

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: 2022-11-09 Expiry Date: 2024-06-05

SCHEDULE 3 ACCREDITED TESTING SCOPE

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
Drug						
1	Drug	1	Solubility	ChP 2020 Vol I / II / IV general notices		2022-11-09
		2	Weight variation	ChP 2020 Vol IV general rule (0100)		2022-11-09
		3	Foam volume	ChP 2020 Vol IV general rule (0101)		2022-11-09
		4	Disintegration and uniformity of dispersion	ChP 2020 Vol IV general rule (0101)		2022-11-09
		5	Total number of deliveries per container; Total number of doses per container; Total number of discharges per	ChP 2020 Vol IV general rule (0111),(0112),(0113)		2022-11-09



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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		2022-11-09
		7	Content of active ingredient in an actuation;Content of active ingredient in a dose;Content of active ingredient in a Unit Spray	ChP 2020 Vol IV general rule ((0111),(0112),(0113)		2022-11-09
		8	Inhaled percentage	ChP 2010Vol II Appendix I L		2022-11-09
		9	Delivery rate	ChP 2020 Vol IV general rule (0113)		2022-11-09
		10	Total amount of spray	ChP 2020 Vol IV general rule (0113)		2022-11-09
		11	Delivery amount in a dose	ChP 2020 Vol IV general rule (0112)		2022-11-09
		12	Optical Rotation	ChP 2020 Vol IV general rule (0621)		2022-11-09
		13	Refractive Index	ChP 2020 Vol IV general rule (0622)		2022-11-09
		14	Acid Value	ChP 2020 Vol IV general rule (0713)		2022-11-09
		15	Saponification Value	ChP 2020Vol IV general rule (0713)		2022-11-09
		16	Hydroxyl Value	ChP 2020 Vol IV general rule (0713)		2022-11-09
		17	Iodine Value	ChP 2020 Vol IV general rule (0713)		2022-11-09



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		18	Peroxide Value	ChP 2020 Vol IV general rule (0713)		2022-11-09
		19	Vitamin A	ChP 2020 Vol IV general rule (0721)		2022-11-09
		20	Vitamin D	ChP 2020 Vol IV general rule (0722)		2022-11-09
		21	Readily Carbonizable Substances	ChP 2020 Vol IV general rule (0842)		2022-11-09
		22	THERMAL ANALYSIS	ChP 2020 Vol IV general rule (0661)		2022-11-09
		23	Total organic carbon	ChP 2020 Vol IV general rule (0682)		2022-11-09
		24	Conductance	ChP 2020 Vol IV general rule (0681)		2022-11-09
		25	Determination of Disintegration	ChP 2020 Vol IV general rule (0921)		2022-11-09
		26	Dissolution Test	ChP 2020 Vol IV general rule (0931)		2022-11-09
		27	Drug Release Test	ChP 2020 Vol IV general rule (0931)		2022-11-09
		28	Tablet Friability	ChP 2020 Vol IV general rule (0923)		2022-11-09
		29	Aerodynamic Assessment of Fine Particles	ChP 2020 Vol IV general rule (0951)		2022-11-09
		30	Identification/Inspect	ChP 20205 Vol IV general rule (identification) (0301)		2022-11-09
				ChP2020 Vol IV General Chapter (Molecular-exclusion Chromatography) (0514)		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				ChP 2020 Vol IV general rule (High Performance Liquid Chromatography) (0512)		2022-11-09
				ChP 2020 Vol IV general rule (ion chromatography) (0513)		2022-11-09
				ChP2020 Vol I / Vol II/Vol IV (Volumetric Analysis)		2022-11-09
				ChP 2020 Vol IV general rule (Infrared Spectrophotometry) (0402)		2022-11-09
				USP 43 (584)		2022-11-09
				EP 10.0 2.2.24		2022-11-09
				Ph.Int. 2019 1.7		2022-11-09
				ChP 2020 Vol IV general rule (Gas Chromatography) (0521)		2022-11-09
				ChP 2020 Vol IV general rule (Raman spectroscopy (0421)		2022-11-09
				USP43 (1120)		2022-11-09
				ChP 2020 Vol IV general rule (Thin-layer Chromatography) (0502)		2022-11-09
				EP10.0 2.2.27		2022-11-09
				USP43 (201)		2022-11-09
				ChP 2020 Vol IV general rule(Electrophoresis) (0541)		2022-11-09
				European pharmacopoeia 10.0 somatropin(Capillary Electrophoresis)		2022-11-09
				ChP 2020 Vol IV general rule (Spectrophotometry and Light-		2022-11-09

