid collector	Dentistry—Stationary dental units and dental patient chairs—Part 7:General requirements YY/T 1043.1-2022 5.1.8		2024-07-10
		12	Silver mercury alloy separator	Dentistry—Stationary dental units and dental patient chairs—Part 8:General requirements YY/T 1043.1-2022 5.1.9		2024-07-10
		13	Liquid absorption protection	Dentistry—Stationary dental units and dental patient chairs—Part 9:General requirements YY/T 1043.1-2022 5.1.10.1		2024-07-10
		14	flammability	Dentistry—Stationary dental units and dental patient chairs—Part 10:General requirements YY/T 1043.1-2022 5.1.10.2		2024-07-10
		15	Gas, water, suction, and wastewater systems	Dentistry—Stationary dental units and dental patient chairs—Part 11:General requirements YY/T 1043.1-2022 5.1.11		2024-07-10
		16	Moving parts	Dentistry—Stationary dental units and dental patient chairs—Part 12:General requirements YY/T 1043.1-2022 5.2.1.1		2024-07-10
		17	Pressure vessels and pressure components for	Dentistry—Stationary dental units and dental patient chairs—Part 13:General requirements YY/T 1043.1-2022 5.2.1.2		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			gases or liquids			
		18	Mechanical hazards of faces, corners, and edges	Dentistry—Stationary dental units and dental patient chairs—Part 14:General requirements YY/T 1043.1-2022 5.2.1.3		2024-07-10
		19	Stability of support system	Dentistry—Stationary dental units and dental patient chairs—Part 15:General requirements YY/T 1043.1-2022 5.2.1.4		2024-07-10
		20	Mechanical requirements for dental treatment machines	Dentistry—Stationary dental units and dental patient chairs—Part 16:General requirements YY/T 1043.1-2022 5.2.2		2024-07-10
		21	Maximum patient mass and static load	Dentistry—Stationary dental units and dental patient chairs—Part 7:General requirements YY/T 1043.1-2022 5.2.3.1		2024-07-10
		22	Headrest stability	Dentistry—Stationary dental units and dental patient chairs—Part 7:General requirements YY/T 1043.1-2022 5.2.3.2		2024-07-10
		23	Armrest stability	Dentistry—Stationary dental units and dental patient chairs—Part 7:General requirements YY/T 1043.1-2022 5.2.3.3		2024-07-10
		24	Carrying capacity and vertical lifting capacity	Dentistry—Stationary dental units and dental patient chairs—Part 7:General requirements YY/T 1043.1-2022 5.2.3.4		2024-07-10
		25	Tilt and stability	Dentistry—Stationary dental units and dental patient chairs—Part 7:General requirements YY/T 1043.1-2022 5.2.3.5		2024-07-10
		26	General Electrical Requirements	Dentistry—Stationary dental units and dental patient chairs—Part 7:General requirements YY/T 1043.1-2022 5.3.1		2024-07-10
		27	Test points for periodic safety checks	Dentistry—Stationary dental units and dental patient chairs—Part 7:General requirements YY/T 1043.1-2022 5.3.2		2024-07-10
		28	Position limitations of dental patient chairs	Dentistry—Stationary dental units and dental patient chairs—Part 7:General requirements YY/T 1043.1-2022 5.3.3		2024-07-10



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		№	Item/ Parameter			
		29	Manufacturer's instructions	Dentistry—Stationary dental units and dental patient chairs—Part 7:General requirements YY/T 1043.1-2022 8		2024-07-10
		30	package	Dentistry—Stationary dental units and dental patient chairs—Part 7:General requirements YY/T 1043.1-2022 9		2024-07-10
		31	mark	Dentistry—Stationary dental units and dental patient chairs—Part 7:General requirements YY/T 1043.1-2022 10		2024-07-10
		32	All items	dentistry—dental units—part 2:water and air supply YY/T 1043.2-2018		2024-07-10
		33	All items	dental handpieces high-speed air turbine handpieces YY 1045-2021		2024-07-10
		34	All items	Dentistry—Coupling dimensions for handpiece connectors YY/T 1012-2021		2024-07-10
		35	General requirements	Dentistry—Coupling dimensions for handpiece connectors YY/T 1012-2021 5.1		2024-07-10
		36	size	Dentistry—Coupling dimensions for handpiece connectors YY/T 1012-2021 5.2		2024-07-10
		37	All items	Dental Rotary instruments - Nominal diameters and designation code number YY/T 1011-2022		2024-07-10
		38	All items	Dentistry— Dental implant unit YY/T 1485-2016		2024-07-10
		39	All items	high-speed dental air turbine unit YY/T 1044-2018		2024-07-10
		40	All items	general techonlogy condition for electric dental engine YY/T 1147-2004		2024-07-10
		41	All items	Dentistry - Dental rubber dam technique - Part 1: Hole punch YY/T 1487.1-2016		2024-07-10
		42	All items	Dentistry— Whitening Accelerator YY/T 1401-2016		2024-07-10
		43	All items	Dental equipment-High-and medium-volume suction systems YY/T 0629-2008		2024-07-10



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		44	Design	Dental equipment-High-and medium-volume suction systems YY/T 0629-2008		2024-07-10
		45	Cleaning and disinfection	Dental equipment-High-and medium-volume suction systems YY/T 0629-2008		2024-07-10
		46	High-volume suction systems	Dental equipment-High-and medium-volume suction systems YY/T 0629-2008		2024-07-10
		47	Medium-volume suction systems	Dental equipment-High-and medium-volume suction systems YY/T 0629-2008		2024-07-10
		48	Air separator	Dental equipment-High-and medium-volume suction systems YY/T 0629-2008		2024-07-10
		49	Accessories	Dental equipment-High-and medium-volume suction systems YY/T 0629-2008		2024-07-10
		50	Noise level	Dental equipment-High-and medium-volume suction systems YY/T 0629-2008		2024-07-10
		51	Waste disposal	Dental equipment-High-and medium-volume suction systems YY/T 0629-2008		2024-07-10
		52	Electrical requirements	Dental equipment-High-and medium-volume suction systems YY/T 0629-2008		2024-07-10
		53	All items	Medical electrical equipment - Part 2-60: Particular requirements for basic safety and essential performance of dental equipment GB 9706.260-2020		2024-07-10
		54	Classification of ME equipment and ME system	Medical electrical equipment - Part 2-60: Particular requirements for basic safety and essential performance of dental equipment GB 9706.260-2020 201.6		2024-07-10
		55	ME equipment identification, marking and documentation	Medical electrical equipment - Part 2-60: Particular requirements for basic safety and essential performance of dental equipment GB 9706.260-2020 201.7		2024-07-10
		56	Protection of ME equipment against	Medical electrical equipment - Part 2-60: Particular requirements for basic safety and essential performance of dental equipment		2024-07-10



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			electric shock hazard	GB 9706.260-2020 201.8		
		57	Protection of ME equipment and ME system against mechanical hazards	Medical electrical equipment - Part 2-60: Particular requirements for basic safety and essential performance of dental equipment GB 9706.260-2020 201.9		2024-07-10
		58	Dangerous situation and fault status of ME equipment	Medical electrical equipment - Part 2-60: Particular requirements for basic safety and essential performance of dental equipment GB 9706.260-2020 201.13		2024-07-10
41	Nerve and Muscle Stimulators	1	All items	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021		2024-07-10
		2	Application conditions	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.4		2024-07-10
		3	General requirements	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.5		2024-07-10
		4	classification	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.6		2024-07-10
		5	Identification, marking and documentation	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.7		2024-07-10
		6	Protection against electric shock hazard	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.8		2024-07-10
		7	Protection against mechanical hazards	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.9		2024-07-10



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		8	Protection against unnecessary and excessive radiation hazards	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.10		2024-07-10
		9	Protection against extreme temperature and other hazards	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.11		2024-07-10
		10	Accuracy of controller and instrument and protection of dangerous output	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.12		2024-07-10
		11		particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.13		2024-07-10
		12	PEMS	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.14		2024-07-10
		13	Structure of me equipment	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.15		2024-07-10
		14	ME system	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.16		2024-07-10
		15	electromagnetic compatibility	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.17		2024-07-10
42	Electronic equipment	1	All items	Medical electrical equipment—part2:--Particular requirements for the safety of nerve and muscle stimulators YY0607-2007		2024-07-10



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				Medical electrical equipment—part2:--Particular requirements for the safety of nerve and muscle stimulators IEC 60601-2-10:1987		2024-07-10
				Medical electrical equipment—part2:--Particular requirements for the safety of nerve and muscle stimulators IEC 60601-2-10:2012		2024-07-10
		2	All items	Electric heating moxibustion equipment YY/T 1490-2016		2024-07-10
		3	Treatment temperature	Electric heating moxibustion equipment YY/T 1490-2016 5.1		2024-07-10
		4	Timing function	Electric heating moxibustion equipment YY/T 1490-2016 5.2		2024-07-10
		5	Noise	Electric heating moxibustion equipment YY/T 1490-2016 5.3		2024-07-10
		6	Noise	Electric heating moxibustion equipment YY/T 1490-2016 5.4		2024-07-10
		7	size of moxibustion head and pad	Electric heating moxibustion equipment YY/T 1490-2016 5.5		2024-07-10
		8	Other requirements of moxibustion pad	Electric heating moxibustion equipment YY/T 1490-2016 5.6		2024-07-10
		9	Manual	Electric heating moxibustion equipment YY/T 1490-2016 5.8		2024-07-10
		10	appearance	Electric heating moxibustion equipment YY/T 1490-2016 5.9		2024-07-10
		11	All items	Test method for measuring output characteristics of the nerve and muscle stimulators YY/T 0696-2021		2024-07-10
		12	All items	Electrodes for nerve and muscle stimulators YY/T 0868-2021		2024-07-10
		13	All items	Interferential current therapy instrument YY/T 0951-2015/XGI-2023		2024-07-10
		14	All items	Electroacupuncture therapy device YY 0780-2018		2024-07-10



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		15	All items	electrical potential therapy equipment YY 0649-2016 4.2		2025-07-18
		16	appearance	electrical potential therapy equipment YY 0649-2016 4.2		2025-07-18
		17	Output voltage	electrical potential therapy equipment YY 0649-2016 4.3		2025-07-18
		18	OUTPUT FREQUENCY	electrical potential therapy equipment YY 0649-2016 4.4		2025-07-18
		19	Output voltage stability	electrical potential therapy equipment YY 0649-2016 4.5		2025-07-18
		20	short-circuit current	electrical potential therapy equipment YY 0649-2016 4.6		2025-07-18
		21	Output overcurrent protection	electrical potential therapy equipment YY 0649-2016 4.7		2025-07-18
		22	Safety measures for electric field space	electrical potential therapy equipment YY 0649-2016 4.8		2025-07-18
		23	Safety range of magnetic field space	electrical potential therapy equipment YY 0649-2016 4.9		2025-07-18
		24	Durability of treatment pads, treatment blankets, and treatment mattresses	electrical potential therapy equipment YY 0649-2016 4.1		2025-07-18
		25	noise	electrical potential therapy equipment YY 0649-2016 4.11		2025-07-18
		26	function	electrical potential therapy equipment YY 0649-2016 4.13		2025-07-18
		27	Electrical safety	electrical potential therapy equipment YY 0649-2016 4.14		2025-07-18
		28	electromagnetic compatibility	electrical potential therapy equipment YY 0649-2016 4.15		2025-07-18



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		29	environmental test	electrical potential therapy equipment YY 0649-2016 4.16		2025-07-18
43	Heat treatment equipment	1	All items	Standard performance and safety specification for cryosurgical medical instruments YY/T 0678-2008		2024-07-10
		2	All items	Liquid nitrogen cryosurgical equipment YY/T 0677-2008		2024-07-10
		3	All items	Semiconductor heating and/or cooling therapy equipment YY/T 0998-2015		2024-07-10
		4	Partial items	Temperature control blanket for medical use YY/T 0952-2022	Except for 5.2.4	2024-07-10
		5	All items	Steam Therapy Apparatus YY/T 1306—2016		2024-07-10
		6	All items	Heating and Magnetic Vibrator Therapeutic Equipment YY/T 0982-2016		2024-07-10
		7	All items	steam therapy apparatus YY/T 1306-2024 5.1		2025-07-18
		8	All items	medical electrical equipment-Part 2: particular requirements for the safety of infant radiant warmers YY 9706.221-2021		2024-07-10
		9	Fumigation temperature	steam therapy apparatus YY/T 1306-2024 5.1		2025-07-18
		10	All items	Particular requirements for the safety of heat radiation therapy equipment YY 0306-2018		2024-07-10
		11	Fumigation time	steam therapy apparatus YY/T 1306-2024 5.2		2025-07-18
		12	Partial items	Contacting far infrared physiotherapy equipment YY/T 0902-2013	Except for 4.2	2024-07-10
		13	Anti dry burning function	steam therapy apparatus YY/T 1306-2024 5.3		2025-07-18
		14	All items	Medical heating pad therapy equipment YY/T 0165-2016		2024-07-10



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		15	Safety protection function	steam therapy apparatus YY/T 1306-2024 5.4		2025-07-18
		16	appearance	steam therapy apparatus YY/T 1306-2024 5.5		2025-07-18
		17	manual	steam therapy apparatus YY/T 1306-2024 5.6		2025-07-18
		18	Electrical safety	steam therapy apparatus YY/T 1306-2024 5.7		2025-07-18
		19	electromagnetic compatibility	steam therapy apparatus YY/T 1306-2024 5.8		2025-07-18
		20	environmental test	steam therapy apparatus YY/T 1306-2024 5.9		2025-07-18
44	Magnetic stimulation equipment	1	All items	Magnetic stimulation equipment YY/T 0994-2015		2024-07-10
45	Force therapy equipment	1	All items	Air-bag type sequential external counter-pulsation device GB 10035-2017		2024-07-10
		2	All items	Compression physiotherapy equipment for limbs YY/T 0833-2020		2024-07-10
		3	All items	Elbow,knee joints passive motion equipment YY/T 0997-2015		2024-07-10
		4	All items	Balance evaluation& exercise systems YY/T 1410-2016		2024-07-10
		5	All items	Walk training platform with suspension YY/T 0900-2013		2024-07-10
		6	All items	Electric cervical and lumbar traction therapy device YY/T 0697-2016		2024-07-10
		7	All items	Table, chair and accessories used for electric cervical and lumbar traction therapy device YY/T 1491-2016		2024-07-10
46	Optical radiation safety	1	All items	Optical radiation safety requirements of wearable devices GB/T 41265-2022		2024-07-10



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	requirements	2	All items	Photobiological safety of lamps and lamp systems GB/T 20145-2006		2024-07-10
		3	All items	Optics and photonics — Operation microscopes — Light hazard from operation microscopes used in ocular surgery YY 1296-2016		2024-07-10
		4	All items	Safety of laser products-Part9: Compilation of maximum permissible exposure to incoherent optical radiation GB/T 7247.9-2016		2024-07-10
		5	All items	Measuring methods for optical radiation safety classification of medical LED equipment YY/T 1534-2017		2024-07-10
		6	All items	General requirements for optical radiation safety GB 44703-2024		2025-07-18
		7	Optical radiation safety risk classification	General requirements for optical radiation safety GB 44703-2024 4		2025-07-18
		8	Optical radiation safety risk identification	General requirements for optical radiation safety GB 44703-2024 5		2025-07-18
		9	Optical radiation safety control requirements for products	General requirements for optical radiation safety GB 44703-2024 6		2025-07-18
		10	Product working process safety control requirements	General requirements for optical radiation safety GB 44703-2024 7		2025-07-18
		11	All items	Photobiological safety of non-coherent light products Part1: General requirements GB/T 30117.1-2024		2025-07-18
		12	Optical radiation hazard	Photobiological safety of non-coherent light products Part1: General requirements GB/T 30117.1-2024 4		2025-07-18



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		13	Risk classification	Photobiological safety of non-coherent light products Part1: General requirements GB/T 30117.1-2024 5		2025-07-18
		14	General evaluation criteria for classification	Photobiological safety of non-coherent light products Part1: General requirements GB/T 30117.1-2024 6		2025-07-18
		15	Continuous light radiation product risk category determination	Photobiological safety of non-coherent light products Part1: General requirements GB/T 30117.1-2024 7		2025-07-18
		16	Identification of risk categories for pulsed light radiation products	Photobiological safety of non-coherent light products Part1: General requirements GB/T 30117.1-2024 8		2025-07-18
		17	Optical radiation risk identification	Photobiological safety of non-coherent light products Part1: General requirements GB/T 30117.1-2024 9		2025-07-18
		18	Optical radiation control measures	Photobiological safety of non-coherent light products Part1: General requirements GB/T 30117.1-2024 10		2025-07-18
47	Medical Optical Radiation Protective Eyewears	1	All items	Medical Light Radiation Protective Eyewears-Evaluation Method-Part1:Decrease of Light Hazard YY/T 0968.1-2014		2024-07-10
		2	All items	Medical Optical Radiation Protective Eyewears-Evaluation Method-Part2:Vision and Color Vision YY/T 0968.2-2014		2024-07-10
48	surgical luminaires	1	All items	Medical electrical equipment Part 2-41:Particulae requirements for the basic safty and essential performance of surgical luminaires and luminaires for diagnosis YY 9706.241-2020		2024-07-10
		2	General requirements	Medical electrical equipment Part 2-41:Particulae requirements for the basic safty and essential performance of surgical luminaires and luminaires for diagnosis YY 9706.241-2020 201.4		2024-07-10
		3	ME equipment identification,	Medical electrical equipment Part 2-42:Particulae requirements for the basic safty and essential performance of surgical		2024-07-10



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			marking and documentation	luminaires and luminaires for diagnosis YY 9706.241-2020 201.7		
		4	Protection of me equipment against electric shock hazard (source)	Medical electrical equipment Part 2-43:Particulae requirements for the basic safty and essential performance of surgical luminaires and luminaires for diagnosis YY 9706.241-2020 201.8		2024-07-10
		5	Protection of ME equipment and me system against mechanical hazards	Medical electrical equipment Part 2-44:Particulae requirements for the basic safty and essential performance of surgical luminaires and luminaires for diagnosis YY 9706.241-2020 201.9		2024-07-10
		6	Protection against unnecessary or excessive radiation hazards (sources)	Medical electrical equipment Part 2-45:Particulae requirements for the basic safty and essential performance of surgical luminaires and luminaires for diagnosis YY 9706.241-2020 201.10		2024-07-10
		7	Protection against stray radiation	Medical electrical equipment Part 2-46:Particulae requirements for the basic safty and essential performance of surgical luminaires and luminaires for diagnosis YY 9706.241-2020 201.11		2024-07-10
		8	Accuracy of controller and instrument and protection of dangerous output	Medical electrical equipment Part 2-47:Particulae requirements for the basic safty and essential performance of surgical luminaires and luminaires for diagnosis YY 9706.241-2020 201.12		2024-07-10
		9	Dangerous situation and fault status of ME equipment	Medical electrical equipment Part 2-48:Particulae requirements for the basic safty and essential performance of surgical luminaires and luminaires for diagnosis YY 9706.241-2020 201.13		2024-07-10
49	operating tables	1	All items	Medical electrical equipment-Part2-46: Particular requirements for the basic safety and essential performance of operating tables YY 9706.246-2023		2024-07-10



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		2	All items	Medical electrical equipment-Part 2-46: Particular requirements for the safety of operating tables YY 0570-2013		2024-07-10
				Medical electrical equipment-Part 2-46: Particular requirements for the safety of operating tables IEC60601-2-46:1998		2024-07-10
		3	All items	Electrically powered operating table YY/T 1106-2008		2024-07-10
		4	All items	electrically powered operating table YY/T 1106-2023 4.1		2025-07-18
		5	appearance	electrically powered operating table YY/T 1106-2023 4.1		2025-07-18
		6	Basic dimensions	electrically powered operating table YY/T 1106-2023 4.2		2025-07-18
		7	Basic parameters of a single action	electrically powered operating table YY/T 1106-2023 4.3		2025-07-18
		8	leakage	electrically powered operating table YY/T 1106-2023 4.4		2025-07-18
		9	Movement stability	electrically powered operating table YY/T 1106-2023 4.5		2025-07-18
		10	Table swing amount	electrically powered operating table YY/T 1106-2023 4.6		2025-07-18
		11	install	electrically powered operating table YY/T 1106-2023 4.7		2025-07-18
		12	material	electrically powered operating table YY/T 1106-2023 4.8		2025-07-18
		13	environmental test	electrically powered operating table YY/T 1106-2023 4.9		2025-07-18
		14	Electrical safety	electrically powered operating table YY/T 1106-2023 4.10		2025-07-18
50	heating devices using blankets,	1	All items	Medical electrical equipment--Part 2-52: Particular requirements for the basic safety and essential performance of medical beds		2024-07-10

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	pads or mattresses			YY 9706.252-2021		
		2	All items	Medical electrical equipment -Part2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013		2024-07-10
				Medical electrical equipment -Part2 : Particular requirements for the safety of electrically operated hospital beds IEC60601-2-38:1996		2024-07-10
		3	All items	Dynamolectric traction-table YY/T 0697-2016		2024-07-10
		4	All items	General maternity beds YY/T 0045-2013		2024-07-10
		5	All items	Medical electrical equipment- Part 2-35 :Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use YY 9706.235-2021		2024-07-10
51	infusion pumps	1	All items	Medical electrical equipment-Part 2-24:Particular requirements for the basic safety and essential performance of infusion pumps and controllers GB 9706.224-2021		2024-07-10
				Medical electrical equipment — Part 2-24:Particular requirements for the safety of infusion pumps and controller IEC 60601-2-24:2012		2024-07-10
		2	All items	Medical electrical equipment — Part 2-24:Particular requirements for the safety of infusion pumps and controller GB 9706.27-2005		2024-07-10
				Medical electrical equipment — Part 2-24:Particular requirements for the safety of infusion pumps and controller IEC 60601-2-24:1998		2024-07-10
		3	All items	Electrical Infusion Pump for Ambulatory Use YY/T 1469—2016		2024-07-10
52	Active implant	1	All items	Implants for surgery Active implantable medical devices Part 5:		2024-07-10

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	medical device			Circulatory support device YY/T 0989.5-2022		
		2	All items	Active implantable medical devices Electromagnetic compatibility Implantable cardiac pacemakers Electromagnetic compatibility testing rules for implantable cardioverter defibrillators and cardiac resynchronization devices YY/T 1874-2023		2024-07-10
		3	All items	Medical electrical equipment-Part 2-31: Particular requirements for the safety of external cardiac pacemakers with internal power source YY 9706.231-2023		2024-07-10
		4	All items	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety, marking and for information to be provided by the manufacturer GB 16174.1-2015		2024-07-10
				Implants for surgery -- Active implantable medical devices -- Part 2 General requirements for safety, marking and for information to be provided by the manufacturer ISO 14708.1-2000		2024-07-10
				Implants for surgery -- Active implantable medical devices -- Part 2 General requirements for safety, marking and for information to be provided by the manufacturer ISO 14708.1-2014		2024-07-10
		5	All items	Implants for surgery -- Active implantable medical devices -- Part 2 Cardiac pacemakers GB 16174.2-2015		2024-07-10
				Implants for surgery -- Active implantable medical devices -- Part 2 Cardiac pacemakers ISO 14708.2-2005		2024-07-10
		6	All items	ISO 14708-7 2013 Implants for surgery — Active implantable medical devices --Part 7 Particular requirements for cochlear implant systems YY 0989.7-2017		2024-07-10
				ISO 14708-7 2013 Implants for surgery — Active implantable medical devices --Part 7 Particular requirements for cochlear implant systems ISO 14708.7-2013		2024-07-10
		7	All items	Implants for surgery - Active implantable medical devices - Part		2024-07-10

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				3: Implantable neurostimulators ISO 14708.3-2007		
		8	All items	Implants for surgery-Active implantable medical devices-Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators) YY 0989.6—2016		2024-07-10
		9	All items	Cardiac Pacemakers-Low-Profile Connectors(IS-1)for Implantable Pacemakers YY/T 0491-2004		2024-07-10
		10	electrode catheter connector	Cardiac Pacemakers-Low-Profile Connectors(IS-1)for Implantable Pacemakers YY/T 0491-2004		2024-07-10
		11	connector cavity	Cardiac Pacemakers-Low-Profile Connectors(IS-1)for Implantable Pacemakers YY/T 0491-2004		2024-07-10
		12	All items	Implantable cardiac pacing lead YY/T 0492-2017		2024-07-10
		13	Physical dimensions	Implantable cardiac pacing lead YY/T 0492-2017		2024-07-10
		14	Appearance	Implantable cardiac pacing lead YY/T 0492-2017		2024-07-10
		15	Measurement of Electrical Characteristic of Electrode Conductor	Implantable cardiac pacing lead YY/T 0492-2017		2024-07-10
		16	Protection against mechanical damage	Implantable cardiac pacing lead YY/T 0492-2017		2024-07-10
		17	Protection against mechanical damage	Implantable cardiac pacing lead YY/T 0492-2017		2024-07-10
		18	X-ray detectability	Implantable cardiac pacing lead YY/T 0492-2017		2024-07-10
		19	Accelerated Aging Life Experiments	Implantable cardiac pacing lead YY/T 0492-2017		2024-07-10



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		20	Chemical performance requirements	Implantable cardiac pacing lead YY/T 0492-2017		2024-07-10
		21	sterilization	Implantable cardiac pacing lead YY/T 0492-2017		2024-07-10
		22	Protection against biological effects	Implantable cardiac pacing lead YY/T 0492-2017		2024-07-10
		23	Packaging and marking	Implantable cardiac pacing lead YY/T 0492-2017		2024-07-10
		24	Random files	Implantable cardiac pacing lead YY/T 0492-2017		2024-07-10
53	Electrical equipment for measurement, control, and laboratory use	1	All items	Safety requirements for electrical equipment for measurement, control, and laboratory use-Part 1: General requirements GB4793.1-2007		2024-07-10
				Electrical equipment for measurement, control, and laboratory use IEC 61010-1: 2001		2024-07-10
				Electrical equipment for measurement, control, and laboratory use IEC 61010-1: 2010		2024-07-10
		2	All items	Safety requirement for electrical equipment for measurement, control and laboratory use-Part 14: Particular requirement for automatic and semi-automatic laboratory equipment for analysis and other purposes GB/T 42125.14-2023		2024-07-10
		3	Identification and documentation	Safety requirement for electrical equipment for measurement, control and laboratory use-Part 14: Particular requirement for automatic and semi-automatic laboratory equipment for analysis and other purposes GB/T 42125.14-2023		2024-07-10
		4	Protection against electric shock	Safety requirement for electrical equipment for measurement, control and laboratory use-Part 14: Particular requirement for automatic and semi-automatic laboratory		2024-07-10



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				equipment for analysis and other purposes GB/T 42125.14-2023 6		
		5	Protection against mechanical hazards	Safety requirement for electrical equipment for measurement, control and laboratory use-Part 14:Particular requirement for automatic and semi-automatic laboratory equipment for analysis and other purposes GB/T 42125.14-2023 7		2024-07-10
		6	Resistance to mechanical stress	Safety requirement for electrical equipment for measurement, control and laboratory use-Part 14:Particular requirement for automatic and semi-automatic laboratory equipment for analysis and other purposes GB/T 42125.14-2023 8		2024-07-10
		7	Prevent flame spread	Safety requirement for electrical equipment for measurement, control and laboratory use-Part 14:Particular requirement for automatic and semi-automatic laboratory equipment for analysis and other purposes GB/T 42125.14-2023 9		2024-07-10
		8	Temperature limits and heat resistance of equipment	Safety requirement for electrical equipment for measurement, control and laboratory use-Part 14:Particular requirement for automatic and semi-automatic laboratory equipment for analysis and other purposes GB/T 42125.14-2023 10		2024-07-10
		9	Prevent the danger of fluid and solid foreign objects	Safety requirement for electrical equipment for measurement, control and laboratory use-Part 14:Particular requirement for automatic and semi-automatic laboratory equipment for analysis and other purposes GB/T 42125.14-2023 11		2024-07-10
		10	Protection against radiation (including laser sources),	Safety requirement for electrical equipment for measurement, control and laboratory use-Part 14:Particular requirement for automatic and semi-automatic laboratory		2024-07-10



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			sound pressure and ultrasonic pressure	equipment for analysis and other purposes GB/T 42125.14-2023 12		
		11	Protection against released gases and substances, explosions and implosions	Safety requirement for electrical equipment for measurement, control and laboratory use-Part 14: Particular requirement for automatic and semi-automatic laboratory equipment for analysis and other purposes GB/T 42125.14-2023 13		2024-07-10
		12	Components and assemblies	Safety requirement for electrical equipment for measurement, control and laboratory use-Part 14: Particular requirement for automatic and semi-automatic laboratory equipment for analysis and other purposes GB/T 42125.14-2023 14		2024-07-10
		13	Protection with interlocking devices	Safety requirement for electrical equipment for measurement, control and laboratory use-Part 14: Particular requirement for automatic and semi-automatic laboratory equipment for analysis and other purposes GB/T 42125.14-2023 15		2024-07-10
		14	Application hazards	Safety requirement for electrical equipment for measurement, control and laboratory use-Part 14: Particular requirement for automatic and semi-automatic laboratory equipment for analysis and other purposes GB/T 42125.14-2023 16		2024-07-10
		15	Risk assessment	Safety requirement for electrical equipment for measurement, control and laboratory use-Part 14: Particular requirement for automatic and semi-automatic laboratory equipment for analysis and other purposes GB/T 42125.14-2023 17		2024-07-10
				Safety requirements for electrical equipment for measurement, control and laboratory use—Part 9: Particular requirements for automatic and semi-automatic laboratory equipment for analysis		2024-07-10



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				and other purposes IEC 61010-2-081:2009		
		16	All items	Safety requirements for electrical for measurement control and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB 4793.6-2008		2024-07-10
				Safety requirements for electrical for measurement control and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials IEC 61010-2-010:2005		2024-07-10
		17	All items	Safety requirements for electrical equipment for measurement control and laboratory use - Part 3: Particular requirements for laboratory equipment for mixing and stirring GB 4793.3-2008		2024-07-10
				Safety requirements for electrical equipment for measurement control and laboratory use - Part 3: Particular requirements for laboratory equipment for mixing and stirring IEC 61010-2-051:2005		2024-07-10
		18	All items	Safety requirements for electrical equipment for measurement, control and laboratory use-Part2-101:Particular requirements for in vitro diagnostic(IVD)medical equipment YY 0648-2008		2024-07-10
		19	All items	Safety requirement for electrical equipment for measurement,control and laboratory use-Particular requirement for autoclaves using steam for the treatment of medical materials and for laboratory process GB 4793.4-2019		2024-07-10
		20	All items	General requirements for in vitro diagnostic medical for self-testing YY/T 1454-2016		2024-07-10
		21	All items	Safety technical specification fou electrical equipment for measurement, control and laboratory use GB 4793-2024		2025-07-18
		22	Marking and documentation	Safety technical specification fou electrical equipment for measurement, control and laboratory use GB 4793-2024 5		2025-07-18
		23	Protection against electric shock	Safety technical specification fou electrical equipment for measurement, control and laboratory use GB 4793-2024 6		2025-07-18



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		24	Protection against mechanical hazards	Safety technical specification for electrical equipment for measurement, control and laboratory use GB 4793-2024 7		2025-07-18
		25	Resistance to mechanical stresses	Safety technical specification for electrical equipment for measurement, control and laboratory use GB 4793-2024 8		2025-07-18
		26	Protection against the spread of fire	Safety technical specification for electrical equipment for measurement, control and laboratory use GB 4793-2024 9		2025-07-18
		27	Equipment temperature limits and resistance to heat	Safety technical specification for electrical equipment for measurement, control and laboratory use GB 4793-2024 10		2025-07-18
		28	Protection against hazards from fluids	Safety technical specification for electrical equipment for measurement, control and laboratory use GB 4793-2024 11		2025-07-18
		29	Protection against radiation, including laser sources, and against sonic and ultrasonic pressure	Safety technical specification for electrical equipment for measurement, control and laboratory use GB 4793-2024 12		2025-07-18
		30	Protection against liberated and substances, explosion and implosion	Safety technical specification for electrical equipment for measurement, control and laboratory use GB 4793-2024 13		2025-07-18
		31	components and subassemblies	Safety technical specification for electrical equipment for measurement, control and laboratory use GB 4793-2024 14		2025-07-18
		32	Protection by interlocks	Safety technical specification for electrical equipment for measurement, control and laboratory use GB 4793-2024 15		2025-07-18
		33	test method	Safety technical specification for electrical equipment for measurement, control and laboratory use GB 4793-2024 16		2025-07-18



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		34	All items	Safety requirements for electrical equipment for measurement, control and laboratory use-Part1: General requirements GB/T 42125.1-2024		2025-07-18
		35	Tests	Safety requirements for electrical equipment for measurement, control and laboratory use-Part1: General requirements GB/T 42125.1-2024 4		2025-07-18
		36	Marking and documentation	Safety requirements for electrical equipment for measurement, control and laboratory use-Part1: General requirements GB/T 42125.1-2024 5		2025-07-18
		37	Protection against electric shock	Safety requirements for electrical equipment for measurement, control and laboratory use-Part1: General requirements GB/T 42125.1-2024 6		2025-07-18
		38	Protection against mechanical hazards	Safety requirements for electrical equipment for measurement, control and laboratory use-Part1: General requirements GB/T 42125.1-2024 7		2025-07-18
		39	Resistance to mechanical stresses	Safety requirements for electrical equipment for measurement, control and laboratory use-Part1: General requirements GB/T 42125.1-2024 8		2025-07-18
		40	Protection against the spread of fire	Safety requirements for electrical equipment for measurement, control and laboratory use-Part1: General requirements GB/T 42125.1-2024 9		2025-07-18
		41	Equipment temperature limits and resistance to heat	Safety requirements for electrical equipment for measurement, control and laboratory use-Part1: General requirements GB/T 42125.1-2024 10		2025-07-18
		42	Protection against hazards from fluids	Safety requirements for electrical equipment for measurement, control and laboratory use-Part1: General requirements GB/T 42125.1-2024 11		2025-07-18



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		43	Protection against radiation, including laser sources, and against sonic and ultrasonic pressure	Safety requirements for electrical equipment for measurement, control and laboratory use-Part1: General requirements GB/T 42125.1-2024 12		2025-07-18
		44	Protection against liberated and substances, explosion and implosion	Safety requirements for electrical equipment for measurement, control and laboratory use-Part1: General requirements GB/T 42125.1-2024 13		2025-07-18
		45	components and subassemblies	Safety requirements for electrical equipment for measurement, control and laboratory use-Part1: General requirements GB/T 42125.1-2024 14		2025-07-18
		46	Protection by interlocks	Safety requirements for electrical equipment for measurement, control and laboratory use-Part1: General requirements GB/T 42125.1-2024 15		2025-07-18
		47	Hazards resulting from application	Safety requirements for electrical equipment for measurement, control and laboratory use-Part1: General requirements GB/T 42125.1-2024 16		2025-07-18
		48	Risk assessment	Safety requirements for electrical equipment for measurement, control and laboratory use-Part1: General requirements GB/T 42125.1-2024 17		2025-07-18
		49	All items	Safety requirements for electrical equipment for measurement, control and laboratory use-Part2: Particular requirements for laboratory equipment for the heating of materials GB/T 42125.2-2024		2025-07-18
		50	Tests	Safety requirements for electrical equipment for measurement,		2025-07-18



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				control and laboratory use-Part2: Particular requirements for laboratory equipment for the heating of materials GB/T 42125.2-2024 4		
		51	Marking and documentation	Safety requirements for electrical equipment for measurement, control and laboratory use-Part2: Particular requirements for laboratory equipment for the heating of materials GB/T 42125.2-2024 5		2025-07-18
		52	Protection against electric shock	Safety requirements for electrical equipment for measurement, control and laboratory use-Part2: Particular requirements for laboratory equipment for the heating of materials GB/T 42125.2-2024 6		2025-07-18
		53	Protection against mechanical hazards	Safety requirements for electrical equipment for measurement, control and laboratory use-Part2: Particular requirements for laboratory equipment for the heating of materials GB/T 42125.2-2024 7		2025-07-18
		54	Resistance to mechanical stresses	Safety requirements for electrical equipment for measurement, control and laboratory use-Part2: Particular requirements for laboratory equipment for the heating of materials GB/T 42125.2-2024 8		2025-07-18
		55	Protection against the spread of fire	Safety requirements for electrical equipment for measurement, control and laboratory use-Part2: Particular requirements for laboratory equipment for the heating of materials GB/T 42125.2-2024 9		2025-07-18
		56	Equipment temperature limits and resistance to heat	Safety requirements for electrical equipment for measurement, control and laboratory use-Part2: Particular requirements for laboratory equipment for the heating of materials GB/T 42125.2-2024 10		2025-07-18
		57	Protection against hazards from fluids	Safety requirements for electrical equipment for measurement,		2025-07-18



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				control and laboratory use-Part2: Particular requirements for laboratory equipment for the heating of materials GB/T 42125.2-2024 11		
		58	Protection against radiation, including laser sources, and against sonic and ultrasonic pressure	Safety requirements for electrical equipment for measurement, control and laboratory use-Part2: Particular requirements for laboratory equipment for the heating of materials GB/T 42125.2-2024 12		2025-07-18
		59	Protection against liberated and substances, explosion and implosion	Safety requirements for electrical equipment for measurement, control and laboratory use-Part2: Particular requirements for laboratory equipment for the heating of materials GB/T 42125.2-2024 13		2025-07-18
		60	components and subassemblies	Safety requirements for electrical equipment for measurement, control and laboratory use-Part2: Particular requirements for laboratory equipment for the heating of materials GB/T 42125.2-2024 14		2025-07-18
		61	Protection by interlocks	Safety requirements for electrical equipment for measurement, control and laboratory use-Part2: Particular requirements for laboratory equipment for the heating of materials GB/T 42125.2-2024 15		2025-07-18
		62	Hazards resulting from application	Safety requirements for electrical equipment for measurement, control and laboratory use-Part2: Particular requirements for laboratory equipment for the heating of materials GB/T 42125.2-2024 16		2025-07-18
		63	Risk assessment	Safety requirements for electrical equipment for measurement, control and laboratory use-Part2: Particular requirements for laboratory equipment for the heating of materials GB/T 42125.2-		2025-07-18



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				2024 17		
		64	All items	Safety requirements for electrical equipment for measurement, control and laboratory use-Part3: Particular requirements for refrigerating equipment GB/T 42125.3-2024		2025-07-18
		65	Tests	Safety requirements for electrical equipment for measurement, control and laboratory use-Part3: Particular requirements for refrigerating equipment GB/T 42125.3-2024 4		2025-07-18
		66	Marking and documentation	Safety requirements for electrical equipment for measurement, control and laboratory use-Part3: Particular requirements for refrigerating equipment GB/T 42125.3-2024 5		2025-07-18
		67	Protection against electric shock	Safety requirements for electrical equipment for measurement, control and laboratory use-Part3: Particular requirements for refrigerating equipment GB/T 42125.3-2024 6		2025-07-18
		68	Protection against mechanical hazards	Safety requirements for electrical equipment for measurement, control and laboratory use-Part3: Particular requirements for refrigerating equipment GB/T 42125.3-2024 7		2025-07-18
		69	Resistance to mechanical stresses	Safety requirements for electrical equipment for measurement, control and laboratory use-Part3: Particular requirements for refrigerating equipment GB/T 42125.3-2024 8		2025-07-18
		70	Protection against the spread of fire	Safety requirements for electrical equipment for measurement, control and laboratory use-Part3: Particular requirements for refrigerating equipment GB/T 42125.3-2024 9		2025-07-18
		71	Equipment temperature limits and resistance to heat	Safety requirements for electrical equipment for measurement, control and laboratory use-Part3: Particular requirements for refrigerating equipment GB/T 42125.3-2024 10		2025-07-18
		72	Protection against hazards from fluids	Safety requirements for electrical equipment for measurement,		2025-07-18