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Scattering) (0401)		
				ChP 2020 Vol IV general rule ICP-OES (0411)		2022-11-09
				USP43 (611)		2022-11-09
				Chp 2020 Vol IV general rule (paper chromatography) 0501		2022-11-09
				USP 40 (621)		2022-11-09
				EP10.0 2.2.26		2022-11-09
				Ph.Int.2015 1.14.2		2022-11-09
				ChP 2020 Vol IV general rule (MS) (0431)		2022-11-09
				ChP 2020 Vol IV general rule (XRD) (0451)	Only method 2	2022-11-09
				ChP 2020 Vol IV general rule (0441)		2022-11-09
		31	Related substances	ChP 2020 Vol IV general rule (High Performance Liquid Chromatography) (0512)		2022-11-09
				ChP2020 Vol IV General Chapter (Molecular-exclusion Chromatography) (0514)		2022-11-09
				ChP 2020 Vol IV general rule (ion chromatography) (0513)		2022-11-09
				ChP 2020 Vol IV general rule (Determination of Optical Rotation) (0621)		2022-11-09
				ChP 2020 Vol IV general rule (Potentiometric Titration and Dead-stop Titration) (0701)		2022-11-09



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				ChP 2020 Vol IV general rule (Non-aqueous Titration) (0702)		2022-11-09
				ChP2020 Vol I / Vol II/Vol IV (Volumetric Analysis)		2022-11-09
				ChP2020 Vol I / Vol II/Vol IV (Gravimetric Analysis)		2022-11-09
				ChP 2020 Vol IV general rule (Gas Chromatography) (0521)		2022-11-09
				ChP 2020 Vol IV general rule (Capillary Electrophoresis) (0542)		2022-11-09
				European pharmacopoeia 10.0 somatropin (Capillary Electrophoresis)		2022-11-09
				ChP 2020 Vol IV general rule (ICP-OES) (0411)		2022-11-09
				USP43 (611)		2022-11-09
				ChP 2020 Vol IV general rule MS (0431)		2022-11-09
				ChP 2020 Vol IV general rule XRD (0451)	Only method 2	2022-11-09
				Chp 2020 Vol IV general rule (paper chromatography) 0501		2022-11-09
				USP 43 (621)		2022-11-09
				EP10.0 2.2.26		2022-11-09
				Ph.Int.2015 1.14.2		2022-11-09
		32	radiochemical purity	Chp 2020 Vol IV general rule (The test of Radiopharmaceutical Preparations) (1401)		2022-11-09



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		№	Item/ Parameter			
				EP10.0 radiopharmaceutical preparations-page 834		2022-11-09
				USP 40 (621)		2022-11-09
		33	radioactivity (radioactive concentration)	Chp 2020 Vol IV general rule(The test of Radiopharmaceutical Preparations) 1401		2022-11-09
				National standard WS1-(X-342)-2004Z		2022-11-09
				USP 40 (821)		2022-11-09
				EP10.0 2.2.66		2022-11-09
				Ph.Int.2015 1.1		2022-11-09
		34	radionuclide identification	Chp 2020 Vol IV general rule(The test of Radiopharmaceutical Preparations) 1401		2022-11-09
				USP 40 (821)		2022-11-09
				EP10.0 2.2.66		2022-11-09
				Ph.Int.2015 1.2		2022-11-09
		35	radionuclidic purity	Chp 2020 Vol IV general rule(The test of Radiopharmaceutical Preparations) 1401		2022-11-09
				USP 40 (821)		2022-11-09
				EP10.0 2.2.66		2022-11-09
				Ph.Int.2015 1.3		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		36	biodistribution	Chp 2020 Vol II page1897		2022-11-09
		37	size	Chp 2020 Vol II page 1893		2022-11-09
		38	Surface contamination and leakage test	Chp 2020 Vol II page-1893		2022-11-09
		39	radioimmunoassay kit testing	National standards for radioimmunoassay kit and general rules of radioimmunoassay kit WS1-(R-01-92)-2004Z		2022-11-09
		40	Assay	ChP 2020 Vol IV general rule (High Performance Liquid Chromatography) (0512)		2022-11-09
				ChP2020 Vol IV General Chapter (Molecular-exclusion Chromatography) (0514)		2022-11-09
				ChP 2020 Vol IV general rule (ion chromatography) (0513)		2022-11-09
				ChP 2020 Vol IV general rule (Determination of Optical Rotation) (0621)		2022-11-09
				ChP 2020 Vol IV general rule (Potentiometric Titration and Dead-stop Titration) (0701)		2022-11-09
				ChP 2020 Vol IV general rule (Non-aqueous Titration) (0702)		2022-11-09
				ChP 2020 Vol IV general rule (Assay of Vitamin A) (0721)		2022-11-09
				ChP 2020 Vol IV general rule (Assay of Vitamin D) (0722)		2022-11-09
				ChP2020 Vol I / Vol II/Vol IV (Volumetric Analysis)		2022-11-09
				ChP2020 Vol I / Vol II/Vol IV (Gravimetric Analysis)		2022-11-09
			ChP 2020 Vol IV general rule (Gas Chromatography) (0521)		2022-11-09	