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				control and laboratory use-Part3: Particular requirements for refrigerating equipment GB/T 42125.3-2024 11		
		73	Protection against radiation, including laser sources, and against sonic and ultrasonic pressure	Safety requirements for electrical equipment for measurement, control and laboratory use-Part3: Particular requirements for refrigerating equipment GB/T 42125.3-2024 12		2025-07-18
		74	Protection against liberated and substances, explosion and implosion	Safety requirements for electrical equipment for measurement, control and laboratory use-Part3: Particular requirements for refrigerating equipment GB/T 42125.3-2024 13		2025-07-18
		75	components and subassemblies	Safety requirements for electrical equipment for measurement, control and laboratory use-Part3: Particular requirements for refrigerating equipment GB/T 42125.3-2024 14		2025-07-18
		76	Protection by interlocks	Safety requirements for electrical equipment for measurement, control and laboratory use-Part3: Particular requirements for refrigerating equipment GB/T 42125.3-2024 15		2025-07-18
		77	Hazards resulting from application	Safety requirements for electrical equipment for measurement, control and laboratory use-Part3: Particular requirements for refrigerating equipment GB/T 42125.3-2024 16		2025-07-18
		78	Risk assessment	Safety requirements for electrical equipment for measurement, control and laboratory use-Part3: Particular requirements for refrigerating equipment GB/T 42125.3-2024 17		2025-07-18
		79	All items	Safety requirements for electrical equipment for measurement, control and laboratory use-Part4: Particular requirements for climate and environment testing and other temperature conditioning equipment GB/T 42125.4-2024		2025-07-18



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		80	Tests	Safety requirements for electrical equipment for measurement, control and laboratory use-Part4: Particular requirements for climate and environment testing and other temperature conditioning equipment GB/T 42125.4-2024 4		2025-07-18
		81	Marking and documentation	Safety requirements for electrical equipment for measurement, control and laboratory use-Part4: Particular requirements for climate and environment testing and other temperature conditioning equipment GB/T 42125.4-2024 5		2025-07-18
		82	Protection against electric shock	Safety requirements for electrical equipment for measurement, control and laboratory use-Part4: Particular requirements for climate and environment testing and other temperature conditioning equipment GB/T 42125.4-2024 6		2025-07-18
		83	Protection against mechanical hazards	Safety requirements for electrical equipment for measurement, control and laboratory use-Part4: Particular requirements for climate and environment testing and other temperature conditioning equipment GB/T 42125.4-2024 7		2025-07-18
		84	Resistance to mechanical stresses	Safety requirements for electrical equipment for measurement, control and laboratory use-Part4: Particular requirements for climate and environment testing and other temperature conditioning equipment GB/T 42125.4-2024 8		2025-07-18
		85	Protection against the spread of fire	Safety requirements for electrical equipment for measurement, control and laboratory use-Part4: Particular requirements for climate and environment testing and other temperature conditioning equipment GB/T 42125.4-2024 9		2025-07-18
		86	Equipment temperature limits and resistance to heat	Safety requirements for electrical equipment for measurement, control and laboratory use-Part4: Particular requirements for climate and environment testing and other temperature conditioning equipment GB/T 42125.4-2024 10		2025-07-18



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		87	Protection against hazards from fluids	Safety requirements for electrical equipment for measurement, control and laboratory use-Part4: Particular requirements for climate and environment testing and other temperature conditioning equipment GB/T 42125.4-2024 11		2025-07-18
		88	Protection against radiation, including laser sources, and against sonic and ultrasonic pressure	Safety requirements for electrical equipment for measurement, control and laboratory use-Part4: Particular requirements for climate and environment testing and other temperature conditioning equipment GB/T 42125.4-2024 12		2025-07-18
		89	Protection against liberated and substances, explosion and implosion	Safety requirements for electrical equipment for measurement, control and laboratory use-Part4: Particular requirements for climate and environment testing and other temperature conditioning equipment GB/T 42125.4-2024 13		2025-07-18
		90	components and subassemblies	Safety requirements for electrical equipment for measurement, control and laboratory use-Part4: Particular requirements for climate and environment testing and other temperature conditioning equipment GB/T 42125.4-2024 14		2025-07-18
		91	Protection by interlocks	Safety requirements for electrical equipment for measurement, control and laboratory use-Part4: Particular requirements for climate and environment testing and other temperature conditioning equipment GB/T 42125.4-2024 15		2025-07-18
		92	Hazards resulting from application	Safety requirements for electrical equipment for measurement, control and laboratory use-Part4: Particular requirements for climate and environment testing and other temperature conditioning equipment GB/T 42125.4-2024 16		2025-07-18
		93	Risk assessment	Safety requirements for electrical equipment for measurement, control and laboratory use-Part4: Particular requirements for		2025-07-18



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				climate and environment testing and other temperature conditioning equipment GB/T 42125.4-2024 17		
		94	All items	Safety requirements for electrical equipment for measurement, control and laboratory use-Part5: Particular equipments for laboratory centrifuges GB/T 42125.5-2024		2025-07-18
		95	Tests	Safety requirements for electrical equipment for measurement, control and laboratory use-Part5: Particular equipments for laboratory centrifuges GB/T 42125.5-2024 4		2025-07-18
		96	Marking and documentation	Safety requirements for electrical equipment for measurement, control and laboratory use-Part5: Particular equipments for laboratory centrifuges GB/T 42125.5-2024 5		2025-07-18
		97	Protection against electric shock	Safety requirements for electrical equipment for measurement, control and laboratory use-Part5: Particular equipments for laboratory centrifuges GB/T 42125.5-2024 6		2025-07-18
		98	Protection against mechanical hazards	Safety requirements for electrical equipment for measurement, control and laboratory use-Part5: Particular equipments for laboratory centrifuges GB/T 42125.5-2024 7		2025-07-18
		99	Resistance to mechanical stresses	Safety requirements for electrical equipment for measurement, control and laboratory use-Part5: Particular equipments for laboratory centrifuges GB/T 42125.5-2024 8		2025-07-18
		100	Protection against the spread of fire	Safety requirements for electrical equipment for measurement, control and laboratory use-Part5: Particular equipments for laboratory centrifuges GB/T 42125.5-2024 9		2025-07-18
		101	Equipment temperature limits and resistance to heat	Safety requirements for electrical equipment for measurement, control and laboratory use-Part5: Particular equipments for laboratory centrifuges GB/T 42125.5-2024 10		2025-07-18
		102	Protection against hazards from fluids	Safety requirements for electrical equipment for measurement,		2025-07-18

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				control and laboratory use-Part5: Particular equipments for laboratory centrifuges GB/T 42125.5-2024 11		
		103	Protection against radiation, including laser sources, and against sonic and ultrasonic pressure	Safety requirements for electrical equipment for measurement, control and laboratory use-Part5: Particular equipments for laboratory centrifuges GB/T 42125.5-2024 12		2025-07-18
		104	Protection against liberated and substances, explosion and implosion	Safety requirements for electrical equipment for measurement, control and laboratory use-Part5: Particular equipments for laboratory centrifuges GB/T 42125.5-2024 13		2025-07-18
		105	components and subassemblies	Safety requirements for electrical equipment for measurement, control and laboratory use-Part5: Particular equipments for laboratory centrifuges GB/T 42125.5-2024 14		2025-07-18
		106	Protection by interlocks	Safety requirements for electrical equipment for measurement, control and laboratory use-Part5: Particular equipments for laboratory centrifuges GB/T 42125.5-2024 15		2025-07-18
		107	Hazards resulting from application	Safety requirements for electrical equipment for measurement, control and laboratory use-Part5: Particular equipments for laboratory centrifuges GB/T 42125.5-2024 16		2025-07-18
		108	Risk assessment	Safety requirements for electrical equipment for measurement, control and laboratory use-Part5: Particular equipments for laboratory centrifuges GB/T 42125.5-2024 17		2025-07-18
		109	All items	General principles for performance evaluation of quantitative real-time polymerase chain reaction analyzer GB/T 42753-2023		2025-07-18
		110	Appearance	General principles for performance evaluation of quantitative real-time polymerase chain reaction analyzer GB/T 42753-2023		2025-07-18



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				5.2		
		111	Temperature control performance	General principles for performance evaluation of quantitative real-time polymerase chain reaction analyzer GB/T 42753-2023 5.6.1		2025-07-18
		112	Fluorescence detection performance	General principles for performance evaluation of quantitative real-time polymerase chain reaction analyzer GB/T 42753-2023 5.6.2		2025-07-18
		113	performance of the machine	General principles for performance evaluation of quantitative real-time polymerase chain reaction analyzer GB/T 42753-2023 5.6.3		2025-07-18
		114	All items	Clinical mass spectrometer-Part 3: Inductively coupled plasma mass spectrometry YY/T 1740.3-2024		2025-07-18
		115	appearance	Clinical mass spectrometer-Part 3: Inductively coupled plasma mass spectrometry YY/T 1740.3-2024 5.2		2025-07-18
		116	Software requirement	Clinical mass spectrometer-Part 3: Inductively coupled plasma mass spectrometry YY/T 1740.3-2024 5.3		2025-07-18
		117	Mass range	Clinical mass spectrometer-Part 3: Inductively coupled plasma mass spectrometry YY/T 1740.3-2024 5.4		2025-07-18
		118	Mass resolution	Clinical mass spectrometer-Part 3: Inductively coupled plasma mass spectrometry YY/T 1740.3-2024 5.5		2025-07-18
		119	Background noise	Clinical mass spectrometer-Part 3: Inductively coupled plasma mass spectrometry YY/T 1740.3-2024 5.6		2025-07-18
		120	Sensitivity	Clinical mass spectrometer-Part 3: Inductively coupled plasma mass spectrometry YY/T 1740.3-2024 5.7		2025-07-18
		121	Precision	Clinical mass spectrometer-Part 3: Inductively coupled plasma mass spectrometry YY/T 1740.3-2024 5.8		2025-07-18
		122	Sample consumption	Clinical mass spectrometer-Part 3: Inductively coupled plasma mass spectrometry YY/T 1740.3-2024 5.9		2025-07-18



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		123	Mass stability	Clinical mass spectrometer-Part 3: Inductively coupled plasma mass spectrometry YY/T 1740.3-2024 5.10		2025-07-18
		124	Oxide ionization yield	Clinical mass spectrometer-Part 3: Inductively coupled plasma mass spectrometry YY/T 1740.3-2024 5.11		2025-07-18
		125	Double charged ion production rate	Clinical mass spectrometer-Part 3: Inductively coupled plasma mass spectrometry YY/T 1740.3-2024 5.12		2025-07-18
		126	Measurement stability	Clinical mass spectrometer-Part 3: Inductively coupled plasma mass spectrometry YY/T 1740.3-2024 5.13		2025-07-18
		127	Contamination-carrying rate	Clinical mass spectrometer-Part 3: Inductively coupled plasma mass spectrometry YY/T 1740.3-2024 5.14		2025-07-18
54	Moist heat sterilized equipment	1	All items	Safety requirements for electrical equipment for measurement control and laboratory use - Part 2-042: Particular requirements for autoclaves and sterilizers using toxic gas for the treatment of medical materials and for laboratory processes GB 4793.8-2008		2024-07-10
		2	All items	Low temperature steam and formaldehyde sterilizers for medical purposes YY/T 0679-2016		2024-07-10
		3	Partial items	Portable Mode Steam Sterilizers YY 0504-2016	Except for 5.18	2024-07-10
		4	Partial items	Steam sterilizer - the performance requirements of biosafety YY 1277-2016	Except for 4.1	2024-07-10
		5	All items	Steam generators for medical use YY/T 0791-2018		2024-07-10
		6	All items	Medical plasma virus inactivated device YY/T 1510-2017		2024-07-10
		7	All items	Dry heat (heated air) sterilizers YY 1275-2016		2024-07-10
55	Chemical disinfection sterilized equipment	1	Partial items	Ethylene oxide sterilizer YY 0503-2016	Except for 5.17.1	2024-07-10



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56	Urine analyzer equipment	1	All items	Urine analyzer YY/T 0475-2011		2024-07-10
		2	All items	Dry chemistry analyzer YY/T 0655-2008		2024-07-10
		3	All items	Urine formed element analyzer(digital imaging automatic identification) YY/T 0996-2015		2024-07-10
		4	All items	General principles for performance evaluation of quantitative real-time polymerase chain reaction analyzer YY/T 0655—2024		2025-07-18
		5		General principles for performance evaluation of quantitative real-time polymerase chain reaction analyzer YY/T 0655—2024 5.2		2025-07-18
		6		General principles for performance evaluation of quantitative real-time polymerase chain reaction analyzer YY/T 0655—2024 5.6.1		2025-07-18
		7		General principles for performance evaluation of quantitative real-time polymerase chain reaction analyzer YY/T 0655—2024 5.6.2		2025-07-18
		8		General principles for performance evaluation of quantitative real-time polymerase chain reaction analyzer YY/T 0655—2024 5.6.3		2025-07-18
57	Blood analysis equipment	1	All items	automatic blood coagulation analytical nstrument YY/T 0659-2017/XG1-2022		2024-07-10
		2	All items	Blood rheometer YY/T 1460-2016		2024-07-10
		3	All items	Hematology analyzer YY/T 0653-2017/XG1-2022		2024-07-10
		4	All items	Erythrocyte sedimentation rate tester YY/T 1251-2014		2024-07-10
		5	All items	Flow cytometer YY/T 0588-2017		2024-07-10



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		6	All items	Centrifugal blood components separation device YY 1413-2016		2024-07-10
		7	All items	Automatic blood analyzer YY/T 1245-2014		2024-07-10
		8	All items	Glycosylated hemoglobin analyzer YY/T 1246-2014		2024-07-10
		9	All items	Heamoglobin instrument YY/T 0032-2004		2024-07-10
		10	All items	General technical requirements for hemoglobin dry chemistry testing systems YY/T 1150-2009		2024-07-10
		11	All items	Dry Hematology Analyzer(centrifuge method) YY/T 1452—2016		2024-07-10
58	Biochemical analysis equipment	1	All items	Automatic chemistry analyzer YY/T 0654-2017		2024-07-10
		2	All items	Semiautomatic biochemistry analyzer YY/T0014-2005		2024-07-10
		3	All items	In vitro diagnostic test systems- General technical requirements for blood-glucose monitoring systems for self-testing GB/T 19634-2021		2024-07-10
59	Electrolyte analyzer	1	All items	Electrolyte analyzer YY/T 0589-2016		2024-07-10
60	Immunoassay Analysis equipment	1	All items	Automatic Time-resolved Fluorescence Counter YY/T 1533-2017		2024-07-10
		2	All items	Detection system of time-resolved fluoroimmunoassay—Part 1:Semi-auto time-resolved fluoroimmunoassay analyser YY/T 1304.1-2015		2024-07-10
		3	All items	Automatic Luminescence Immunoassay Analyzer YY/T 1155-2019		2024-07-10
		4	All items	Semi-automatic chemiluminescence immunoassay analyzer YY/T 1174-2010		2024-07-10



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		5	All items	Polymerase Chain Reaction Analyzer YY/T1173-2010		2024-07-10
		6	All items	Fluorescence immunochromatography analyzer YY/T 1792-2021		2024-07-10
		7	All items	ELISA analytical instruments YY/T 1529-2024		2025-07-18
		8	All items	High-throughput gene sequencer YY/T 1723-2020		2024-07-10
		9	appearance	ELISA analytical instruments YY/T 1529-2024 4.1		2025-07-18
		10	gene sequencing	High-throughput gene sequencer YY/T 1723-2020 4.1		2024-07-10
		11	Wavelength accuracy and half-peak width	ELISA analytical instruments YY/T 1529-2024 4.2.1		2025-07-18
		12	throughput of gene sequencing	High-throughput gene sequencer YY/T 1723-2020 4.2		2024-07-10
		13	Absorbance accuracy	ELISA analytical instruments YY/T 1529-2024 4.2.2		2025-07-18
		14	valid throughput of gene sequencing	High-throughput gene sequencer YY/T 1723-2020 4.3		2024-07-10
		15	Linearity	ELISA analytical instruments YY/T 1529-2024 4.2.3		2025-07-18
		16	read length of gene sequencing	High-throughput gene sequencer YY/T 1723-2020 4.4		2024-07-10
		17	Absorbance repeatability	ELISA analytical instruments YY/T 1529-2024 4.2.4		2025-07-18
		18	base calling	High-throughput gene sequencer YY/T 1723-2020 4.5		2024-07-10
		19	Absorbance stability	ELISA analytical instruments YY/T 1529-2024 4.2.5		2025-07-18



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		20	quality of base calling	High-throughput gene sequencer YY/T 1723-2020 4.6		2024-07-10
		21	Sensitivity	ELISA analytical instruments YY/T 1529-2024 4.2.6		2025-07-18
		22	high-throughput gene sequencer	High-throughput gene sequencer YY/T 1723-2020 4.7		2024-07-10
		23	Channel difference	ELISA analytical instruments YY/T 1529-2024 4.2.7		2025-07-18
		24	All items	Colloidal gold immunochromatographic reader YY/T 1582-2018		2024-07-10
		25	Average liquid residue of the cleaning module	ELISA analytical instruments YY/T 1529-2024 4.2.8		2025-07-18
		26	appearance	Colloidal gold immunochromatographic reader YY/T 1582-2018 3.1		2024-07-10
		27	Filling module accuracy and precision	ELISA analytical instruments YY/T 1529-2024 4.2.9		2025-07-18
		28	resolution ratio	Colloidal gold immunochromatographic reader YY/T 1582-2018 3.2		2024-07-10
		29	Incubation module temperature accuracy and fluctuation	ELISA analytical instruments YY/T 1529-2024 4.2.10		2025-07-18
		30	accuracy	Colloidal gold immunochromatographic reader YY/T 1582-2018 3.3		2024-07-10
		31	Repeatability of clinical programs	ELISA analytical instruments YY/T 1529-2024 4.2.11		2025-07-18
		32	repeatability	Colloidal gold immunochromatographic reader YY/T 1582-2018 3.4		2024-07-10



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		33	Sample carrying contamination	ELISA analytical instruments YY/T 1529-2024 4.2.12		2025-07-18
		34	linearity	Colloidal gold immunochromatographic reader YY/T 1582-2018 3.5		2024-07-10
		35	Software function	ELISA analytical instruments YY/T 1529-2024 4.6		2025-07-18
		36	channel consistency (if applicable)	Colloidal gold immunochromatographic reader YY/T 1582-2018 3.6		2024-07-10
		37	stability	Colloidal gold immunochromatographic reader YY/T 1582-2018 3.7		2024-07-10
		38	function	Colloidal gold immunochromatographic reader YY/T 1582-2018 3.8		2024-07-10
		39	All items	Clinical mass spectrometer-Part 2: Matrix-assisted laser desorption ionization-time of flight mass spectrometer YY/T 1740.2-2021		2024-07-10
		40	All items	High performance liquid chromatography GB/T 26792-2019		2024-07-10
		41	All items	General specification for mass spectrometers GB/T 33864-2017		2024-07-10
		42	appearance	General specification for mass spectrometers GB/T 33864-2017		2024-07-10
		43	mass range	General specification for mass spectrometers GB/T 33864-2017		2024-07-10
		44	mass accuracy	General specification for mass spectrometers GB/T 33864-2017		2024-07-10
		45	mass stability	General specification for mass spectrometers GB/T 33864-2017		2024-07-10
		46	mass resolution	General specification for mass spectrometers GB/T 33864-2017		2024-07-10
		47	limit of detection	General specification for mass spectrometers GB/T 33864-2017		2024-07-10



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		48	reproducibility	General specification for mass spectrometers GB/T 33864-2017		2024-07-10
		49	safety	General specification for mass spectrometers GB/T 33864-2017		2024-07-10
		50	transport and transportation storage	General specification for mass spectrometers GB/T 33864-2017		2024-07-10
		51	environmental suitability	General specification for mass spectrometers GB/T 33864-2017		2024-07-10
		52	All items	Method of performance testing for liquid chromatography-tandem quadrupole mass spectrometry GB/T 35410-2017		2024-07-10
		53	resolution	Method of performance testing for liquid chromatography-tandem quadrupole mass spectrometry GB/T 35410-2017		2024-07-10
		54	mass range	Method of performance testing for liquid chromatography-tandem quadrupole mass spectrometry GB/T 35410-2017		2024-07-10
		55	灵敏度	Method of performance testing for liquid chromatography-tandem quadrupole mass spectrometry GB/T 35410-2017		2024-07-10
		56	linear correlation coefficient	Method of performance testing for liquid chromatography-tandem quadrupole mass spectrometry GB/T 35410-2017		2024-07-10
		57	mass stability	Method of performance testing for liquid chromatography-tandem quadrupole mass spectrometry GB/T 35410-2017		2024-07-10
		58	mass accuracy	Method of performance testing for liquid chromatography-tandem quadrupole mass spectrometry GB/T 35410-2017		2024-07-10
		59	Area repeatability	Method of performance testing for liquid chromatography-tandem quadrupole mass spectrometry GB/T 35410-2017		2024-07-10
		60	Qualitative repeatability	Method of performance testing for liquid chromatography-tandem quadrupole mass spectrometry GB/T 35410-2017		2024-07-10
		61	Retention time repeatability	Method of performance testing for liquid chromatography-tandem quadrupole mass spectrometry GB/T 35410-2017		2024-07-10
		62	scanning speed	Method of performance testing for liquid chromatography-		2024-07-10

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		№	Item/ Parameter			
				tandem quadrupole mass spectrometry GB/T 35410-2017		
61	Liquid chromatography	1	All items	Clinical mass spectrometer-Part1: Liquid chromatography-mass spectrometer YY/T 1740.1-2021		2024-07-10
		2	appearance	Clinical mass spectrometer-Part1: Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.2		2024-07-10
		3	mass range	Clinical mass spectrometer-Part1: Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.3		2024-07-10
		4	mass accuracy and mass resolution	Clinical mass spectrometer-Part1: Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.4		2024-07-10
		5	scanning speed	Clinical mass spectrometer-Part1: Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.5		2024-07-10
		6	Accuracy of flow rate of infusion pump	Clinical mass spectrometer-Part1: Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.6		2024-07-10
		7	Accuracy of autosampler and column incubator	Clinical mass spectrometer-Part1: Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.7		2024-07-10
		8	Linearity of autosampler	Clinical mass spectrometer-Part1: Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.8		2024-07-10
		9	sensitivity	Clinical mass spectrometer-Part1: Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.9		2024-07-10
		10	Precision	Clinical mass spectrometer-Part1: Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.10		2024-07-10
		11	linear	Clinical mass spectrometer-Part1: Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.11		2024-07-10
		12	Carryover rate	Clinical mass spectrometer-Part1: Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.12		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		13	Software	Clinical mass spectrometer-Part1: Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.13		2024-07-10
		14	environmental test	Clinical mass spectrometer-Part1: Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.14		2024-07-10
		15	Electrical safety	Clinical mass spectrometer-Part1: Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.15		2024-07-10
		16	electromagnetic compatibility	Clinical mass spectrometer-Part1: Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.16		2024-07-10
62	Inspection auxiliary equipment	1	All items	Thermostatic water bath YY/T 0086-2020		2024-07-10
		2	All items	Automated blood culture system YY/T 0656-2008		2024-07-10
		3	All items	Electrophoresis device YY 0087-2004		2024-07-10
63	Medical Centrifuge	1	All items	Medical centrifuge YY/T 0657-2017		2024-07-10
64	Inspection and other auxiliary equipment	1	All items	Medical biochemical incubator YY/T 1641-2018		2024-07-10
		2	All items	Medical freezer YY/T 1757-2021		2024-07-10
		3	All items	Automated feces analyzer YY/T 1745-2021		2024-07-10
		4	All items	Sperm quality analyzer YY/T 1795-2021		2024-07-10
65	Other medical analysis equipment	1	All items	Technical equipment of area fluorescent imaging microarray scanner GB/T 33806-2017		2024-07-10
		2	essential function	Technical equipment of area fluorescent imaging microarray scanner GB/T 33806-2017		2024-07-10
		3	stability	Technical equipment of area fluorescent imaging microarray scanner GB/T 33806-2017		2024-07-10



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		4	Resolution	Technical requipment of area fluorescent imaging microarray scanner GB/T 33806-2017		2024-07-10
		5	Lowest limit of detection	Technical requipment of area fluorescent imaging microarray scanner GB/T 33806-2017		2024-07-10
		6	linearity	Technical requipment of area fluorescent imaging microarray scanner GB/T 33806-2017		2024-07-10
		7	Location Variation	Technical requipment of area fluorescent imaging microarray scanner GB/T 33806-2017		2024-07-10
		8	Dynamic Range	Technical requipment of area fluorescent imaging microarray scanner GB/T 33806-2017		2024-07-10
		9	safety	Technical requipment of area fluorescent imaging microarray scanner GB/T 33806-2017		2024-07-10
		10	environment test	Technical requipment of area fluorescent imaging microarray scanner GB/T 33806-2017		2024-07-10
		11	appearance	Technical requipment of area fluorescent imaging microarray scanner GB/T 33806-2017		2024-07-10
66	Cardiopulmonary bypass systems	1	All items	Cardiopulmonary bypass systems--Centrifugal pump-head YY/T 1739-2020		2024-07-10
		2	Cardiopulmonary bypass systems-Assessment method of red blood cell damage in continuous flow blood pumps	Cardiopulmonary bypass systems-Assessment method of red blood cell damage in continuous flow blood pumps YY/T 1620-2018 5.2.6		2024-07-10
		3	All items	Cardiopulmonary bypass systems-Roller blood pump GB 12260-2017		2024-07-10
		4	Appearance and structure of blood pump	Cardiopulmonary bypass systems-Roller blood pump GB 12260-2017 5.2		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
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		5	Constant current performance	Cardiopulmonary bypass systems-Roller blood pump GB 12260-2017 5.3		2024-07-10
		6	Pulsatility	Cardiopulmonary bypass systems-Roller blood pump GB 12260-2017 5.4		2024-07-10
		7	Mechanical properties	Cardiopulmonary bypass systems-Roller blood pump GB 12260-2017 5.5		2024-07-10
		8	Reflux performance	Cardiopulmonary bypass systems-Roller blood pump GB 12260-2017 5.6		2024-07-10
		9	Safety monitoring function	Cardiopulmonary bypass systems-Roller blood pump GB 12260-2017 5.7		2024-07-10
		10	Noise	Cardiopulmonary bypass systems-Roller blood pump GB 12260-2017 5.8		2024-07-10
67	Usability test of medical devices	1	All items	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016		2024-07-10
		2	General requirements	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 4.1		2024-07-10
		3	Usability engineering file	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 4.2		2024-07-10
		4	All items	Medical devices-Part 1:Application of usability engineering to medical devices IEC 62366-1:2015		2024-07-10
				Medical devices-Application of usability engineering to medical devices IEC 62366-1:2005 4.2		2024-07-10
		5	Scaling of the Usability Engineering effort	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 4.3		2024-07-10
				Medical devices-Application of usability engineering to medical devices IEC 62366-1:2005 4.3		2024-07-10
		6	Application specification	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 5.1		2024-07-10
		7	Frequently used functions	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 5.2		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
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		8	Identification of hazards and hazardous situations related to usability	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 5.3		2024-07-10
				Medical devices-Application of usability engineering to medical devices IEC 62366-1:2005 5.3		2024-07-10
		9	Primary operating function	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 5.4		2024-07-10
		10	Usability specification	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 5.5		2024-07-10
		11	Availability validation plan	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 5.6		2024-07-10
		12	User interface design and implementation	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 5.7		2024-07-10
		13	Usability verification	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 5.8		2024-07-10
		14	Usability validation	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 5.9		2024-07-10
		15	accompanying document	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 6		2024-07-10
		16	Training and materials for training	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 7		2024-07-10
		17	All items	Medical electrical equipment-Part1-6: General equipments for basic safety and essential performance-Collateral standard: Usability IEC 60601-1-6:2010		2024-07-10
		18	Conditions for application to ME EQUIPMENT	Medical electrical equipment-Part1-6: General equipments for basic safety and essential performance-Collateral standard: Usability IEC 60601-1-6:2010 4.1		2024-07-10
		19	USABILITY ENGINEERING	Medical electrical equipment-Part1-6: General equipments for		2024-07-10



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			PROCESS for ME EQUIPMENT	basic safety and essential performance-Collateral standard: Usability IEC 60601-1-6:2010 4.2		
		20	Replacement of requirement given in IEC 62366	Medical electrical equipment-Part1-6: General equipments for basic safety and essential performance-Collateral standard: Usability IEC 60601-1-6:2010 5		2024-07-10
		21	General equipments	Medical devices-Part 1:Application of usability engineering to medical devices IEC 62366-1:2015 4.1		2024-07-10
		22	Prepare use specification	Medical devices-Part 1:Application of usability engineering to medical devices IEC 62366-1:2015 5.1		2024-07-10
		23	Identify user interface characteristics related to safety and potential use errors	Medical devices-Part 1:Application of usability engineering to medical devices IEC 62366-1:2015 5.2		2024-07-10
		24	Identify and describe hazard-related use scenarios	Medical devices-Part 1:Application of usability engineering to medical devices IEC 62366-1:2015 5.4		2024-07-10
		25	Select the hazard-related use scenarios for summative evaluation	Medical devices-Part 1:Application of usability engineering to medical devices IEC 62366-1:2015 5.5		2024-07-10
		26	Establish user interface specification	Medical devices-Part 1:Application of usability engineering to medical devices IEC 62366-1:2015 5.6		2024-07-10
		27	Establish user interface evaluation plan	Medical devices-Part 1:Application of usability engineering to medical devices IEC 62366-1:2015 5.7		2024-07-10
		28	Perform user interface design, implementation	Medical devices-Part 1:Application of usability engineering to medical devices IEC 62366-1:2015 5.8		2024-07-10



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			on and formative			
		29	Perform summative evaluation of the usability of the user interface	Medical devices-Part 1:Application of usability engineering to medical devices IEC 62366-1:2015 5.9		2024-07-10
		30	User interface of unknown provenance	Medical devices-Part 1:Application of usability engineering to medical devices IEC 62366-1:2015 5.10		2024-07-10
		31	All items	Medical electrical equipment-Part1-6: General equipments for basic safety and essential performance-Collateral standard: Usability YY/T 9706.106-2021		2024-07-10
		32	Conditions for application to ME EQUIPMENT	Medical electrical equipment-Part1-6: General equipments for basic safety and essential performance-Collateral standard: Usability YY/T 9706.106-2021 4.1		2024-07-10
		33	USABILITY ENGINEERING PROCESS for ME EQUIPMENT	Medical electrical equipment-Part1-6: General equipments for basic safety and essential performance-Collateral standard: Usability YY/T 9706.106-2021 4.2		2024-07-10
		34	Replacement of requirement given inYY/T 1474-2016	Medical electrical equipment-Part1-6: General equipments for basic safety and essential performance-Collateral standard: Usability YY/T 9706.106-2021 5		2024-07-10
68	Magnetic resonance equipment	1	All items	Medical Electrical Equipment for medical imaging-Part 1: Determination of essential image quality parameters YY/T 0482-2022		2024-07-10
		2	SNR	Medical Electrical Equipment for medical imaging-Part 1: Determination of essential image quality parameters YY/T 0482-2022 4.2		2024-07-10
		3	Uniformity	Medical Electrical Equipment-Part 2-33:Particular Requirements for the Safety of Magnetic Resonance Equipment		2024-07-10



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				for Medical Diagnosis YY/T 0482-2022 4.3		
		4	Electromagnetic compatibility	Medical Electrical Equipment-Part 2-33:Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis YY/T 0482-2022 4.4		2024-07-10
		5	Two dimensional geometric distortion	Medical Electrical Equipment-Part 2-33:Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis YY/T 0482-2022 4.5		2024-07-10
		6	Spatula resolution	Medical Electrical Equipment-Part 2-33:Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis YY/T 0482-2022 4.6		2024-07-10
		7	artifact	Medical Electrical Equipment-Part 2-33:Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis YY/T 0482-2022 4.7		2024-07-10
		8	Constancy test	Medical Electrical Equipment-Part 2-33:Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis YY/T 0482-2022 5		2024-07-10
		9	All items	Medical Electrical Equipment-Part 2-33:Particular Requirements for the basic safety and essential performance of Magnetic Resonance Equipment for Medical Diagnosis YY 9706.233-2021 201.7		2024-07-10
		10	ACCOMPANYING DOCUMENTS	Medical Electrical Equipment-Part 2-33:Particular Requirements for the basic safety and essential performance of Magnetic Resonance Equipment for Medical Diagnosis YY 9706.233-2021 201.7		2024-07-10
		11	protection form electrical charge	Medical Electrical Equipment-Part 2-33:Particular Requirements for the basic safety and essential performance of Magnetic Resonance Equipment for Medical Diagnosis YY 9706.233-2021 201.8		2024-07-10
		12	protection form	Medical Electrical Equipment-Part 2-33:Particular		2024-07-10

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			mechenial	Requirements for the basic safety and essential performance of Magnetic Resonance Equipment for Medical Diagnosis YY 9706.233-2021 201.9		
		13	Pressure vessels and parts subject to pressure	Medical Electrical Equipment-Part 2-33:Particular Requirements for the basic safety and essential performance of Magnetic Resonance Equipment for Medical Diagnosis YY 9706.233-2021 201.12		2024-07-10
		14	Emergency field shut-down unit	Medical Electrical Equipment-Part 2-33:Particular Requirements for the basic safety and essential performance of Magnetic Resonance Equipment for Medical Diagnosis YY 9706.233-2021 201.15		2024-07-10
		15	Medical device system	Medical Electrical Equipment-Part 2-33:Particular Requirements for the basic safety and essential performance of Magnetic Resonance Equipment for Medical Diagnosis YY 9706.233-2021 201.16		2024-07-10
		16	Electromagnetic compatibility	Medical Electrical Equipment-Part 2-33:Particular Requirements for the basic safety and essential performance of Magnetic Resonance Equipment for Medical Diagnosis YY 9706.233-2021 202		2024-07-10
69	Traditional Chinese medicine device	1	All items	Meridian stimulator YY/T 1666-2019		2024-07-10
		2	All items	Electrical resistance detector at acupuncture points equipment YY/T 1661-2019		2024-07-10
		3	All items	Tongue features acquisition device YY/T 1488-2016		2024-07-10
		4	Working Condition	Tongue features acquisition device YY/T 1488-2016 4.1		2024-07-10
		5	Optical requirements	Tongue features acquisition device YY/T 1488-2016 4.2		2024-07-10
		6	imaging quality	Tongue features acquisition device YY/T 1488-2016 4.3		2024-07-10



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		7	Structural requirements	Tongue features acquisition device YY/T 1488-2016 4.4		2024-07-10
		8	function	Tongue features acquisition device YY/T 1488-2016 4.5		2024-07-10
		9	manual	Tongue features acquisition device YY/T 1488-2016 4.7		2024-07-10
		10	Working Condition	Pulse graph acquisition device for traditional chinese medicine YY/T 1489-2016 4.1		2024-07-10
		11	Safety limits of mechanical force	Pulse graph acquisition device for traditional chinese medicine YY/T 1489-2016 4.2		2024-07-10
		12	Accuracy of applied mechanical force	Pulse graph acquisition device for traditional chinese medicine YY/T 1489-2016 4.3		2024-07-10
		13	Accuracy of pulse pressure	Pulse graph acquisition device for traditional chinese medicine YY/T 1489-2016 4.4		2024-07-10
		14	Accuracy of pulse rate	Pulse graph acquisition device for traditional chinese medicine YY/T 1489-2016 4.5		2024-07-10
		15	Pressure relief function	Pulse graph acquisition device for traditional chinese medicine YY/T 1489-2016 4.6		2024-07-10
		16	Effective geometry of sensor	Pulse graph acquisition device for traditional chinese medicine YY/T 1489-2016 4.7		2024-07-10
		17	Time constant of dynamic amplifier	Pulse graph acquisition device for traditional chinese medicine YY/T 1489-2016 4.8		2024-07-10
		18	appearance	Pulse graph acquisition device for traditional chinese medicine YY/T 1489-2016 4.10		2024-07-10
		19	manual	Pulse graph acquisition device for traditional chinese medicine YY/T 1489-2016 4.11		2024-07-10
70	Particular requirements for the basic safety and	1	All items	Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use YY 9706.257-2021		2024-07-10



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	essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use	2	Classification of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use YY 9706.257-2021 201.6		2024-07-10
		3	ME EQUIPMENT identification, marking and documents .	Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use YY 9706.257-2021 201.7		2024-07-10
		4	Protection against electrical HAZARDS from ME EQUIPMENT	Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use YY 9706.257-2021 201.8		2024-07-10
		5	Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use YY 9706.257-2021 201.9		2024-07-10
		6	Protection against unwanted and excessive radiation HAZARDS	Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use YY 9706.257-2021 201.10		2024-07-10
		7	Protection against excessive temperatures and other HAZARDS	Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use YY 9706.257-2021 201.11		2024-07-10
		8	Accuracy of controls and instruments and protection against hazardous outputs	Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use YY 9706.257-2021 201.12		2024-07-10



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		9	HAZARDOUS SITUATIONS and fault conditions	Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use YY 9706.257-2021 201.13		2024-07-10
		10	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use YY 9706.257-2021 201.14		2024-07-10
		11	Construction of ME EQUIPMENT	Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use YY 9706.257-2021 201.15		2024-07-10
		12	ME SYSTEMS	Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use YY 9706.257-2021 201.16		2024-07-10
		13	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS.	Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use YY 9706.257-2021 201.17		2024-07-10
71	medical robots	1	All items	Medical electrical equipment-Part 2-77 :Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment YY 9706.277-2023		2024-07-10
		2	All items	Medical electrical equipment-Part 2-78: Particular requirements for the basic safety and essential performance of medical robots for rehabilitation,assessment,compensation or alleviation YY 9706.278-2023		2025-07-18
72	Assisted surgical medical	1	All items	Assisted surgical medical equipment and assisted surgical medical system employing robotictchnology YY/T 1712-2021		2024-07-10



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	equipment and assisted surgical medical system employing robotictchnology	2	master-slave operationl RA equipment accuracy	Assisted surgical medical equipment and assisted surgical medical system employing robotictchnology YY/T 1712-2021 4.2		2024-07-10
		3	Positioning accuracy of navigation guided RA equipment	Assisted surgical medical equipment and assisted surgical medical system employing robotictchnology YY/T 1712-2021 4.3		2024-07-10
		4	maximumspace and effective workspace	Assisted surgical medical equipment and assisted surgical medical system employing robotictchnology YY/T 1712-2021 4.4		2024-07-10
		5	Load carrying capacity of manipulator	Assisted surgical medical equipment and assisted surgical medical system employing robotictchnology YY/T 1712-2021 4.5		2024-07-10
		6	master-slave operationl delay time	Assisted surgical medical equipment and assisted surgical medical system employing robotictchnology YY/T 1712-2021 4.6		2024-07-10
		7	environmental test	Assisted surgical medical equipment and assisted surgical medical system employing robotictchnology YY/T 1712-2021 4.7		2024-07-10
		8	safety requirements	Assisted surgical medical equipment and assisted surgical medical system employing robotictchnology YY/T 1712-2021 4.8		2024-07-10
73	Haemodialysis equipment	1	All items	Medical electrical equipment-Part 2-16: Particular requirements for the basicsafety and essential performance of haemodialysis , haemodiafiltration andhaemofiltration equipment GB 9706.216-2021		2024-07-10
		2	All items	Medical electrical equipment-Part 2-39 : Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment GB 9706.239-2021		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
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74	Medical device software	3	All items	Haemodialysis equipment 2010- YY 0054-2010		2024-07-10
		4	All items	Continuous blood purification equipment YY 0645-2018		2024-07-10
		1	All items	Software engineering-Software product Quality Requirements and Evaluation(SQuaRE)-Requirements for quality of Commercial Off-The-Self(COTS)software product and instructions for testing GB/T 25000.51-2016		2024-07-10
		2	All items	Medical electrical equipment--Part 1-4:General requirements for safety--collateral standard:programmable electrical medical systems YY/T 0708-2009		2024-07-10
		3	All items	Medical device software--Software life cycle processes YY/T 0664-2020		2024-07-10
		4	All items	Special technical requirements for medical image storage and transmission system software YY/T 1861-2023		2024-07-10
		5	All items	Special technical requirements for coronary artery CT image processing software YY/T 1862-2023		2024-07-10
		6	All items	Health software—Part 1:General requirements for product safety GB/T 42984.1-2023		2025-07-18
		7	Health software requirements for products	Health software—Part 1:General requirements for product safety GB/T 42984.1-2023 4		2025-07-18
		8	Health software - software life cycle processes	Health software—Part 1:General requirements for product safety GB/T 42984.1-2023 5		2025-07-18
		9	Health software products validation	Health software—Part 1:General requirements for product safety GB/T 42984.1-2023 6		2025-07-18
		10	Health software product identification and accompanying	Health software—Part 1:General requirements for product safety GB/T 42984.1-2023 7		2025-07-18