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				ChP 2020 Vol IV general rule (Protein content) (0731)		2022-11-09
				ChP 2020 Vol IV general rule (Determination of acetic acid in synthetic peptides) (0872)		2022-11-09
				ChP 2020 Vol IV general rule (Capillary Electrophoresis) (0542)		2022-11-09
				ChP 2020 Vol IV general rule (Spectrophotometry and Light-Scattering) (0401)		2022-11-09
				ChP 2020 Vol IV general rule ICP-OES (0411)		2022-11-09
				USP43 (611)		2022-11-09
				Chp 2020 Vol IV general rule (Microbiological Assay of Antibiotics) (1201)		2022-11-09
				Chp 2020 Vol IV general rule (AAS) (0406)		2022-11-09
				Chp 2020 Vol IV general rule (MS) (0431)		2022-11-09
				Chp 2020 Vol IV general rule (XRD) (0451)	Only method 2	2022-11-09
				ChP 2020 Vol IV general rule (Nuclear Magnetic Resonance Spectroscopy) (0441)		2022-11-09
		41	Volumetric Analysis	ChP2020 Vol I / Vol II/Vol IV (Volumetric Analysis)		2022-11-09
		42	Gravimetric Analysis	ChP2020 Vol I / Vol II/Vol IV (Gravimetric Analysis)		2022-11-09
		43	Chlorides	ChP 2020 Vol IV general rule (0801)		2022-11-09
				USP 40 (221)		2022-11-09



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		№	Item/ Parameter			
				EP 10.0 2.4.4		2022-11-09
				Ph. Int. 2015 2.2.1		2022-11-09
		44	Sulfates	ChP 2020 Vol IV general rule (0802)		2022-11-09
				USP 40 (221)		2022-11-09
				EP 10.0 2.4.13		2022-11-09
				Ph.Int. 2019 2.2.2		2022-11-09
		45	Sulfide	ChP 2020 Vol IV general rule (0803)		2022-11-09
		46	Cyanides	ChP 2020 Vol IV general rule (0806)		2022-11-09
		47	Iron	ChP 2020 Vol IV general rule (0807)		2022-11-09
				USP 43 (241)		2022-11-09
		48	Heavy Metals	ChP 2020 Vol IV general rule (0821)		2022-11-09
				EP 10.0 2.4.8	only A/C/D	2022-11-09
				Ph.Int. 2019 2.2.3	only Method A	2022-11-09
		49	Ammonium	ChP 2020 Vol IV general rule (0808)		2022-11-09
				EP 10.0 2.4.1	only Method A	2022-11-09
		50	Description	ChP 2020 Vol IV		2022-11-09



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		№	Item/ Parameter			
		51	Inorganic iron	ChP2020 Vol I / Vol II/Vol IV		2022-11-09
		52	Arsenic	ChP 2020 Vol IV general rule (0822)		2022-11-09
		53	Ratio of sedimental volume	ChP 2020 Vol IV general rule (0105),(0106),(0123),(0126)		2022-11-09
		54	Metal particles	ChP 2020 Vol IV general rule (0105)		2022-11-09
		55	Determination of Dispersibility	ChP 2020 Vol IV general rule (0100),(0104),(0188)		2022-11-09
		56	Uniformity of appearance	ChP 2020 Vol IV general rule (0115)		2022-11-09
		57	2-Ethyl hexanoic acid	ChP 2020 Vol IV general rule (0873)		2022-11-09
		58	Solvent Residue	ChP 2020 Vol IV general rule (0861)		2022-11-09
		59	Color of Solution	ChP 2020 Vol IV general rule (0901)		2022-11-09
		60	Clarity of Solution	ChP 2020 Vol IV general rule (0902)		2022-11-09
		61	Particulate Matter	ChP 2020 Vol IV general rule (0903)		2022-11-09
		62	Determination of Particle Size	ChP 2020 Vol IV general rule (0104),(0982)		2022-11-09
		63	Minimum Fill	ChP 2020 Vol IV general rule (0942)		2022-11-09
		64	Melting Point	ChP 2020 Vol IV general rule (0612)		2022-11-09
				EP10.0 2.2.14		2022-11-09
				USP43 (741)		2022-11-09



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		№	Item/ Parameter				
		65	pH Value	ChP 2020 Vol IV general rule (0631)		2022-11-09	
				EP10.0 2.2.3		2022-11-09	
				USP43 (971)		2022-11-09	
		66	Loss on Drying	ChP 2020 Vol IV general rule (0831)			2022-11-09
				EP10.0 2.2.32			2022-11-09
				USP43 (731)			2022-11-09
		67	WATER DETERMINATION	ChP 2020 Vol IV general rule(0832)			2022-11-09
				EP10.0 2.5.32			2022-11-09
				USP43 (921)			2022-11-09
		68	Residue on Ignition	ChP 2020 Vol IV general rule (0841)			2022-11-09
				EP10.0 2.4.16			2022-11-09
				USP43 (281)			2022-11-09
		69	Content Uniformity	ChP 2020 Vol IV general rule (0941)			2022-11-09
				EP10.0 2.9.6			2022-11-09
				USP43 (905)			2022-11-09
70	Adhesive property	ChP 2020 Vol IV general rule (0952)			2022-11-09		