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		№	Item/ Parameter			
			documents			
		11	Post launch activities for health software products	Health software—Part 1:General requirements for product safety GB/T 42984.1-2023 8		2025-07-18
75	Industrial,scientific and medical robots	1	All items	Industrial,scientific and medical robots—Electromagnetic compatibility—Immunity tests GB/T 38326-2019		2024-07-10
		2	Electrostatic discharge immunity test	Industrial,scientific and medical robots—Electromagnetic compatibility—Immunity tests GB/T 38326-2019		2024-07-10
		3	Electrical fast transient/burst immunity test	Industrial,scientific and medical robots—Electromagnetic compatibility—Immunity tests GB/T 38326-2019		2024-07-10
		4	Surge immunity test	Industrial,scientific and medical robots—Electromagnetic compatibility—Immunity tests GB/T 38326-2019		2024-07-10
		5	conducted disturbances, induced by radio-frequency fields	Industrial,scientific and medical robots—Electromagnetic compatibility—Immunity tests GB/T 38326-2019		2024-07-10
		6	conducted disturbances, induced by radio-frequency fields	Industrial,scientific and medical robots—Electromagnetic compatibility—Immunity tests GB/T 38326-2019		2024-07-10
		7	Power frequency magnetic field immunity	Industrial,scientific and medical robots—Electromagnetic compatibility—Immunity tests GB/T 38326-2019		2024-07-10
		8	Voltage dips, short interruptions and voltage variations	Industrial,scientific and medical robots—Electromagnetic compatibility—Immunity tests GB/T 38326-2019		2024-07-10
		9	CE	Industrial,scientific and medical robots—Electromagnetic		2024-07-10

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				compatibility—Emission methods of measurement and limits GB/T 38336-2019		
		10	RE (30MHz~1GHz)	Industrial,scientific and medical robots—Electromagnetic compatibility—Emission methods of measurement and limits GB/T 38336-2019		2024-07-10
		11	RE (1GHz~6GHz)	Industrial,scientific and medical robots—Electromagnetic compatibility—Emission methods of measurement and limits GB/T 38336-2019		2024-07-10
		12	harmonic current	Industrial,scientific and medical robots—Electromagnetic compatibility—Emission methods of measurement and limits GB/T 38336-2019		2024-07-10
		13	voltage fluctuations and flicker	Industrial,scientific and medical robots—Electromagnetic compatibility—Emission methods of measurement and limits GB/T 38336-2019		2024-07-10
76	Electromagnetic compatibility of electrically powered wheelchairs	1	All items	Wheelchairs-Part 21:Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters and battery chargers GB/T 18029.21-2012		2024-07-10
		2	CE	Wheelchairs-Part 21:Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters and battery chargers GB/T 18029.21-2012 5.3.1、5.4.1		2024-07-10
		3	RE (30MHz~1GHz)	Wheelchairs-Part 21:Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters and battery chargers GB/T 18029.21-2012 5.2.1、5.3.2、5.4.2		2024-07-10
		4	harmonic current	Wheelchairs-Part 21:Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters and battery chargers GB/T 18029.21-2012 5.3.3、5.4.3		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	voltage fluctuations and flicker	Wheelchairs-Part 21:Requirements and test methods for electromagnetic compatibility of eletrically powered wheelchairs and scooters and battery chargers GB/T 18029.21-2012 5.3.4、5.4.4		2024-07-10
		6	Electrostatic discharge immunity test	Wheelchairs-Part 21:Requirements and test methods for electromagnetic compatibility of eletrically powered wheelchairs and scooters and battery chargers GB/T 18029.21-2012 5.2.2、5.3.5、5.4.5		2024-07-10
		7	RS	Wheelchairs-Part 21:Requirements and test methods for electromagnetic compatibility of eletrically powered wheelchairs and scooters and battery chargers GB/T 18029.21-2012 5.2.3、5.3.6、5.4.6		2024-07-10
		8	Electrical fast transientburst immunity test	Wheelchairs-Part 21:Requirements and test methods for electromagnetic compatibility of eletrically powered wheelchairs and scooters and battery chargers GB/T 18029.21-2012 5.3.7、5.4.7		2024-07-10
		9	Surge immunity test	Wheelchairs-Part 21:Requirements and test methods for electromagnetic compatibility of eletrically powered wheelchairs and scooters and battery chargers GB/T 18029.21-2012 5.3.8、5.4.8		2024-07-10
		10	conducted disturbances, induced by radio-frequency fields	Wheelchairs-Part 21:Requirements and test methods for electromagnetic compatibility of eletrically powered wheelchairs and scooters and battery chargers GB/T 18029.21-2012 5.3.9、5.4.9		2024-07-10
		11	Voltage dips, short interruptions and voltage variations	Wheelchairs-Part 21:Requirements and test methods for electromagnetic compatibility of eletrically powered wheelchairs and scooters and battery chargers GB/T 18029.21-2012 5.3.10、5.4.10		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
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		12	Power frequency magnetic field immunity	Wheelchairs-Part 21:Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters and battery chargers GB/T 18029.21-2012 5.2.4		2024-07-10
77	Medical electrical equipment Electromagnetic compatibility	1	harmonic current	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 0505-2012	Use only when quoted or requested by customer.	2024-07-10
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2024-07-10
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014	Use only when quoted or requested by customer.	2024-07-10
				Electromagnetic compatibility (EMC) -- Part 3-2: Limits -- Limits for harmonic current emissions (equipment input current ≤ 16 A per phase GB 17625.1-2022	Except for three phases equipment	2024-07-10
				Electromagnetic compatibility (EMC) -- Part 3-2: Limits -- Limits for harmonic current emissions (equipment input current ≤ 17 A per phase IEC 61000-3-2:2014		2024-07-10
		2	voltage fluctuations and flicker	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 0505-2012	Use only when quoted or requested by	2024-07-10



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					customer.	
		3	voltage fluctuations and flicker	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2024-07-10
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014	Use only when quoted or as agreed in a specific contract	2024-07-10
				Electromagnetic compatibility(EMC)-Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤16 A per phase and not subject to conditional connection GB/T 17625.2-2007		2024-07-10
				Electromagnetic compatibility(EMC)-Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤16 A per phase and not subject to conditional connection IEC 61000-3-3:2013		2024-07-10
		4	Electrostatic discharge immunity test	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 0505-2012	Use only when quoted or requested by customer.	2024-07-10
		5	Electrostatic discharge immunity test	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2024-07-10



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		№	Item/ Parameter			
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014	Use only when quoted or requested by customer.	2024-07-10
				Testing and measuring techniques - Electrostatic discharge immunity test GB/T 17626.2-2018		2024-07-10
				Testing and measuring techniques - Electrostatic discharge immunity test IEC 61000-4-2:2008		2024-07-10
				Testing and measuring techniques - Electrostatic discharge immunity test IEC 61000-4-2:2001	Use only when quoted or requested by customer.	2024-07-10
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2024-07-10
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity CISPR 14-2:2015		2024-07-10
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2024-07-10
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2024-07-10
		6	Electrical fast transient/burst immunity test	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 0505-2012	Use only when quoted or requested	2024-07-10



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		№	Item/ Parameter			
					by customer.	
		7	Electrical fast transient/burst immunity test	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2024-07-10
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014	Use only when quoted or requested by customer.	2024-07-10
				Testing and measurement techniques -- Electrical fast transient/burst immunity test GB/T 17626.4-2018		2024-07-10
				Testing and measurement techniques -- Electrical fast transient/burst immunity test IEC 61000-4-4:2012		2024-07-10
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2024-07-10
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity CISPR 14-2:2015		2024-07-10
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2024-07-10
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2024-07-10
		8	Surge immunity test	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 0505-2012	Use only when quoted or requested by	2024-07-10



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					customer.	
		9	Surge immunity test	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2024-07-10
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014	Use only when quoted or requested by customer.	2024-07-10
				Testing and measurement techniques - Surge immunity test GB/T 17626.5-2019		2024-07-10
				Testing and measurement techniques - Surge immunity test IEC 61000-4-5:2014		2024-07-10
				Testing and measurement techniques - Surge immunity test IEC 61000-4-5:2005	Use only when quoted or requested by customer.	2024-07-10
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2024-07-10
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity CISPR 14-2:2015		2024-07-10
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2024-07-10



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				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2024-07-10
		10	conducted disturbances, induced by radio-frequency fields	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 0505-2012	Use only when quoted or requested by customer.	2024-07-10
		11	conducted disturbances, induced by radio-frequency fields	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2024-07-10
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014	Use only when quoted or requested by customer.	2024-07-10
				Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields GB/T 17626.6-2017		2024-07-10
				Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields IEC 61000-4-6:2013		2024-07-10
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2024-07-10
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity CISPR 14-2:2015		2024-07-10



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		№	Item/ Parameter			
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2024-07-10
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2024-07-10
		12	Voltage dips, short interruptions and voltage variations	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 0505-2012	Use only when quoted or requested by customer.	2024-07-10
		13	Voltage dips, short interruptions and voltage variations	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2024-07-10
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014	Use only when quoted or requested by customer.	2024-07-10
				Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests GB/T 17626.11-2023		2024-07-10
				Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests IEC 61000-4-11: 2004	Use only when quoted or requested by customer.	2024-07-10
				Voltage dips, short interruptions and voltage variations immunity tests for equipment with input current more than 16 A per phase		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				GB/T 17626.34-2012		
				Voltage dips, short interruptions and voltage variations immunity tests for equipment with input current more than 16 A per phase IEC 61000-4-34:2009		2024-07-10
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2024-07-10
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity CISPR 14-2:2015		2024-07-10
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2024-07-10
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2024-07-10
		14	Power frequency magnetic field immunity	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 0505-2012	Use only when quoted or requested by customer.	2024-07-10
		15	Power frequency magnetic field immunity	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2024-07-10
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014	Use only when quoted or requested by customer.	2024-07-10



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		№	Item/ Parameter			
				Testing and measurement techniques - Power frequency magnetic field immunity test GB/T 17626.8-2006		2024-07-10
				Testing and measurement techniques - Power frequency magnetic field immunity test IEC 61000-4-8:2009		2024-07-10
				Testing and measurement techniques - Power frequency magnetic field immunity test IEC 61000-4-8:2001	Use only when quoted or requested by customer.	2024-07-10
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2024-07-10
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2024-07-10
		16	CE	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 0505-2012	Use only when quoted or requested by customer.	2024-07-10
		17	CE	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2024-07-10
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014	Use only when quoted or requested by customer.	2024-07-10



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				Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emissio GB 4343.1-2018		2024-07-10
				Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emissio CISPR 14-1:2011		2024-07-10
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement GB 4824-2019	Except for low voltage DC mains port	2024-07-10
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement CISPR 11:2016		2024-07-10
				Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement GB/T 9254.1-2021		2024-07-10
				Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement CISPR 32:2015		2024-07-10
				Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment GB/T 17743-2021		2024-07-10
				Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment CISPR 15: 2018		2024-07-10
		18	RE (1GHz~18GHz)	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 0505-2012	Use only when quoted or requested by	2024-07-10



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					customer.	
		19	RE (1GHz~18GHz)	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2024-07-10
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014	Use only when quoted or requested by customer.	2024-07-10
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement GB 4824-2019		2024-07-10
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement CISPR 11:2016		2024-07-10
				Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement GB/T 9254.1-2021		2024-07-10
				Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement CISPR 32:2015		2024-07-10
		20	RE (30MHz~1GHz)	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 0505-2012	Use only when quoted or requested by customer.	2024-07-10
		21	RE	Medical electrical equipment - Part 1 - 2: General requirements		2024-07-10



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			(30MHz~1GHz)	for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014	Use only when quoted or requested by customer.	2024-07-10
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement GB 4824-2019		2024-07-10
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement CISPR 11:2016		2024-07-10
				Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement GB/T 9254.1-2021		2024-07-10
				Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement CISPR 32:2015		2024-07-10
				Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emissio GB 4343.1-2018		2024-07-10
				Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emissio CISPR 14-1:2011		2024-07-10
				Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment GB/T 17743-2021		2024-07-10



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		№	Item/ Parameter			
				Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment CISPR 15: 2018		2024-07-10
		22	RE (9kHz~31MHz)	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 0505-2012	Use only when quoted or requested by customer.	2024-07-10
		23	RE (9kHz~30MHz)	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2024-07-10
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014	Use only when quoted or requested by customer.	2024-07-10
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement GB 4824-2019		2024-07-10
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement CISPR 11:2016		2024-07-10
				Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment GB/T 17743-2021		2024-07-10
				Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment CISPR 15: 2018		2024-07-10



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		24	click	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 0505-2012	Use only when quoted or requested by customer.	2024-07-10
		25	click	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2024-07-10
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014	Use only when quoted or requested by customer.	2024-07-10
				Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emissio GB 4343.1-2018		2024-07-10
				Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emissio CISPR 14-1:2011		2024-07-10
		26	disturbance power	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 0505-2012	Use only when quoted or requested by customer.	2024-07-10
		27	disturbance power	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2024-07-10



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				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014	Use only when quoted or requested by customer.	2024-07-10
				Electromagnetic compatibility -- Requirements for household appliances, electric tools and similar apparatus -- Part 1: Emissio GB 4343.1-2018		2024-07-10
				Electromagnetic compatibility -- Requirements for household appliances, electric tools and similar apparatus -- Part 1: Emissio CISPR 14-1:2011		2024-07-10
		28	RS	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 0505-2012	Use only when quoted or requested by customer.	2024-07-10
		29	RS	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2024-07-10
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014	Use only when quoted or requested by customer.	2024-07-10
				Electromagnetic compatibility (EMC) -- Part 4-3: Testing and measurement techniques -- Radiated, radio-frequency, electromagnetic field immunity test GB/T 17626.3-2023		2024-07-10



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				Electromagnetic compatibility (EMC) -- Part 4-4: Testing and measurement techniques -- Radiated, radio-frequency, electromagnetic field immunity test IEC 61000-4-3:2010	Use only when quoted or requested by customer.	2024-07-10
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2024-07-10
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 3: Immunity CISPR 14-2:2015		2024-07-10
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2024-07-10
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2024-07-10
78	radiotherapy treatment planning systems	1	All items	Medical electrical equipment radiotherapy treatment planning systems YY 0637-2013		2024-07-10
79	Artificial Intelligence Medical Device	1	All items	Artificial intelligence medical device—Quality requirements and evaluation—Part 3: General requirements for data annotation YY/T 1833.3-2022		2024-07-10
		2	All items	Artificial intelligence medical device—Computer assisted analysis software for pulmonary images—Algorithm performance test methods YY/T 1858-2022		2024-07-10
		3	All items	Artificial intelligence medical device—Quality requirements and evaluation—Part 2: General requirements for datasets YY/T 1833.2-2022		2024-07-10



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		4	All items	IEEE Recommended Practice for the Quality Management of Datasets for Medical Artificial Intelligence IEEE 2801-2022		2024-07-10
		5	All items	Artificial intelligence medical device — Quality requirement and evaluation — Part 4: traceability YY/T 1833.4-2023		2025-07-18
		6	Requirement on traceability	Artificial intelligence medical device — Quality requirement and evaluation — Part 4: traceability YY/T 1833.4-2023 4		2025-07-18
		7	Evaluation methods	Artificial intelligence medical device — Quality requirement and evaluation — Part 4: traceability YY/T 1833.4-2023 5		2025-07-18
		8	All items	Artificial intelligence medical device — Quality requirement and evaluation — Part 5: pretraining model YY/T 1833.5-2024		2025-07-18
		9	Documentation for pretraining model	Artificial intelligence medical device — Quality requirement and evaluation — Part 5: pretraining model YY/T 1833.5-2024 4		2025-07-18
		10	Quality characteristics for pretraining model	Artificial intelligence medical device — Quality requirement and evaluation — Part 5: pretraining model YY/T 1833.5-2024 5		2025-07-18
		11	Evaluation methods	Artificial intelligence medical device — Quality requirement and evaluation — Part 5: pretraining model YY/T 1833.5-2024 6		2025-07-18
		12	All items	Artificial intelligence medical device — Specific requirement for datasets: color fundus images of diabetic retinopathy YY/T 1949-2024		2025-07-18
		13	Requirement for dataset manual	Artificial intelligence medical device — Specific requirement for datasets: color fundus images of diabetic retinopathy YY/T 1949-2024 4		2025-07-18
		14	Quality characteristics for dataset	Artificial intelligence medical device — Specific requirement for datasets: color fundus images of diabetic retinopathy YY/T 1949-2024 5		2025-07-18
		15	Evaluation methods	Artificial intelligence medical device — Specific requirement for datasets: color fundus images of diabetic retinopathy YY/T		2025-07-18



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				1949-2024 6		
80	Cybersecurity for Medical Electrical Equipment	1	All items	Basic Requirements of Cybersecurity for Medical Electrical Equipment YY /T1843-2022		2024-07-10
81	Measurement control and laboratory use—EMC	1	harmonic current	Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 1: General requirements GB/T 18268.1-2010		2024-07-10
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 1: General requirements IEC 61326-1:2005(第 1 版)		2024-07-10
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 2-6: Particular requirements -- In vitro diagnostic (IVD) medical equipment GB/T 18268.26-2010		2024-07-10
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 2-6: Particular requirements -- In vitro diagnostic (IVD) medical equipment IEC 61326-2-6:2005		2024-07-10
				Electromagnetic compatibility (EMC) -- Part 3-2: Limits -- Limits for harmonic current emissions (equipment input current ≤ 16 A per phase GB 17625.1-2022		2024-07-10
				Electromagnetic compatibility (EMC) -- Part 3-2: Limits -- Limits for harmonic current emissions (equipment input current ≤ 17 A per phase IEC 61000-3-2:2014		2024-07-10
		2	voltage fluctuations and flicker	Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 1: General requirements GB/T 18268.1-2010		2024-07-10
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 1: General requirements IEC 61326-1:2005(第 1 版)		2024-07-10



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				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 2-6: Particular requirements -- In vitro diagnostic (IVD) medical equipment GB/T 18268.26-2010		2024-07-10
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 2-6: Particular requirements -- In vitro diagnostic (IVD) medical equipment IEC 61326-2-6:2005		2024-07-10
				Electromagnetic compatibility(EMC)-Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤16 A per phase and not subject to conditional connection GB/T 17625.2-2007		2024-07-10
				Electromagnetic compatibility(EMC)-Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤16 A per phase and not subject to conditional connection IEC 61000-3-3:2013		2024-07-10
		3	Electrostatic discharge immunity test	Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 1: General requirements GB/T 18268.1-2010		2024-07-10
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 1: General requirements IEC 61326-1:2005(第1版)		2024-07-10
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 2-6: Particular requirements -- In vitro diagnostic (IVD) medical equipment GB/T 18268.26-2010		2024-07-10
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 2-6: Particular requirements -- In vitro diagnostic (IVD) medical equipment IEC 61326-2-6:2005		2024-07-10
				Testing and measuring techniques - Electrostatic discharge immunity test GB/T 17626.2-2018		2024-07-10



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				Testing and measuring techniques - Electrostatic discharge immunity test IEC 61000-4-2:2008		2024-07-10
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2024-07-10
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity CISPR 14-2:2015		2024-07-10
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2024-07-10
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2024-07-10
		4	Electrical fast transient/burst immunity test	Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements GB/T 18268.1-2010		2024-07-10
				Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements IEC 61326-1:2005(第1版)		2024-07-10
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 2-6: Particular requirements -- In vitro diagnostic (IVD) medical equipment GB/T 18268.26-2010		2024-07-10
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 2-6: Particular requirements -- In vitro diagnostic (IVD) medical equipment IEC 61326-2-6:2005		2024-07-10
				Testing and measurement techniques -- Electrical fast transient/burst immunity test GB/T 17626.4-2018		2024-07-10
				Testing and measurement techniques -- Electrical fast transient/burst immunity test IEC 61000-4-4:2012		2024-07-10
				Electromagnetic Compatibility—Requirements For Household		2024-07-10



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				Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity CISPR 14-2:2015		2024-07-10
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2024-07-10
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2024-07-10
		5	Surge immunity test	Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements GB/T 18268.1-2010		2024-07-10
				Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements IEC 61326-1:2005(第 1 版)		2024-07-10
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 2-6: Particular requirements -- In vitro diagnostic (IVD) medical equipment GB/T 18268.26-2010		2024-07-10
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 2-6: Particular requirements -- In vitro diagnostic (IVD) medical equipment IEC 61326-2-6:2005		2024-07-10
				Testing and measurement techniques - Surge immunity test GB/T 17626.5-2019		2024-07-10
				Testing and measurement techniques - Surge immunity test IEC 61000-4-5:2014		2024-07-10
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2024-07-10
				Electromagnetic Compatibility—Requirements For Household		2024-07-10



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				Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity CISPR 14-2:2015		
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2024-07-10
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2024-07-10
		6	conducted disturbances, induced by radio-frequency fields	Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements GB/T 18268.1-2010		2024-07-10
				Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements IEC 61326-1:2005(第1版)		2024-07-10
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 2-6: Particular requirements -- In vitro diagnostic (IVD) medical equipment GB/T 18268.26-2010		2024-07-10
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 2-6: Particular requirements -- In vitro diagnostic (IVD) medical equipment IEC 61326-2-6:2005		2024-07-10
				Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields GB/T 17626.6-2017		2024-07-10
				Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields IEC 61000-4-6:2013		2024-07-10
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2024-07-10
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2:		2024-07-10



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				Immunity CISPR 14-2:2015		
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2024-07-10
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2024-07-10
		7	Voltage dips, short interruptions and voltage variations	Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements GB/T 18268.1-2010		2024-07-10
				Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements IEC 61326-1:2005(第 1 版)		2024-07-10
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 2-6: Particular requirements -- In vitro diagnostic (IVD) medical equipment GB/T 18268.26-2010		2024-07-10
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 2-6: Particular requirements -- In vitro diagnostic (IVD) medical equipment IEC 61326-2-6:2005		2024-07-10
				Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests GB/T 17626.11-2023		2024-07-10
				Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests IEC 61000-4-11: 2004		2024-07-10
				Voltage dips, short interruptions and voltage variations immunity tests for equipment with input current more than 16 A per phase GB/T 17626.34-2012		2024-07-10
				Voltage dips, short interruptions and voltage variations immunity tests for equipment with input current more than 16 A per phase IEC 61000-4-34:2009		2024-07-10



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				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2024-07-10
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity CISPR 14-2:2015		2024-07-10
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2024-07-10
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2024-07-10
		8	Power frequency magnetic field immunity	Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements GB/T 18268.1-2010		2024-07-10
				Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements IEC 61326-1:2005(第 1 版)		2024-07-10
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 2-6: Particular requirements -- In vitro diagnostic (IVD) medical equipment GB/T 18268.26-2010		2024-07-10
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 2-6: Particular requirements -- In vitro diagnostic (IVD) medical equipment IEC 61326-2-6:2005		2024-07-10
				Testing and measurement techniques - Power frequency magnetic field immunity test GB/T 17626.8-2006		2024-07-10
				Testing and measurement techniques - Power frequency magnetic field immunity test IEC 61000-4-8:2009		2024-07-10
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2024-07-10
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2024-07-10



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82	Nucleic acid extraction system	1	All items	Nucleic acid extraction system YY/T 1908-2023		2024-07-10
		2	appearance	Nucleic acid extraction system YY/T 1908-2023 4.1		2024-07-10
		3	Sample addition accuracy and repeatability	Nucleic acid extraction system YY/T 1908-2023 4.2		2024-07-10
		4	Motion performance of robotic arm	Nucleic acid extraction system YY/T 1908-2023 4.3		2024-07-10
		5	Temperature control	Nucleic acid extraction system YY/T 1908-2023 4.4		2024-07-10
		6	Surface flux density	Nucleic acid extraction system YY/T 1908-2023 4.5		2024-07-10
		7	Static pressure difference	Nucleic acid extraction system YY/T 1908-2023 4.6		2024-07-10
		8	Ultraviolet lamp	Nucleic acid extraction system YY/T 1908-2023 4.7		2024-07-10
		9	Bead residue	Nucleic acid extraction system YY/T 1908-2023 4.8		2024-07-10
		10	Nucleic acid contamination	Nucleic acid extraction system YY/T 1908-2023 4.9		2024-07-10
		11	Consistency of nucleic acid extraction	Nucleic acid extraction system YY/T 1908-2023 4.10		2024-07-10
		12	Software function	Nucleic acid extraction system YY/T 1908-2023 4.11		2024-07-10
		13	Other functions	Nucleic acid extraction system YY/T 1908-2023 4.12		2024-07-10
83	Digital polymerase chain reaction	1	All items	Digital polymerase chain reaction analysis system YY/T 1918-2023		2024-07-10



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	analysis system	2	Appearance requirement	Digital polymerase chain reaction analysis system YY/T 1918-2023 5.1		2024-07-10
		3	Reaction unit uniformity	Digital polymerase chain reaction analysis system YY/T 1918-2023 5.2		2024-07-10
		4	Temperature control	Digital polymerase chain reaction analysis system YY/T 1918-2023 5.3		2024-07-10
		5	Fluorescence intensity repeatability	Digital polymerase chain reaction analysis system YY/T 1918-2023 5.4		2024-07-10
		6	Fluorescent interference	Digital polymerase chain reaction analysis system YY/T 1918-2023 5.5		2024-07-10
		7	Sample detection accuracy	Digital polymerase chain reaction analysis system YY/T 1918-2023 5.6		2024-07-10
		8	Sample detection repeatability	Digital polymerase chain reaction analysis system YY/T 1918-2023 5.7		2024-07-10
		9	Sample linearity	Digital polymerase chain reaction analysis system YY/T 1918-2023 5.8		2024-07-10
		10	Fluorescence linearity	Digital polymerase chain reaction analysis system YY/T 1918-2023 5.9		2024-07-10
		11	Software function	Digital polymerase chain reaction analysis system YY/T 1918-2023 5.10		2024-07-10
84	Medical carbon dioxide incubator	1	All items	Medical carbon dioxide incubator YY/T 1621-2018		2024-07-10
		2	Working environment conditions	Medical carbon dioxide incubator YY/T 1621-2018 4.1		2024-07-10
		3	Appearance and structure	Medical carbon dioxide incubator YY/T 1621-2018 4.2		2024-07-10
		4	Temperature display and control	Medical carbon dioxide incubator YY/T 1621-2018 4.3		2024-07-10



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			performance			
		5	Carbon dioxide concentration display and control performance	Medical carbon dioxide incubator YY/T 1621-2018 4.4		2024-07-10
		6	Relative humidity control performance	Medical carbon dioxide incubator YY/T 1621-2018 4.5		2024-07-10
		7	Noise	Medical carbon dioxide incubator YY/T 1621-2018 4.6		2024-07-10
		8	Alarm	Medical carbon dioxide incubator YY/T 1621-2018 4.7		2024-07-10
		9	Door opening recovery time	Medical carbon dioxide incubator YY/T 1621-2018 4.8		2024-07-10
		10	Thermal insulating property	Medical carbon dioxide incubator YY/T 1621-2018 4.9		2024-07-10
		11	Prevent the generation of condensate water	Medical carbon dioxide incubator YY/T 1621-2018 4.10		2024-07-10
		12	Over temperature protection	Medical carbon dioxide incubator YY/T 1621-2018 4.11		2024-07-10
85	Oral treatment equipment	1	All items	Dentistry—Operating lights YY/T 1120-2021		2024-07-10
		2	General requirements	Dentistry—Operating lights YY/T 1120-2021 5.1		2024-07-10
		3	Adjustment range of illumination	Dentistry—Operating lights YY/T 1120-2021 5.2.1		2024-07-10
		4	Lighting spot	Dentistry—Operating lights YY/T 1120-2021 5.2.2		2024-07-10
		5	The illuminance on the patient's eyes	Dentistry—Operating lights YY/T 1120-2021 5.2.3		2024-07-10



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		6	Chromaticity uniformity	Dentistry—Operating lights YY/T 1120-2021 5.2.4		2024-07-10
		7	Correlated color temperature	Dentistry—Operating lights YY/T 1120-2021 5.2.5		2024-07-10
		8	Radiation heat inside the spot	Dentistry—Operating lights YY/T 1120-2021 5.2.6		2024-07-10
		9	shadow	Dentistry—Operating lights YY/T 1120-2021 5.2.7		2024-07-10
		10	Color rendering index	Dentistry—Operating lights YY/T 1120-2021 5.2.8		2024-07-10
		11	UV irradiance	Dentistry—Operating lights YY/T 1120-2021 5.2.9		2024-07-10
		12	Compatibility with UV cured repair materials	Dentistry—Operating lights YY/T 1120-2021 5.2.10		2024-07-10
		13	Moving parts	Dentistry—Operating lights YY/T 1120-2021 5.3.1		2024-07-10
		14	Operation control	Dentistry—Operating lights YY/T 1120-2021 5.3.2		2024-07-10
		15	turn round	Dentistry—Operating lights YY/T 1120-2021 5.3.3		2024-07-10
		16	General stability	Dentistry—Operating lights YY/T 1120-2021 5.3.4.1		2024-07-10
		17	Stability after position adjustment	Dentistry—Operating lights YY/T 1120-2021 5.3.4.2		2024-07-10
		18	Control force	Dentistry—Operating lights YY/T 1120-2021 5.3.4.3		2024-07-10
		19	mechanical strength	Dentistry—Operating lights YY/T 1120-2021 5.3.4.4		2024-07-10
		20	Spatter	Dentistry—Operating lights YY/T 1120-2021 5.3.5		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		21	suspended mass	Dentistry—Operating lights YY/T 1120-2021 5.3.6		2024-07-10
		22	Cleaning and disinfection	Dentistry—Operating lights YY/T 1120-2021 5.4		2024-07-10
		23	Electrical safety requirements	Dentistry—Operating lights YY/T 1120-2021 5.5		2024-07-10
		24	Availability requirements	Dentistry—Operating lights YY/T 1120-2021 5.6		2024-07-10
		25	Manufacturer's instructions	Dentistry—Operating lights YY/T 1120-2021 8		2024-07-10
		26	package	Dentistry—Operating lights YY/T 1120-2021 9		2024-07-10
		27	mark	Dentistry—Operating lights YY/T 1120-2021 10		2024-07-10
86	Physiological parameter analysis and measurement equipment	1	All items	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023	except for 201.102	2024-07-10
		2	General requirements	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 201.4		2024-07-10
		3	General requirements for ME equipment testing	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 201.5		2024-07-10
		4	Classification of ME devices and ME systems	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 201.6		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	ME device identification, labeling, and documentation	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 201.7		2024-07-10
		6	Protection of ME equipment against electric shock hazards	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 201.8		2024-07-10
		7	Protection of ME equipment and ME systems against mechanical	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 201.9		2024-07-10
		8	Protection against unwanted or excessive radiation hazards (sources)	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 201.10		2024-07-10
		9	Protection against ultra mild and other hazards (sources)	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 201.11		2024-07-10
		10	Accuracy of controllers and instruments and protection against hazardous outputs	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 201.12		2024-07-10
		11	Dangerous situations and fault states of ME equipment	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 201.13		2024-07-10
		12	Programmable	Medical electrical equipment—Part 2-56:Particular requirements		2024-07-10

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			Medical Electrical Systems (PEMS)	for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 201.14		
		13	The structure of ME equipment	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 201.15		2024-07-10
		14	ME system	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 201.16		2024-07-10
		15	Electromagnetic compatibility of ME equipment and ME systems	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 201.17		2024-07-10
		16	Laboratory performance requirements	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 201.101		2024-07-10
		17	Probe, probe cable extension and probe sleeve	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 201.103		2024-07-10
		18	Electromagnetic compatibility requirements and tests	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 202		2024-07-10
		19	usability	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				2023 206		
		20	General requirements, testing, and guidelines for alarm systems in medical electrical equipment and medical electrical systems	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 208		2024-07-10
		21	Requirements for medical electrical equipment and systems used in home care environments	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 211		2024-07-10
		22	Requirements for medical electrical equipment and medical electrical systems used in emergency medical service environments	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 212		2024-07-10
87	orthopaedic surgical navigation equipment employing robotic	1	All items	Requirements and test methods for orthopaedic surgical navigation equipment employing robotic technology YY/T 1901-2023		2024-07-10
		2	General requirements	Requirements and test methods for orthopaedic surgical navigation equipment employing robotic technology YY/T 1901-2023 4.1		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	technology	3	robotic manipulator positioning equipment performance	Requirements and test methods for orthopaedic surgical navigation equipment employing robotic technology YY/T 1901-2023 4.2		2024-07-10
		4	tracker performance	Requirements and test methods for orthopaedic surgical navigation equipment employing robotic technology YY/T 1901-2023 4.3		2024-07-10
		5	system performance	Requirements and test methods for orthopaedic surgical navigation equipment employing robotic technology YY/T 1901-2023 4.4		2024-07-10
		6	Installation repeatability	Requirements and test methods for orthopaedic surgical navigation equipment employing robotic technology YY/T 1901-2023 4.5		2024-07-10
		7	protection functions	Requirements and test methods for orthopaedic surgical navigation equipment employing robotic technology YY/T 1901-2023 4.6		2024-07-10
		8	liquid cooling	Requirements and test methods for orthopaedic surgical navigation equipment employing robotic technology YY/T 1901-2023 4.8		2024-07-10
		9	software requirements	Requirements and test methods for orthopaedic surgical navigation equipment employing robotic technology YY/T 1901-2023 4.10		2024-07-10
88	Intravascular optical coherence tomograph	1	All items	Intravascular optical coherence tomograph YY/T 1895-2023		2024-07-10
		2	light source	Intravascular optical coherence tomograph YY/T 1895-2023 4.1		2024-07-10
		3	resolution	Intravascular optical coherence tomograph YY/T 1895-2023 4.2		2024-07-10
		4	sensitivity	Intravascular optical coherence tomograph YY/T 1895-2023 4.3		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	scanning performance	Intravascular optical coherence tomograph YY/T 1895-2023 4.4		2024-07-10
		6	measurement performance	Intravascular optical coherence tomograph YY/T 1895-2023 4.5		2024-07-10
		7	pullback performance	Intravascular optical coherence tomograph YY/T 1895-2023 4.6		2024-07-10
		8	intravascular imaging catheter	Intravascular optical coherence tomograph YY/T 1895-2023 4.7		2024-07-10
		9	Connection between catheter connection controller and intravascular imaging catheter	Intravascular optical coherence tomograph YY/T 1895-2023 4.8		2024-07-10
89	LEDs	1	All items	Optical radiation safety of LEDs — Part 1: Safety requirements and classification GB/T 39771.1-2021		2024-07-10
		2	Optical radiation safety limiting value	Optical radiation safety of LEDs — Part 1: Safety requirements and classification GB/T 39771.1-2021 4		2024-07-10
		3	grade classification	Optical radiation safety of LEDs — Part 1: Safety requirements and classification GB/T 39771.1-2021 5		2024-07-10
		4	general requirements	Optical radiation safety of LEDs--Part 2:Measurement methods GB/T 39771.2-2021 4		2024-07-10
		5	Testing requirements	Optical radiation safety of LEDs--Part 2:Measurement methods GB/T 39771.2-2021 5		2024-07-10
		6	measuring method	Optical radiation safety of LEDs--Part 2:Measurement methods GB/T 39771.2-2021 6		2024-07-10
90	NIRS	1	All items	Medical electrical equipment--Part 2-71;Particular requirements for the basicsafety and essential performance of functional near-infrared spectroscopy (NIRS)equipment GB 9706.271-2021		2024-07-10
		2	ESSENTIAL PERFORMANCE	Medical electrical equipment--Part 2-71;Particular requirements for the basicsafety and essential performance of functional near-		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				infrared spectroscopy (NIRS)equipment GB 9706.271-2021 201.4.3		
		3	ME EQUIPMENT identification, marking and documents	Medical electrical equipment--Part 2-71;Particular requirements for the basicsafety and essential performance of functional near-infrared spectroscopy (NIRS)equipment GB 9706.271-2021 201.7.2		2024-07-10
		4	Protection against electrical HAZARDS from ME EQUIPMENT	Medical electrical equipment--Part 2-71;Particular requirements for the basicsafety and essential performance of functional near-infrared spectroscopy (NIRS)equipment GB 9706.271-2021 201.8		2024-07-10
		5	Performance of FUNCTIONAL NIRS EQUIPMENT	Medical electrical equipment--Part 2-71;Particular requirements for the basicsafety and essential performance of functional near-infrared spectroscopy (NIRS)equipment GB 9706.271-2021 201.12.1.101		2024-07-10
91	Components of electric upper limb	1	All items	Components of electric upper limb GB/T 18027-2021		2024-07-10
		2	General requirement	Components of electric upper limb GB/T 18027-2021		2024-07-10
		3	Major technical performance	Components of electric upper limb GB/T 18027-2021		2024-07-10
		4	Reliability	Components of electric upper limb GB/T 18027-2021		2024-07-10
		5	Reliability	Components of electric upper limb GB/T 18027-2021		2024-07-10
		6	Reliability	Components of electric upper limb GB/T 18027-2021		2024-07-10
		7	Reliability	Components of electric upper limb GB/T 18027-2021		2024-07-10
92	Coronary CT image processing	1	All items	Artificial intelligence medical device—Coronary CT image processing software—Algorithm performance test methods YY/T 1907-2023		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
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	software— Algorithm performance test methods	2	Requirement on algorithm performance testing	Artificial intelligence medical device—Coronary CT image processing software—Algorithm performance test methods YY/T 1907-2023		2024-07-10
		3	Test methods under different application scenario	Artificial intelligence medical device—Coronary CT image processing software—Algorithm performance test methods YY/T 1907-2023		2024-07-10
		4	Algorithm quality characteristics and test methods	Artificial intelligence medical device—Coronary CT image processing software—Algorithm performance test methods YY/T 1907-2023		2024-07-10
93	Nitrous oxide inhalation sedation and analgesia equipment	1	All items	Anaesthetic and respiratory equipment- Medical endoscopes- Video endoscopes YY/T 1873-2023		2024-07-10
		2	general requirements	Anaesthetic and respiratory equipment- Medical endoscopes- Video endoscopes YY/T 1873-2023 4		2024-07-10
		3	supply of power	Anaesthetic and respiratory equipment- Medical endoscopes- Video endoscopes YY/T 1873-2023 6		2024-07-10
		4	accuracy of controllers and instruments and protection against dangerous outputs	Anaesthetic and respiratory equipment- Medical endoscopes- Video endoscopes YY/T 1873-2023 7		2024-07-10
		5	leak	Anaesthetic and respiratory equipment- Medical endoscopes- Video endoscopes YY/T 1873-2023 8		2024-07-10
		6	connecting port	Anaesthetic and respiratory equipment- Medical endoscopes- Video endoscopes YY/T 1873-2023 9		2024-07-10
		7	additional requirements attached	Anaesthetic and respiratory equipment- Medical endoscopes- Video endoscopes YY/T 1873-2023 11		2024-07-10
		8	Identifiers, tags, and files	Anaesthetic and respiratory equipment- Medical endoscopes- Video endoscopes YY/T 1873-2023 12		2024-07-10



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94	Spirometers intended for the measurement of time forced expired volumes in humans	1	All items	Anaesthetic and respiratory equipmentSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021		2024-07-10
		2	electric safety	Anaesthetic and respiratory equipmentSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 4.1		2024-07-10
		3	safety of machinery	Anaesthetic and respiratory equipmentSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 4.2		2024-07-10
		4	a mark on a scale or display	Anaesthetic and respiratory equipmentSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 5.1		2024-07-10
		5	mark recognizability	Anaesthetic and respiratory equipmentSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 5.2		2024-07-10
		6	durability of mark	Anaesthetic and respiratory equipmentSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 5.3		2024-07-10
		7	marking of spirometer or its packaging	Anaesthetic and respiratory equipmentSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 5.4		2024-07-10
		8	operation instruction	Anaesthetic and respiratory equipmentSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 5.5		2024-07-10
		9	technical instruction	Anaesthetic and respiratory equipmentSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 5.6		2024-07-10
		10	measuring range	Anaesthetic and respiratory equipmentSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 6		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		11	accuracy	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 7.1		2024-07-10
		12	write time	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 7.2		2024-07-10
		13	graphic displays aspect ratio	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 7.3		2024-07-10
		14	Volume record	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 7.4		2024-07-10
		15	Forced exhalation start	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 7.5		2024-07-10
		16	Forced expiratory termination	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 7.6		2024-07-10
		17	linearity	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 7.7		2024-07-10
		18	repeatability	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 7.8		2024-07-10
		19	Expiratory impedance	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 7.9		2024-07-10
		20	Effects of a hand-held spirometer or attachment falling	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 8.1		2024-07-10