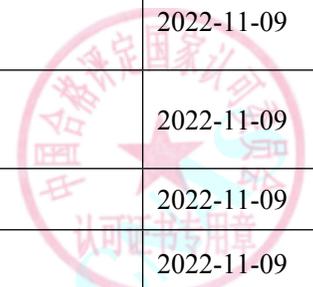


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		№	Item/ Parameter			
				ChP 2020 Vol IV general rule (0121)		2022-11-09
				ChP 2020 Vol IV general rule (0122)		2022-11-09
		71	TDS adhesion tests	USP43 (3)		2022-11-09
		72	Ointment wright	ChP 2020 Vol IV general rule (0122)		2022-11-09
		73	Heat resistance	ChP 2020 Vol IV general rule (0122)		2022-11-09
		74	Transmittance of solution	ChP 2020 Vol IV general rule (0401)		2022-11-09
		75	Absorbance	ChP 2020 Vol IV general rule (0401)		2022-11-09
		76	Determination of Molecular Weight and Molecular Weight Distribution	ChP 2020 Vol IV general rule (0514)		2022-11-09
				European Pharmacopoeia Page 3650		2022-11-09
		77	Protein Content	ChP 2020 Vol IV general rule (0731)		2022-11-09
		78	Acetic acid in synthetic polypeptide	ChP 2020 Vol IV general rule (0872)		2022-11-09
		79	assay of lyophilizing thrombin powder	CHP 2020 Vol II page 1845		2022-11-09
		80	assay of trypsin	CHP 2020 Vol II page 1395		2022-11-09
		81	assay of trypsin in pancreatin	CHP 2020 Vol II page 1397		2022-11-09



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		82	assay of pepsin	CHP 2020 Vol II page 901		2022-11-09
		83	assay of chymotrypsin	CHP 2020 Vol II page 1880		2022-11-09
		84	assay of urokinase	CHP 2020 Vol II page 653		2022-11-09
		85	assay of asparaginase (Escherichia), asparaginase (Ervinia)	CHP 2015 Vol II page 50,52		2022-11-09
		86	assay of defibrase	National Drug Specifications Vol 16 page 88		2022-11-09
		87	assay of lysozyme	Ministry of health drug specifications Vol II ,sixth book,page141		2022-11-09
		88	assay of pancreatic kininogenase	CHP 2020 Vol II page 1399		2022-11-09
				Ministry of health drug specifications Vol II ,sixth book,page111		2022-11-09
		89	Bacterial Endotoxin test	ChP 2020 Vol IV general rule (9251)		2022-11-09
				USP 43 (85)		2022-11-09
				EP 10.0 2.6.14		2022-11-09
				JP 17		2022-11-09
		90	osmotic pressure	ChP 2020 Vol IV general notices (0632)		2022-11-09
		91	Visible foreign matter	ChP 2020 Vol IV general notices (0904)	Except Method III	2022-11-09



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		№	Item/ Parameter			
		92	Nitrogen	ChP 2020 Vol IV general rule Method3 (0704)		2022-11-09
		93	Specific absorbance	ChP 2020 Vol IV general rule (Spectrophotometry and Light-Scattering)0401 (0401)		2022-11-09
		94	molar substitution	ChP 2020 Vol IV general rule (0521)		2022-11-09
				Ministry of health drug specifications Vol II ,sixth book, Appendix 7		2022-11-09
				National Drug Specifications YBH15182006, YBH02202010		2022-11-09
		95	Viscosity	ChP 2020 Vol IV general rule (0633)		2022-11-09
		96	Hemorrhagic toxicity	National Drug Specifications Vol 16 page 88		2022-11-09
				Import Drug Registrations JX20010046		2022-11-09
		97	Neurotoxicity	National Drug Specifications Vol 16 page 88		2022-11-09
		98	Thymus peptide biological activity	National Drug Specifications Vol 16 page 118		2022-11-09
		99	Transfer factor biological activity	National Drug Specifications Vol 16 page 104		2022-11-09
		100	Crystallinity	ChP 2020 Vol IV general rule (0981)	Only the second method	2022-11-09
		101	Test for depressor substances	Chp 2020 Volume IV Chp 2015 Volume IV (1145)		2022-11-09
		102	assay of amylopsin in pancreatin	ChP 2020 Vol II page 1397		2022-11-09
		103	assay of pancrelipase in	ChP 2020 Vol II page 1397		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			pancreatin			
		104	activity determination	National Drug Specifications Vol 16 page 82		2022-11-09
		105	determination of immunogenicity	National Drug Specifications (Trial Implementation)WS1-XG-053-2000-2005		2022-11-09
		106	activity determination of Cytochrome C	ChP 2020 Vol IV general rule (1206)		2022-11-09
		107	shape forming ability	ChP 2020 Vol IV general rule (0122)		2022-11-09
		108	content of alcohol	ChP 2020 Vol IV general rule (0711)	only GC Method I (capillary column chromatography)	2022-11-09
		109	Test for Undue Toxicity	Chp 2020 Volume IV Chp 2015 Volume IV (1141)		2022-11-09
		110	Test for Allergen	Chp 2020 Volume IV Chp 2015 Volume IV (1147)		2022-11-09
		111	Test for Pyrogen	Chp 2020 Volume IV Chp 2015 Volume IV (1142)		2022-11-09
				General principles of four parts of Chinese Pharmacopoeia 2020 Edition (9301) Monocyte activation test, MAT		2022-11-09
		112	Test for Haemolysis and Agglomeration	Chp2020 volume IV Chp2015 volume IV (1148)		2022-11-09
		113	Biological Assay of Protamine Sulfate	Chp2020 volume IV Chp2015 volume IV (1213)		2022-11-09



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		114	Biological Assay of Luteinsing Hormone	Chp2020 volume IV Chp2015 volume IV (1217)		2022-11-09
		115	Biological Assay of Vasopressin	Chp2020 Volume IV General Rules 1205		2022-11-09
		116	Biological Assay of pressor substance	Chp2020 volume IV General Rules 1144		2022-11-09
		117	Toxicity Test of Sodium Stibogluconate	Chp 2020 Volume IV Chp 2015 Volume IV (1215)		2022-11-09
		118	biopotency of chorionic gonadotrophin	ChP 2020Vol IVgeneral rule (1209)		2022-11-09
		119	biopotency of Insulin	ChP 2020 Vol IVgeneral rule (1211)		2022-11-09
				USP43 (121)		2022-11-09
		120	potency of solliche-stimulating hormone	ChP 2020 Vol IVgeneral rule (1216)		2022-11-09
		121	biopotency of growth hormone	ChP 2020 Vol IVgeneral rule (1219)		2022-11-09
		122	Disintegration test	ChP2020 Vol IV, general rule(0108) (0108)		2022-11-09
		123	General quality control method for crude drugs	ChP2020 Vol IV, general rule(0212) (0212)		2022-11-09
		124	Microscopical indentification	ChP2020 Vol IV, general rule(2001) (2001)		2022-11-09
		125	Foreign Matter	ChP2020 Vol IV, general rule(2301) (2301)		2022-11-09
		126	lead,cadmium,arsenic, mercury, copper	ChP2020 Vol IV, general rule(2321) (2321)		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		127	Ash	ChP2020 Vol IV, general rule(2302) (2302)		2022-11-09
		128				2022-11-09
		129				2022-11-09
		130				2022-11-09
		131				2022-11-09
		132				2022-11-09
		133				2022-11-09
		134				2022-11-09
		135				2022-11-09
		136				2022-11-09
		137				2022-11-09
		138				2022-11-09
		139				2022-11-09
		140				2022-11-09
		141				2022-11-09
		142				2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		143				2022-11-09
		144				2022-11-09
		145				2022-11-09
		146				2022-11-09
		147				2022-11-09
		148				2022-11-09
		149				2022-11-09
		150				2022-11-09
		151				2022-11-09
		152				2022-11-09
		153				2022-11-09
		154				2022-11-09
		155				2022-11-09
		156				2022-11-09
		157				2022-11-09
		158				2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		159				2022-11-09
		160				2022-11-09
		161				2022-11-09
		162				2022-11-09
		163				2022-11-09
		164				2022-11-09
		165				2022-11-09
		166				2022-11-09
		167				2022-11-09
		168				2022-11-09
		169				2022-11-09
		170				2022-11-09
		171				2022-11-09
		172				2022-11-09
		173				2022-11-09
		174				2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		175				2022-11-09
		176				2022-11-09
		177				2022-11-09
		178				2022-11-09
		179				2022-11-09
		180				2022-11-09
		181				2022-11-09
		182				2022-11-09
		183				2022-11-09
		184				2022-11-09
		185				2022-11-09
		186				2022-11-09
		187				2022-11-09
		188				2022-11-09
		189				2022-11-09
		190				2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		191				2022-11-09
		192				2022-11-09
		193				2022-11-09
		194				2022-11-09
		195				2022-11-09
		196				2022-11-09
		197				2022-11-09
		198				2022-11-09
		199				2022-11-09
		200				2022-11-09
		201				2022-11-09
		202				2022-11-09
		203				2022-11-09
		204				2022-11-09
		205				2022-11-09
		206				2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		207				2022-11-09
		208				2022-11-09
		209				2022-11-09
		210				2022-11-09
		211				2022-11-09
		212				2022-11-09
		213				2022-11-09
		214				2022-11-09
		215				2022-11-09
		216				2022-11-09
		217				2022-11-09
		218				2022-11-09
		219				2022-11-09
		220				2022-11-09
		221				2022-11-09
		222				2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		223				2022-11-09
		224				2022-11-09
		225				2022-11-09
		226				2022-11-09
		227				2022-11-09
		228				2022-11-09
		229				2022-11-09
		230				2022-11-09
		231				2022-11-09
		232				2022-11-09
		233				2022-11-09
		234				2022-11-09
		235				2022-11-09
		236				2022-11-09
		237				2022-11-09
		238				2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		239				2022-11-09
		240				2022-11-09
		241				2022-11-09
		242				2022-11-09
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		246				2022-11-09
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		248				2022-11-09
		249				2022-11-09
		250				2022-11-09
		251				2022-11-09
		252				2022-11-09
		253				2022-11-09
		254				2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		255				2022-11-09
		256				2022-11-09
		257				2022-11-09
		258				2022-11-09
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		262				2022-11-09
		263				2022-11-09
		264				2022-11-09
		265				2022-11-09
		266				2022-11-09
		267				2022-11-09
		268				2022-11-09
		269				2022-11-09
		270				2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		271				2022-11-09
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		273				2022-11-09