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		№	Item/ Parameter			
		21	calibration	Anaesthetic and respiratory equipmentSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 8.2		2024-07-10
		22	Disassemble and reassemble	Anaesthetic and respiratory equipmentSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 8.3		2024-07-10
		23	Reusable spirometer and components	Anaesthetic and respiratory equipmentSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 9.1		2024-07-10
		24	Spirometer and its components require treatment prior to use	Anaesthetic and respiratory equipmentSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 9.2		2024-07-10
		25	Spirometer and parts in aseptic packaging	Anaesthetic and respiratory equipmentSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 9.3		2024-07-10
95	Active implant medical device	1	All items	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023		2024-07-10
		2	General requirements for active implantable medical devices	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 5		2024-07-10
		3	Requirements for particular active implantable medical devices	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 6		2024-07-10
		4	General arrangement of the packaging	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 7		2024-07-10



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		5	General markings for active implantable medical devices	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 8		2024-07-10
		6	Markings on the sales packaging	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 9		2024-07-10
		7	Construction of the sales packaging	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 10		2024-07-10
		8	Markings on the sterile pack	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 11		2024-07-10
		9	Construction of the non-reusable pack	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 12		2024-07-10
		10	Markings on the active implantable medical device	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 13		2024-07-10
		11	Protection from unintentional biological effects being caused by the active implantable medical device	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 14		2024-07-10
		12	Protection from harm to the patient or user caused by external physical features of the active implantable medical device	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 15		2024-07-10
		13	Protection from harm to the patient	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 16		2024-07-10



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			caused by electricity			
		14	Protection from harm to the patient caused by heat	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 17		2024-07-10
		15	Protection from ionizing radiation released or emitted from the active implantable medical device	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 18		2024-07-10
		16	Protection from unintended effects caused by the active implantable medical device	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 19		2024-07-10
		17	Protection of the active implantable medical device from damage caused by external defibrillators	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 20		2024-07-10
		18	Protection of the active implantable medical device from changes caused by electrical fields applied directly to the patient	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 21		2024-07-10
		19	Protection of the active implantable	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 22		2024-07-10



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		№	Item/ Parameter			
			medical device from changes caused by miscellaneous medical treatments			
		20	Protection of the active implantable medical device from mechanical forces	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 23		2024-07-10
		21	Protection of the active implantable medical device from damage caused by electrostatic discharge	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 24		2024-07-10
		22	Protection of the active implantable medical device from damage caused by atmospheric pressure changes	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 25		2024-07-10
		23	Protection of the active implantable medical device from damage caused by temperature changes	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 26		2024-07-10
		24	Protection of the active implantable medical device from electromagnetic non-ionizing	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 27		2024-07-10



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		№	Item/ Parameter			
			radiation			
		25	Accompanying documentation	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 28		2024-07-10
		26	All items	Active implantable medical devicesElectromagnetic compatibilityEMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices YY/T 1874-2023		2024-07-10
		27	0HZ ≤ f ≤ 3000MHz band test requirements	Active implantable medical devicesElectromagnetic compatibilityEMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices YY/T 1874-2023 4		2024-07-10
		28	Frequency band above 3000MHz	Active implantable medical devicesElectromagnetic compatibilityEMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices YY/T 1874-2023 5		2024-07-10
		29	The device is protected from the effects of electromagnetic fields in the therapeutic environment	Active implantable medical devicesElectromagnetic compatibilityEMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices YY/T 1874-2023 6		2024-07-10
		30	Other attached documents	Active implantable medical devicesElectromagnetic compatibilityEMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices YY/T 1874-2023 7		2024-07-10
		31	All items	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety, marking and for information to be provided by the manufacturer GB 16174.1-2024		2025-07-18



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		№	Item/ Parameter			
		32	General requirements for active implantable parts	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety, marking and for information to be provided by the manufacturer GB 16174.1-2024 5		2025-07-18
		33	General arrangement of the packaging	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety, marking and for information to be provided by the manufacturer GB 16174.1-2024 7		2025-07-18
		34	General markings for active implantable medical devices	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety, marking and for information to be provided by the manufacturer GB 16174.1-2024 8		2025-07-18
		35	Markings on the sales packaging	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety, marking and for information to be provided by the manufacturer GB 16174.1-2024 9		2025-07-18
		36	Construction of the sales packaging	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety, marking and for information to be provided by the manufacturer GB 16174.1-2024 10		2025-07-18
		37	Markings on the sterile pack	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety, marking and for information to be provided by the manufacturer GB 16174.1-2024 11		2025-07-18
		38	Construction of the non-reusable pack	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety, marking and for information to be provided by the manufacturer GB 16174.1-2024 12		2025-07-18
		39	Markings on the active implantable medical device	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety, marking and for information to be provided by the manufacturer GB 16174.1-2024 13		2025-07-18
		40	Protection from unintentional biological effects being caused by the	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety, marking and for information to be provided by the manufacturer GB 16174.1-2024 14		2025-07-18



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			active implantable medical device			
		41	Protection from harm to the patient or user caused by external physical features of the active implantable medical device	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety, marking and for information to be provided by the manufacturer GB 16174.1-2024 15		2025-07-18
		42	Protection from harm to the patient caused by electricity	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety, marking and for information to be provided by the manufacturer GB 16174.1-2024 16		2025-07-18
		43	Protection from harm to the patient caused by heat	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety, marking and for information to be provided by the manufacturer GB 16174.1-2024 17		2025-07-18
		44	Protection from ionizing radiation released or emitted from the active implantable medical device	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety, marking and for information to be provided by the manufacturer GB 16174.1-2024 18		2025-07-18
		45	Protection from unintended effects caused by the active implantable medical device	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety, marking and for information to be provided by the manufacturer GB 16174.1-2024 19		2025-07-18
		46	Protection of the active implantable medical device from damage caused by	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety, marking and for information to be provided by the manufacturer GB 16174.1-2024 20		2025-07-18



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			external defibrillators			
		47	Protection of the active implantable medical device from changes caused by electrical fields applied directly to the patient	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety, marking and for information to be provided by the manufacturer GB 16174.1-2024 21		2025-07-18
		48	Protection of the active implantable medical device from changes caused by miscellaneous medical treatments	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety, marking and for information to be provided by the manufacturer GB 16174.1-2024 22		2025-07-18
		49	Protection of the active implantable medical device from mechanical forces	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety, marking and for information to be provided by the manufacturer GB 16174.1-2024 23		2025-07-18
		50	Protection of the active implantable medical device from damage caused by electrostatic discharge	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety, marking and for information to be provided by the manufacturer GB 16174.1-2024 24		2025-07-18
		51	Protection of the active implantable medical device from damage caused by atmospheric	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety, marking and for information to be provided by the manufacturer GB 16174.1-2024 25		2025-07-18



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			pressure changes			
		52	Protection of the active implantable medical device from damage caused by temperature changes	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety, marking and for information to be provided by the manufacturer GB 16174.1-2024 26		2025-07-18
		53	Protection of the active implantable medical device from electromagnetic non-ionizing radiation	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety, marking and for information to be provided by the manufacturer GB 16174.1-2024 27		2025-07-18
		54	Accompanying documentation	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety, marking and for information to be provided by the manufacturer GB 16174.1-2024 28		2025-07-18
		55	All items	Implants for surgery -- Active implantable medical devices -- Part 2 Cardiac pacemakers GB 16174.2-2024		2025-07-18
		56	Measurement of IMPLANTABLE PULSE GENERATOR characteristics	Implants for surgery -- Active implantable medical devices -- Part 2 Cardiac pacemakers GB 16174.2-2024 6.1		2025-07-18
		57	Measurement of the electrical characteristics of a LEAD	Implants for surgery -- Active implantable medical devices -- Part 2 Cardiac pacemakers GB 16174.2-2024 6.2		2025-07-18
		58	Markings on the sales packaging	Implants for surgery -- Active implantable medical devices -- Part 2 Cardiac pacemakers GB 16174.2-2024 9		2025-07-18
		59	Markings on the	Implants for surgery -- Active implantable medical devices -- Part		2025-07-18



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			sterile pack	2 Cardiac pacemakers GB 16174.2-2024 11		
		60	Markings on the active implantable medical device	Implants for surgery -- Active implantable medical devices -- Part 2 Cardiac pacemakers GB 16174.2-2024 13		2025-07-18
		61	Protection from harm to the patient caused by electricity	Implants for surgery -- Active implantable medical devices -- Part 2 Cardiac pacemakers GB 16174.2-2024 16		2025-07-18
		62	Protection from harm to the patient caused by heat	Implants for surgery -- Active implantable medical devices -- Part 2 Cardiac pacemakers GB 16174.2-2024 17		2025-07-18
		63	Protection from unintended effects caused by the device	Implants for surgery -- Active implantable medical devices -- Part 2 Cardiac pacemakers GB 16174.2-2024 19		2025-07-18
		64	Protection of the active implantable medical device from mechanical forces	Implants for surgery -- Active implantable medical devices -- Part 2 Cardiac pacemakers GB 16174.2-2024 23		2025-07-18
		65	Protection of the active implantable medical device from damage caused by atmospheric pressure changes	Implants for surgery -- Active implantable medical devices -- Part 2 Cardiac pacemakers GB 16174.2-2024 25		2025-07-18
		66	Accompanying documentation	Implants for surgery -- Active implantable medical devices -- Part 2 Cardiac pacemakers GB 16174.2-2024 28		2025-07-18
96	Extracorporeal circulation and blood treatment	1	All items	General requirements for the safety of blood/intravenous fluid/Irrigation fluid warmers YY/T 1856-2023		2024-07-10
		2	general rule	General requirements for the safety of blood/intravenous fluid/Irrigation fluid warmers YY/T 1856-2023 4		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
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equipment		3	Modifications and supplements to the corresponding content in GB 9706.1-2020	General requirements for the safety of blood/intravenous fluid/Irrigation fluid warmers YY/T 1856-2023 5		2024-07-10
		4	General requirements	General requirements for the safety of blood/intravenous fluid/Irrigation fluid warmers YY/T 1856-2023 5.1		2024-07-10
		5	ME device identification, labeling, and documentation	General requirements for the safety of blood/intravenous fluid/Irrigation fluid warmers YY/T 1856-2023 5.2		2024-07-10
		6	Protection of ME equipment against electric shocks	General requirements for the safety of blood/intravenous fluid/Irrigation fluid warmers YY/T 1856-2023 5.3		2024-07-10
		7	Protection of ME equipment and ME systems against mechanical hazards	General requirements for the safety of blood/intravenous fluid/Irrigation fluid warmers YY/T 1856-2023 5.4		2024-07-10
		8	Protection against ultra mild and other hazards (sources)	General requirements for the safety of blood/intravenous fluid/Irrigation fluid warmers YY/T 1856-2023 5.5		2024-07-10
		9	Accuracy of controllers and instruments and prevention of hazardous outputs	General requirements for the safety of blood/intravenous fluid/Irrigation fluid warmers YY/T 1856-2023 5.6		2024-07-10
		10	Dangerous situations and fault states of ME equipment	General requirements for the safety of blood/intravenous fluid/Irrigation fluid warmers YY/T 1856-2023 5.7		2024-07-10



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		11	The structure of ME equipment	General requirements for the safty of blood/intravenous fluid/Irrigation fluid warmers YY/T 1856-2023 5.8		2024-07-10
97	Medical magnetic resonance equipment	1	All items	General requirements for medical magnetic resonace equipment YY/T 1840-2023		2024-07-10
		2	Image performance	General requirements for medical magnetic resonace equipment YY/T 1840-2023 4.1		2024-07-10
		3	Magnet requirements	General requirements for medical magnetic resonace equipment YY/T 1840-2023 4.2		2024-07-10
		4	Static magnetic field performance	General requirements for medical magnetic resonace equipment YY/T 1840-2023 4.3		2024-07-10
		5	Software requirements	General requirements for medical magnetic resonace equipment YY/T 1840-2023 4.4		2024-07-10
		6	Mechanical properties	General requirements for medical magnetic resonace equipment YY/T 1840-2023 4.5		2024-07-10
		7	The working stability of the equipment	General requirements for medical magnetic resonace equipment YY/T 1840-2023 4.6		2024-07-10
		8	Performance of door control components	General requirements for medical magnetic resonace equipment YY/T 1840-2023 4.7		2024-07-10
		9	secure	General requirements for medical magnetic resonace equipment YY/T 1840-2023 4.8		2024-07-10
		10	environmental test	General requirements for medical magnetic resonace equipment YY/T 1840-2023 4.9		2024-07-10
		11	appearance	General requirements for medical magnetic resonace equipment YY/T 1840-2023 4.10		2024-07-10
98	Cutting tools for osseous tissue ultrasonic	1	All items	Cutting tools for osseous tissue ultrasonic surgical equipunt YY/T 1853-2022		2024-07-10
		2	Structure and dimensions	Cutting tools for osseous tissue ultrasonic surgical equipunt YY/T 1853-2022 4.1		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	surgical equipment	3	performance	Cutting tools for osseous tissue ultrasonic surgical equipment YY/T 1853-2022 4.2		2024-07-10
		4	appearance	Cutting tools for osseous tissue ultrasonic surgical equipment YY/T 1853-2022 4.3		2024-07-10
		5	work requirements	Cutting tools for osseous tissue ultrasonic surgical equipment YY/T 1853-2022 4.4		2024-07-10
		6	material quality	Cutting tools for osseous tissue ultrasonic surgical equipment YY/T 1853-2022 4.5		2024-07-10
		7	adaptability	Cutting tools for osseous tissue ultrasonic surgical equipment YY/T 1853-2022 4.6		2024-07-10
		8	corrosion resistance	Cutting tools for osseous tissue ultrasonic surgical equipment YY/T 1853-2022 4.7		2024-07-10
Clean area (room)						
1	laboratory animal - requirements of environment and housing facilities		all parameters	Laboratory animal -Requirements of environment and housing facilities GB 14925-2023		2025-07-18
2	clean room(zone) of the pharmaceutical industry		all parameters	clean room(zone) of the pharmaceutical industry		2025-07-18
3	clean room	1	temperature	Code for design of clean room GB50073-2013 6.1		2024-07-10
		2	relative humidity	Code for design of clean room GB50073-2013 6.1		2024-07-10
		3	static pressure	Code for design of clean room GB50073-2013 6.2		2024-07-10

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		№	Item/ Parameter			
		4	air flow pattern	Code for design of clean room GB50073-2013 6.3		2024-07-10
		5	airflow velocity	Code for design of clean room GB50073-2013 6.3		2024-07-10
		6	noise	Code for design of clean room GB50073-2013 4.4		2024-07-10
		7	illumination	Code for design of clean room GB50073-2013 9.2		2024-07-10
		8	air volume	Code for design of clean room GB50073-2013 A.3.1		2024-07-10
		9	air cleanliness	Code for design of clean room GB50073-2013 A.3.5		2024-07-10
		10	air supply volume	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.1		2024-07-10
		11	air volume of room or system	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.1		2024-07-10
		12	room exhaust	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.16		2024-07-10
		13	section wind speed	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.1		2024-07-10
		14	sectional wind speed nonuniformity	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.3		2024-07-10
		15	airflow speed of air supply or specific boundary	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.1		2024-07-10
		16	static pressure	Code for construction and acceptance of cleanroom GB50591-2010 16.2 附录,E.2		2024-07-10
		17	cleanliness of 0.6m after opening	Code for construction and acceptance of cleanroom GB50591-2010 16.2 附录,E.2		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		18	portal airflow velocity	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.2		2024-07-10
		19	concentration of ammonia in room	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.14		2024-07-10
		20	cleanliness level	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.4		2024-07-10
		21	temperature	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.5		2024-07-10
		22	relative humidity	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.5		2024-07-10
		23	temperature and humidity toggle range	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.5.2		2024-07-10
		24	regional temperature difference and regional humidity difference	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.5.2		2024-07-10
		25	noise	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.6		2024-07-10
		26	illumination	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.7		2024-07-10
		27	tightness	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 G.2-G.4	only test pressure attenuation method	2024-07-10
		28	air flow pattern	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.12.1		2024-07-10
		29	directional flow	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.12.2		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		30	streamline parallelism	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.12.3		2024-07-10
		31	recovrey time of cleanliness	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.11		2024-07-10
		32	Sedimentation bacteria or phytoplankton	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.8.2,E.8.3	only test Settlement method	2024-07-10
		33	temperature	Specification for production management of aseptic medical instruments YY 0033-2000 附录 C		2024-07-10
		34	relative humidity	Specification for production management of aseptic medical instruments YY 0033-2000 附录 C		2024-07-10
		35	airflow velocity	Specification for production management of aseptic medical instruments YY 0033-2000 附录 C		2024-07-10
		36	ventilation	Specification for production management of aseptic medical instruments YY 0033-2000 附录 C		2024-07-10
		37	static pressure	Specification for production management of aseptic medical instruments YY 0033-2000 附录 C		2024-07-10
		38	airborne particles	Specification for production management of aseptic medical instruments YY 0033-2000 附录 A、附录 C		2024-07-10
		39	airborne microbe	Specification for production management of aseptic medical instruments YY 0033-2000 附录 A、附录 C		2024-07-10
4	Class II biological safety cabinets	40	settling microbe	Specification for production management of aseptic medical instruments YY 0033-2000 附录 A、附录 C		2024-07-10
		1	appearance	Class II biological safety cabinets YY0569-2011 5.1		2024-07-10
		2	structure	Class II biological safety cabinets YY0569-2011 5.2		2024-07-10
		3	HEPA completeness	Class II biological safety cabinets YY0569-2011 5.4.2		2024-07-10



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		№	Item/ Parameter			
		4	noise	Class II biological safety cabinets YY0569-2011 5.4.3		2024-07-10
		5	illumination	Class II biological safety cabinets YY0569-2011 5.4.4		2024-07-10
		6	vibration	Class II biological safety cabinets YY0569-2011 5.4.5		2024-07-10
		7	downflow air velocity	Class II biological safety cabinets YY0569-2011 5.4.7		2024-07-10
		8	inflow air velocity	Class II biological safety cabinets YY0569-2011 5.4.8		2024-07-10
		9	air flow pattern	Class II biological safety cabinets YY0569-2011 5.4.9		2024-07-10
		10	temperature rise	Class II biological safety cabinets YY0569-2011 5.4.12		2024-07-10
		11	UV lamp	Class II biological safety cabinets YY0569-2011 5.4.14		2024-07-10
5	clean bench		all parameters	clean bench JG/T 292-2010		2024-07-10
6	biosafety laboratories	1	minimum negative pressure relative to the atmosphere	Architectural and technical code for biosafety laboratories GB 50346-2011 3.3		2024-07-10
		2	minimum negative pressure difference of adjacent room	Architectural and technical code for biosafety laboratories GB 50346-2011 3.3		2024-07-10
		3	cleanliness level	Architectural and technical code for biosafety laboratories GB 50346-2011 3.3		2024-07-10
		4	minimum number of ventilation	Architectural and technical code for biosafety laboratories GB 50346-2011 3.3		2024-07-10
		5	temperature	Architectural and technical code for biosafety laboratories GB 50346-2011 3.3		2024-07-10