		274				2022-11-09
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		276				2022-11-09
		277				2022-11-09
		278				2022-11-09
		279				2022-11-09
		280				2022-11-09
		281				2022-11-09
		282				2022-11-09
		283				2022-11-09
		284				2022-11-09
		285				2022-11-09
		286				2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		287				2022-11-09
		288				2022-11-09
		289				2022-11-09
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		293				2022-11-09
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		299				2022-11-09
		300				2022-11-09
		301				2022-11-09
		302				2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		303				2022-11-09
		304				2022-11-09
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		310				2022-11-09
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		312				2022-11-09
		313				2022-11-09
		314				2022-11-09
		315				2022-11-09
		316				2022-11-09
		317				2022-11-09
		318				2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		319				2022-11-09
		320				2022-11-09
		321				2022-11-09
		322				2022-11-09
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		324				2022-11-09
		325				2022-11-09
		326				2022-11-09
		327				2022-11-09
		328				2022-11-09
		329				2022-11-09
		330				2022-11-09
		331				2022-11-09
		332				2022-11-09
		333				2022-11-09
		334				2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		335				2022-11-09
		336				2022-11-09
		337				2022-11-09
		338				2022-11-09
		339				2022-11-09
		340				2022-11-09
		341				2022-11-09
		342				2022-11-09
		343				2022-11-09
		344				2022-11-09
		345				2022-11-09
		346				2022-11-09
		347				2022-11-09
		348				2022-11-09
		349				2022-11-09
		350				2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		351				2022-11-09
		352				2022-11-09
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		356				2022-11-09
		357				2022-11-09
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		363				2022-11-09
		364				2022-11-09
		365				2022-11-09
		366				2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		367				2022-11-09
		368				2022-11-09
		369				2022-11-09
		370				2022-11-09
		371				2022-11-09
		372				2022-11-09
		373				2022-11-09
		374				2022-11-09
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		376				2022-11-09
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		379				2022-11-09
		380				2022-11-09
		381				2022-11-09
		382				2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		383				2022-11-09
		384	Material about Injection	ChP2020 Vol IV, general rule(2400) (2400)		2022-11-09
		385	Methanol	ChP2020 Vol IV, general rule(0871) (0871)		2022-11-09
		386	Residue of Sulfur Dioxide	ChP2020 Vol IV, general rule(2331) (2331)		2022-11-09
		387	Mycotoxin	ChP2020 Vol IV, general rule(2351)		2022-11-09
		388	Extractives	ChP2020 Vol IV, general rule(2201) (2201)		2022-11-09
		389	Tanninoids	ChP2020 Vol IV, general rule(2202) (2202)		2022-11-09
		390	Cineol	ChP2020 Vol IV, general rule(2203) (2203)		2022-11-09
		391	Volatile Oil	ChP2020 Vol IV, general rule(2204) (2204)		2022-11-09
		392	polymerase chain reaction	ChP2020 Vol IV 1001 1001		2022-11-09
				(0541) (0541)		2022-11-09
		393	morphological identification	ChP2020 Vol I, the ordinary case		2022-11-09
Biological product						
1	Biological product	1	virus titration(plaque assay)	ChP2020 Vol III, monographs		2022-11-09
		2	Identity(plaque assay)	ChP2020 Vol III, monographs		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		3	Determination of 2-phenoxyethanol content	ChP2020 Vol III, Monographs		2022-11-09
		4	Host residue protein(ELISA)	ChP2020 Vol III/IV, general rule (3414)		2022-11-09
		5	Residual carbodiimide content	ChP 2020 Vol III/IV general rule (3206)		2022-11-09
		6	O-acetyl content	ChP 2020 Vol III/IV general rule (3117)		2022-11-09
		7	pH	ChP2020 Vol III/IV, general rule (0631)		2022-11-09
		8	protein content (immunodiffusion method)	ChP 2020 Vol III, monographs		2022-11-09
		9	Efficacy (Skin test)	ChP2020 Vol III, monographs		2022-11-09
		10	Analysis of amino acid	Imported drug registration standards JS20140093		2022-11-09
		11	Purity of albumin	ChP2020 Vol III, Monographs		2022-11-09
		12	Diphtheria antibody	ChP2020 Vol III/IV, general rule (3513)		2022-11-09
		13	Determination of phenol content	ChP2020 Vol III/IV, general rule (3113)		2022-11-09
		14	disintegration test	ChP 2020 Vol III/IV general rule (0921)		2022-11-09
		15	virus titration	ChP2020 Vol III, Monographs, Drug registration standards WB4-(ZB-070)-2010		2022-11-09
		16	Virus Titration (Cytopathic)	ChP2020 Vol III, Monographs, Drug registration standards WS4-(ZB-004)-2011		2022-11-09

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		17	virus titration(micro plate CPE)	ChP2020 VolⅢ, Monographs, Drug registration standards WS4-(ZB-004)-2011		2022-11-09
		18	Test for reversion of neurovirulence in mice	ChP2020 Vol Ⅲ, monographs		2022-11-09
		19	Identity(single radial immunodiffusion)	ChP2020 Vol Ⅲ, monographs		2022-11-09
		20	Virus inactivated validation	National Drug Standards YBS00282016		2022-11-09
		21	Test for Adventitious virus(Cell culture method)	ChP 2020 Vol Ⅲ general rule (3302)		2022-11-09
		22	Determination of insoluble particles	ChP2020 VolⅢ/Ⅳ General rule (0903)		2022-11-09
				EP 10.0		2022-11-09
		23	Residual solvents	ChP2020 VolⅢ/Ⅳ General rule (0861)		2022-11-09
		24	Purity(HPLC method)	ChP 2020 Vol Ⅲ general rule (0512)		2022-11-09
		25	Test for the absence of contaminating organisms	ChP2020 Vol Ⅲ/Ⅳ, general rule, monographs (1101)		2022-11-09
		26	Residue bacteria protein	ChP 2020 Vol Ⅲ general rule (3412),(3413),(3414)		2022-11-09
		27	Potency of monoclonal antibody	ChP2020 VolⅢ/Ⅳ General rule		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		28	Protein purity(SDS PAGE)	ChP 2020 Vol III general rule (0541)		2022-11-09
		29	Protein purity(HPLC method)	ChP 2020 Vol III general rule (0512)		2022-11-09
		30	Protein molecular weight (SDS PAGE)	ChP 2020 Vol III general rule (0541)		2022-11-09
		31	Protein content	ChP 2020 Vol IV general notices (0731)		2022-11-09
		32	Protein content (TCA-Lowry method)	Imported drug registration standards JS20040032		2022-11-09
		33	Protein nitrogen content	Imported drug registration standards JS20130109/JS20130110		2022-11-09
		34	protein content (Lowry method)	ChP 2020 Vol III/IV, general rule (0731)		2022-11-09
		35	protein content (UV method)	ChP 2020 Vol III/IV, general rule (0731)		2022-11-09
		36	Nitrogen content	ChP 2020 Vol III/IV general rule (0704)		2022-11-09
		37	Isoelectric focusing electrophoresis	ChP 2020 Vol III general rule (0541)		2022-11-09
		38	Test for reversion to toxicity (pertussis vaccine)	ChP2020 Vol III, monograph		2022-11-09
		39	Test for reversion to toxicity (toxoid)	ChP2020 Vol III, monograph		2022-11-09
		40	Molecular size distribution	ChP 2020 Vol III/IV general rule (3419)		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		41	polyscharide content	ChP 2020 Vol III/IV general rule (3103)		2022-11-09
		42	polysaccharide content	ChP 2020 Vol III, monographs		2022-11-09
		43	polyscharide content	Drug registration standards, Import drug registration standards JS20140079		2022-11-09
		44	molecular size test (Vi-PS)	ChP 2020 Vol III/IV general rule (3420)		2022-11-09
		45	Distribution of molecular size	ChP 2020 Vol III/IV general rule (3121) (3122)		2022-11-09
		46	Phenol content	Import drug registration standards JS20140079		2022-11-09
		47	Virurs titer(Cell culture method)	Adenov titration assay NIFDC-SOP-B-T-0580		2022-11-09
		48	moisture content (weight loss method)	ChP 2020 Vol III/IV, general role (0831)		2022-11-09
		49	content in high molecular weight conjugate	ChP 2020 Vol III/IV general rule (3119)		2022-11-09
		50	total solids	ChP 2020 Vol III/IV general rule (3101)		2022-11-09
		51	Hypersensitive test/Sensitization test	ChP2020 Vol IV, general rule (1147)		2022-11-09
		52	Content (HPLC)	ChP2020 Vol III/IV general rule (0512), (3124)		2022-11-09
		53	Analysis of nucleotide	Import drug registration standards JS20140093		2022-11-09
		54	nucleic acid content	ChP 2020 Vol III/IV general rule (0401)		2022-11-09