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		№	Item/ Parameter			
		6	relative humidity	Architectural and technical code for biosafety laboratories GB 50346-2011 3.3		2024-07-10
		7	noise	Architectural and technical code for biosafety laboratories GB 50346-2011 3.3		2024-07-10
		8	average illumination	Architectural and technical code for biosafety laboratories GB 50346-2011 3.3		2024-07-10
		9	tightness	Architectural and technical code for biosafety laboratories GB 50346-2011 3.3	only test pressure attenuation method	2024-07-10
7	hospital clean operating department	1	maximum bacterial concentration	Architectural and technical code for hospital clean operating department GB50333-2013 3.0.2,3.0.3	only test Settlement method	2024-07-10
		2	air cleanliness	Architectural and technical code for hospital clean operating department GB50333-2013 3.0.2,3.0.3		2024-07-10
		3	pressure	Architectural and technical code for hospital clean operating department GB50333-2013 4.0.1		2024-07-10
		4	minimum number of ventilation	Architectural and technical code for hospital clean operating department GB50333-2013 4.0.1		2024-07-10
		5	airflow velocity	Architectural and technical code for hospital clean operating department GB50333-2013 4.0.1		2024-07-10
		6	temperature	Architectural and technical code for hospital clean operating department GB50333-2013 4.0.1		2024-07-10
		7	relative humidity	Architectural and technical code for hospital clean operating department GB50333-2013 4.0.1		2024-07-10
		8	minimum fresh air volume	Architectural and technical code for hospital clean operating department GB50333-2013 4.0.1		2024-07-10
		9	noise	Architectural and technical code for hospital clean operating department GB50333-2013 4.0.1		2024-07-10



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8	industrial cleanroom	10	minimum illumination	Architectural and technical code for hospital clean operating department GB50333-2013 4.0.1		2024-07-10
		11	minimum recovery time of cleanliness	Architectural and technical code for hospital clean operating department GB50333-2013 4.0.1		2024-07-10
		1	temperature	ChP2025 Vol IV, general rule 9205 Table 1		2025-11-12
		2	relative humidity	ChP2025 Vol IV, general rule 9205 Table 1		2025-11-12
		3	static pressure	ChP2025 Vol IV General rule 9205 Table 1		2025-11-12
		4	number of ventilation	ChP2025 Vol IV, general rule 9205 Table 1		2025-11-12
		5	downflow air velocity	ChP2025 Vol IV, general rule 9205 Table 1		2025-11-12
		6	air distribution	ChP2025 Vol IV, general rule 9205 Table 1		2025-11-12
		7	airborne particles	ChP2025 Vol IV, general rule 9205 Table 3		2025-11-12
		8	phytoplankton	ChP2025 Vol IV, general rule 9205 Table 5		2025-11-12
		9	Sedimentation bacteria	ChP2025 Vol IV, general rule 9205 Table 5		2025-11-12
		10	microorganisms on the surfaces	ChP2025 Vol IV, general rule 9205 Table 5		2025-11-12
		11	filter integrity	ChP2025 Vol IV, general rule 9205 Table 1		2025-11-12
		12	airborne particles	GMP Appendix 1 Article 48		2024-07-10
		13	phytoplankton	GMP Appendix 1 Article 48		2024-07-10
		14	Sedimentation	GMP Appendix 1 Article 48		2024-07-10

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		№	Item/ Parameter			
			bacteria			
		15	microorganisms on the surfaces	GMP Appendix 1 Article 48		2024-07-10
		16	static pressure	GMP Article 48		2024-07-10
9	medical class II biological safety cabinets	1	exterior	Guide for the check of medical class II biological safety cabinets YY/T 1540-2017 5.1		2024-07-10
		2	upstream concentration	Guide for the check of medical class II biological safety cabinets YY/T 1540-2017 5.2		2024-07-10
		3	Alarm and interlocking system sampling port	Guide for the check of medical class II biological safety cabinets YY/T 1540-2017 5.3		2024-07-10
		4	aispeed display	Guide for the check of medical class II biological safety cabinets YY/T 1540-2017 5.4		2024-07-10
		5	filter integrity	Guide for the check of medical class II biological safety cabinets YY/T 1540-2017 5.5		2024-07-10
		6	noise	Guide for the check of medical class II biological safety cabinets YY/T 1540-2017 5.6		2024-07-10
		7	illumination	Guide for the check of medical class II biological safety cabinets YY/T 1540-2017 5.7		2024-07-10
		8	downflow air velocity	Guide for the check of medical class II biological safety cabinets YY/T 1540-2017 5.8		2024-07-10
		9	inflow air velocity	Guide for the check of medical class II biological safety cabinets YY/T 1540-2017 5.9		2024-07-10
		10	air flow pattern	Guide for the check of medical class II biological safety cabinets YY/T 1540-2017 5.10		2024-07-10
		11	ultraviolet lamp	Guide for the check of medical class II biological safety		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				cabinets YY/T 1540-2017 5.11		
Food						
1	Food	1	Acute oral toxicity test	National food safety standard, Acute oral toxicity test GB 15193.3-2014		2024-07-10
		2	Bacterial reverse mutation test	National food safety standard, Bacterial reverse mutation test GB 15193.4-2014		2024-07-10
		3	Mammalian erythrocyte micronucleus test	National food safety standard, Mammalian erythrocyte micronucleus test GB 15193.5-2014		2024-07-10
		4	Mammalian bone marrow cell chromosome aberration test	National food safety standard, Mammalian bone marrow cell chromosome aberration test GB 15193.6-2014		2024-07-10
		5	Mice spermatogonial cells or spermatocyte chromosome aberration test	National food safety standard, Mice spermatogonial cells or spermatocyte chromosome aberration test GB 15193.8-2014		2024-07-10
		6	Rodent dominant lethal test	National food safety standard, Rodent dominant lethal test GB 15193.9-2014		2024-07-10
		7	In vitro mammalian cell HGPRT gene mutation test	National food safety standard, In vitro mammalian cell HGPRT gene mutation test GB 15193.12-2014		2024-07-10
		8	Twenty eight days oral toxicity test	National food safety standard, Twenty-eight days oral toxicity test GB15193.22—2014		2024-07-10
		9	Ninety days oral toxicity test	National food safety standard, Ninety days oral toxicity test GB15193.13—2015		2024-07-10



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		№	Item/ Parameter			
		10	Teratogenicity study	National food safety standard, Teratogenicity study GB15193.14-2015		2024-07-10
		11	Reproductive toxicity test	National food safety standard, Reproductive toxicity test GB 15193.15-2015		2024-07-10
		12	Toxicokinetic test	National food safety standard, Toxicokinetic test GB 15193.16-2014		2024-07-10
		13	Chronic toxicity and carcinogenicity combined study	National food safety standard, Chronic toxicity and carcinogenicity combined study GB15193.17-2015		2024-07-10
		14	In vitro mammalian cell TK gene mutation test	National food safety standard, In vitro mammalian cell TK gene mutation test GB 15193.20-2014		2024-07-10
Health Food						
1	Health Food	1	Bacterial reverse mutation test	Technical Guidelines for Safety and Toxicology Inspection and Evaluation of the Health Food and Its Raw Materials (2020)、National food safety standard, Bacterial reverse mutation test GB 15193.4-2014		2024-07-10
		2	Mammalian erythrocyte micronucleus test	Technical Guidelines for Safety and Toxicology Inspection and Evaluation of the Health Food and Its Raw Materials (2020)、National food safety standard, Mammalian erythrocyte micronucleus test GB 15193.5-2014		2024-07-10
		3	Acute oral toxicity test	Technical Guidelines for Safety and Toxicology Inspection and Evaluation of the Health Food and Raw Materials (2020)、National food safety standard, Acute oral toxicity test GB 15193.3-2014		2024-07-10
		4	Mammalian bone marrow cell chromosome aberration test	Technical Guidelines for Safety and Toxicology Inspection and Evaluation of the Health Food and Raw Materials (2020)、National food safety standard, Mammalian bone marrow cell chromosome aberration test GB 15193.6-2014		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	Mice spermatogonial cells or spermatocyte chromosome aberration test	Technical Guidelines for Safety and Toxicology Inspection and Evaluation of the Health Food and Raw Materials (2020)、National food safety standard, Mice spermatogonial cells or spermatocyte chromosome aberration test GB 15193.8-2014		2024-07-10
		6	Rodent dominant lethal test	Technical Guidelines for Safety and Toxicology Inspection and Evaluation of the Health Food and Raw Materials (2020)、National food safety standard, Rodent dominant lethal test GB 15193.9-2014		2024-07-10
		7	In vitro mammalian cell HGPRT gene mutation test	Technical Guidelines for Safety and Toxicology Inspection and Evaluation of the Health Food and Raw Materials (2020)、National food safety standard, In vitro mammalian cell HGPRT gene mutation test GB 15193.12-2014		2024-07-10
		8	In vitro mammalian cell TK gene mutation test	Technical Guidelines for Safety and Toxicology Inspection and Evaluation of the Health Food and Raw Materials (2020)、National food safety standard, In vitro mammalian cell TK gene mutation test GB 15193.20-2014		2024-07-10
		9	28 days oral toxicity test	Technical Guidelines for Safety and Toxicology Inspection and Evaluation of the Health Food and Raw Materials (2020)、National food safety standard, Twenty-eight days oral toxicity test GB15193.22—2014		2024-07-10
		10	90 days oral toxicity test	Technical Guidelines for Safety and Toxicology Inspection and Evaluation of the Health Food and Raw Materials (2020)、National food safety standard, Ninety days oral toxicity test GB15193.13—2015		2024-07-10
		11	Reproductive toxicity test	Technical Guidelines for Safety and Toxicology Inspection and Evaluation of the Health Food and Raw Materials (2020)、National food safety standard, Reproductive toxicity test GB 15193.15-2015		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		12	Toxicokinetic test	Technical Guidelines for Safety and Toxicology Inspection and Evaluation of the Health Food and Raw Materials (2020)、National food safety standard, Toxicokinetic test GB 15193.16-2014		2024-07-10
		13	Chronic toxicity and carcinogenicity combined study	Technical Guidelines for Safety and Toxicology Inspection and Evaluation of the Health Food and Raw Materials (2020)、National food safety standard, Chronic toxicity and carcinogenicity combined study GB15193.17-2015		2024-07-10
		14	Contribute to enhancing the immune function	Testing & Assessment Methods for Health Food Function ,Method for the Assessment of Contribute to enhancing the immune function (2023)Page 18		2024-07-10
		15	Assisting memory improvement function	Testing & Assessment Methods for Health Food Function ,Method for the assessment of Assisting memory improvement function (2023)Page 52		2024-07-10
		16	Contribute to Aassisting Normal blood pressure function	Testing & Assessment Methods for Health Food Function ,Method for the assessment of Contribute to assisting Normal blood pressure function (2023)Page 147		2024-07-10
		17	Contribute to sleep improvement function	Testing & Assessment Methods for Health Food Function,Method for the assessment of Contribute to sleep improvement function (2023)Page 72		2024-07-10
		18	Alleviating physical fatigue function	Testing & Assessment Methods for Health Food Function ,Method for the assessment of Alleviating physical fatigue function (2023)Page75		2024-07-10
		19	Anoxia endurance function	Testing & Assessment Methods for Health Food Function ,Method for the assessment of Anoxia endurance function (2023)Page 81		2024-07-10
		20	Auxiliary protective function against the hazards of ionizing	Testing & Assessment Methods for Health Food Function ,Method for the assessment of Auxiliary protective function against the hazards of ionizing radiation (2023)Page157		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			radiation			
		21	Teratogenicity study	Technical Guidelines for Safety and Toxicology Inspection and Evaluation of the Health Food and Raw Materials (2020)、National food safety standard, Teratogenicity study GB15193.14-2015		2024-07-10
		22	Contribute to improve bone density function	Testing & Assessment Methods for Health Food Function ,Method for the assessment of Contribute to improve bone density function (2023)Page 88		2024-07-10
		23	Protection against chemical injury of liver function	Testing & Assessment Methods for Health Food Function ,Method for the assessment of Protection against chemical injury of liver function (2023)Page 150		2024-07-10
		24	Contribute to assessment of Regulating Gastrointestinal Tract Flora Function	Testing & Assessment Methods for Health Food Function ,Method for the assessment of Contribute to assessment of Regulating Gastrointestinal Tract Flora Function (2023)Page 113		2024-07-10
		25	Contribute to Relaxing Bowels and Relieving Constipation function	Testing & Assessment Methods for Health Food Function ,Method for the assessment of Contribute to Relaxing Bowels and Relieving Constipation function (2023)Page 124		2024-07-10
		26	Contribute to antioxidative function	Testing & Assessment Methods for Health Food Function,Method for the assessment of Contribute to antioxidative function 2023, Page31		2024-07-10
		27	Assisting the protection of gastric mucosa function	Testing & Assessment Methods for Health Food Function,Method for the assessment of Assisting the protection of gastric mucosa function (2023), Page 128		2024-07-10
		28	Contribute to assisting blood	Testing & Assessment Methods for Health Food Function,Method for the assessment of Contribute to assisting		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			sugar keep function	blood sugar keep function (2023), Page 137		
		29	Improve nutritional anemia function	Testing & Assessment Methods for Health Food Function, Method for the assessment of Improve nutritional anemia function (2023), Page 96		2024-07-10
		30	Contribute to maintaining healthy levels of blood lipids (cholesterol / triglycerides)	Testing & Assessment Methods for Health Food Function, Method for the assessment of Contribute to maintaining healthy levels of blood lipids (cholesterol / triglycerides) (2023), Page 132		2024-07-10
		31	Contribute to alleviating lead excretion function	Testing & Assessment Methods for Health Food Function, Method for the assessment of Contribute to alleviating lead excretion function (2023), Page 165		2024-07-10
		32	Contribute to controlling body fat function	Testing & Assessment Methods for Health Food Function, Method for the assessment of contribute to Helps to controlling body fat function (2023), Page 84		2024-07-10
		33	Clear pharynx and moisten throat function	Testing & Assessment Methods for Health Food Function, Method for the assessment of Clear pharynx and moisten throat function (2023) Page 67		2024-07-10
		34	Facilitate digestion function	Testing & Assessment Methods for Health Food Function, Method for the assessment of Facilitate digestion function (2023) Page 119		2024-07-10
Cosmetics						
1	Cosmetic	1	Acute Oral Toxicity Test	Safety and Technical Standards for Cosmetics, Acute Oral Toxicity Test (2015) Chapter 6, No.2		2024-07-10
		2	Acute Dermal Toxicity Test	Safety and Technical Standards for Cosmetics, Acute Dermal Toxicity Test (2015) Chapter 6, No.3		2024-07-10
		3	Dermal Irritation/Corrosion	Safety and Technical Standards for Cosmetics, Dermal Irritation/Corrosion Test (2015) Chapter 6, No.4		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			Test			
		4	Acute Eye Irritation/Corrosion Test	Safety and Technical Standards for Cosmetics, Acute Eye Irritation/Corrosion Test (2015) Chapter 6, No.5		2024-07-10
		5	Skin Sensitisation Test	Safety and Technical Standards for Cosmetics, Skin Sensitisation Test (2015) Chapter 6, No.6		2024-07-10
		6	Skin Phototoxicity Test	Safety and Technical Standards for Cosmetics, Skin Phototoxicity Test (2015) Chapter 6, No.7		2024-07-10
		7	In Vivo Mammalian Bone Marrow Cell Chromosome Aberration Test	Safety and Technical Standards for Cosmetics, In Vivo Mammalian Bone Marrow Cell Chromosome Aberration Test (2015) Chapter 6, No.9		2024-07-10
		8	In Vitro Mammalian Cell Gene Mutation Test	Safety and Technical Standards for Cosmetics, In Vitro Mammalian Cell Gene Mutation Test (2015) Chapter 6, No.10		2024-07-10
		9	In Vivo Mammalian Bone Marrow Cell Chromosome Aberration Test	Safety and Technical Standards for Cosmetics, In Vivo Mammalian Bone Marrow Cell Chromosome Aberration Test (2015) Chapter 6, No.11		2024-07-10
		10	Mammalian Erythrocyte Micronucleus Test	Safety and Technical Standards for Cosmetics, Mammalian Erythrocyte Micronucleus Test (2015) Chapter 6, No.12		2024-07-10
		11	Testicle Cells Chromosome Aberration Test	Safety and Technical Standards for Cosmetics, Testicle Cells Chromosome Aberration Test (2015) Chapter 6, No.13		2024-07-10
		12	Subchronic Oral Toxicity Test	Safety and Technical Standards for Cosmetics, Subchronic Oral Toxicity Test (2015) Chapter 6, No.14		2024-07-10
		13	Subchronic Dermal Toxicity Test	Safety and Technical Standards for Cosmetics, Subchronic Dermal Toxicity Test (2015) Chapter 6, No.15		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		14	Combined Chronic Toxicity/Carcinogenicity Test	Safety and Technical Standards for Cosmetics, Combined Chronic Toxicity/Carcinogenicity Test (2015) Chapter 6, No.17		2024-07-10
		15	Skin absorption: in vivo method	skin absorption--in vivo method OECD 427(2004)		2024-07-10
		16	Guidelines for the testing of chemicals: 3T3 NRU phototoxicity test	The announcement for Safety and Technical Standards for Cosmetics (2016, No.147)		2024-07-10
		17	Skin Photoallergy Test	The announcement for Safety and Technical Standards for Cosmetics (2017, No.136) Annex 2		2024-07-10
		18	In Vitro Skin Irritation: Reconstructed Human Epidermis Test Method	In Vitro Skin Irritation: Reconstructed Human Epidermis Test Method OECD TG439 (2021)		2024-07-10
		19	In Vitro Skin Corrosion: Reconstructed Human Epidermis (RhE) Test Method	In Vitro Skin Corrosion: Reconstructed Human Epidermis (RhE) Test Method OECD TG431 (2021)		2024-07-10
		20	Short Time Exposure In Vitro Test Method (STE)	Short Time Exposure In Vitro Test Method OECD TG491 (2020)、The announcement for Safety and Technical Standards for Cosmetics OECD TG491 (2020)、(2019, No.12) Annex 3		2024-07-10
		21	In Vitro Mammalian Cells Micronucleus Test	The announcement for Safety and Technical Standards for Cosmetics (2021, No.17) Annex 6		2024-07-10
		22	In Chemico Skin Sensitisation: Direct Peptide Reactivity	The announcement for Safety and Technical Standards for Cosmetics (2019, No.12) Annex 6		2024-07-10



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			Assay (DPRA)			
		23	Skin Sensitization: Local Lymph Node Assay: BrdU- ELISA (LLNA:BrdU- ELISA)	The announcement for Safety and Technical Standards for Cosmetics (2019, No.12) Annex 5		2024-07-10
		24	In Vitro Skin Corrosion: Transcutaneous Electrical Resistance Test (TER)	The announcement for Safety and Technical Standards for Cosmetics (2017, No.136) Annex 1		2024-07-10
		25	IN VITRO SKIN SENSITISATION ASSAYS ADDRESSING THE AOP KEY EVENT ON KERATINOCYTE ACTIVATION	IN VITRO SKIN SENSITISATION ASSAYS ADDRESSING THE AOP KEY EVENT ON KERATINOCYTE ACTIVATION OECD TG442D(2022) Annex IB		2024-07-10
		26	Teratogenicity Test	The announcement for Safety and Technical Standards for Cosmetics (2019, No.12) Annex 10		2024-07-10
		27	Fluorescein Leakage In Vitro Test Method	The announcement for Safety and Technical Standards for Cosmetics (2023, No.41) Annex 11		2024-07-10
		28	IN VITRO SKIN SENSITISATION: HUMAN CELL	Technical Specification for the Safety of Cosmetics (Edition 2015) Chapter 6.26 (Announcement No. 41 of 2023 by NMPA, Annex 9)		2025-07-18



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		№	Item/ Parameter			
			LINE ACTIVATION TEST (H-CLAT)			
		29	Skin Sensitization: Local Lymph Node Assay: DA	Technical Specification for the Safety of Cosmetics (Edition 2015) Chapter 6.22 (Announcement No. 12 of 2019 by NMPA, Annex 4)		2025-07-18
		30	Repeated Dose 28- Day Oral Toxicity Study	Technical Specification for the Safety of Cosmetics (Edition 2015) Chapter 6.39 (Announcement No. 12 of 2024 by NMPA, Annex 8)		2025-07-18
Not grouped						
1	medical devices	1	molecular weight of collagen	Tissue engineering medical device products—Collagen protein— Part 2:Determination of molecular weight of type I collagen— Sodium dodecyl sulfate polyacrylamide gel electrophoresis YY/T 1805.2-2021		2024-07-10
		2	Quantification of collagen based on marker peptide	Tissue engineering medical device products—Collagen protein— Part 3:quantification of collagen based on marker peptide detection-liquid chromatography-mass spectrometry YY/T 1805.3-2022		2024-07-10
		3	Quantification of remnant DNA	Tissue engineered medical products-Quantification of remnant DNA in biological materials utilizing animal tissues and their derivatives: Fluorescence method YY/T 1876-2023		2024-07-10



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