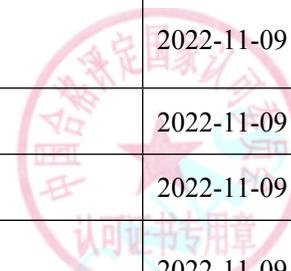


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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		55	polysaccharide content(ribose method)	ChP 2020 Vol III/IV general rule (3421)		2022-11-09
		56	bacteria counting	ChP 2020 Vol III, monographs		2022-11-09
		57	Determination of metacresol content	ChP2020 Vol III/IV, general rule (3144)		2022-11-09
		58	Test for the absence of contaminating organisms (Animal Test)	ChP2020 Vol III, monographs		2022-11-09
		59	Identity test (acid-fast stained smear)	ChP2020 Vol III, monographs		2022-11-09
		60	Identity test	ChP2020 Vol III, Monographs, Drug registration standards YBS01402011		2022-11-09
		61	Identity test (Immunodot)	ChP2020 Vol III/IV General rule (3402)		2022-11-09
		62	Identity (SDS-PAGE method)	ChP 2020 Vol III/IV general rule (3404)		2022-11-09
		63	Identity (immunodiffusion method)	ChP 2020 Vol III/IV general rule (3403)		2022-11-09
		64	Identity (WB method)	ChP 2020 Vol III/IV general rule (3401)		2022-11-09
		65	Identity test (Immunogenicity)	ChP2020 Vol III, monographs		2022-11-09
		66	Identity test (Intracerebral neutralization test)	ChP2020 Vol III, monographs		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		67	identity test	ChP2020 Vol III, monographs		2022-11-09
		68	Identity test (Gel immunoprecipitation test)	ChP2020 Vol III, monograph		2022-11-09
		69	Identity test (Skin test)	ChP2020 Vol III, monographs		2022-11-09
		70	Identity test of vaccine, live (Plaque method)	ChP2020 Vol III, monographs		2022-11-09
		71	identity test	Drug registration standards, Import drug registration standards JS20140079		2022-11-09
		72	Identity test (Neutralization test)	ChP2020 Vol III, monograph		2022-11-09
		73	Identification (cell culture)	ChP2020 Vol III, Monographs, Drug registration standards WS4-(ZB-004)-2011		2022-11-09
		74	Identity test (Flocculation test)	ChP2020 Vol III, monograph		2022-11-09
		75	T cell proliferation	ChP 2020 Vol III R-NIFDC-SOP-B-T-0582-01		2022-11-09
		76	Determination of Residual Polysorbate 80 Content (Colorimetry Method)	ChP 2020 Vol III general rule (3203)		2022-11-09
		77	Residual PEG (colorimetric method)	ChP 2020 Vol III general rule (3202)		2022-11-09
		78	Inspection for morphology and	ChP2020 Vol III, monographs		2022-11-09



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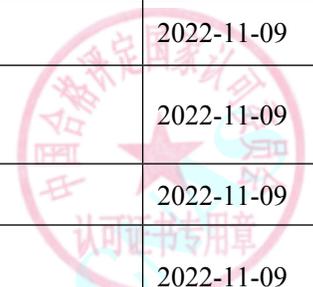
№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			colony of bacilli			
79			Bacteria/Yeast/Virus Seed Identification (ELISA)	ChP 2020 Vol III monograph		2022-11-09
80			Bacteria/Yeast/Virus seed identification (Nucleic Acid Electrophoresis)	ChP 2020 Vol III monograph		2022-11-09
81			Identification of virus seed/strain (sequencing)	Drug registration standard WS4-(ZB-004)-2011		2022-11-09
82			Identification of bacteria	Bergey's Manual of Determinative Bacteriology,ChP2020 Vol III, Monographs		2022-11-09
83			Potency test for antitoxins (Animal test)	ChP2020 Vol III/IV, general rule (3507), (3508), (3509), (3510)		2022-11-09
84			Determination of glycin content	ChP2020 Vol III, Monographs		2022-11-09
85			Antibiotic residue (ELISA)	ChP2020 Vol III, Monographs, Drug registration standards YBS00282015		2022-11-09
86			Test for purity of antisera/antitoxins	ChP2020 Vol III, Monographs		2022-11-09
87			Ag and Ab content (ELISA method)	ChP 2020 Vol III, Monographs		2022-11-09
88			Test fo Visible Particles	ChP 2020 Vol III general rule (0904)		2022-11-09
				EP 10 2.9.20.PARTICULATE CONTAMINATION: VISIBLE PARTICLES		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		89	Potency test for rabies antiserum (MNT)	ChP2020 Vol III/IV, general rule (3512) 1		2022-11-09
		90	Potency test for rabies antiserum (RIFFT)	ChP2020 Vol III/IV, general rule (3512) 2		2022-11-09
		91	Potency test for rabies vaccine (NIH)	ChP2020 Vol III/IV, general rule (3503)		2022-11-09
		92	Test for purity of toxoid	ChP2020Vol III, Monographs		2022-11-09
		93	Flocculation unit test of toxoid	ChP2020 Vol III, general rule (3506)		2022-11-09
		94	Potency test for toxoid	ChP2020 Vol III, general rule (3504),(3505)		2022-11-09
		95	KPI test	Import drug registration standards JS20140093		2022-11-09
		96	Determination of Particle Size Distribution	ChP 2020 Vol III general rule (0982)		2022-11-09
		97	Analysis of phosphorus	Import drug registration standards JS20140093		2022-11-09
		98	Determination of ammonium sulfate content	ChP2020 Vol III, general rule (3104)		2022-11-09
		99	NaCl content	ChP 2020 Vol III/IV general rule (3107)		2022-11-09
		100	saccharide and saccharide alcohols (HPLC)	ChP 2020Vol III, monographs		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		101	Immunogenicity (ELISA)	ChP2020 Vol III, Monographs WS ₄ -(ZB-004)-2011		2022-11-09
		102	immunogenicity	National Drug Standards YBS00282016		2022-11-09
		103	Concentrations	ChP2020 Vol III, monographs		2022-11-09
		104	Aluminum (aluminium hydroxide/aluminium phosphate) (titrimetric method)	ChP 2020 Vol III general rule (3106)		2022-11-09
		105	residual cyanide content	ChP 2020 Vol III/IV general rule (0806)		2022-11-09
		106	residual DOC content	Drug registration standards		2022-11-09
		107	Thermal stability test	ChP2020 Vol III, Monographs, Drug registration standards YBS00282015		2022-11-09
		108	Test for safety and identify of botulinum toxin	Registration Standards JS20120050		2022-11-09
		109	Lactose content	Registration Standards		2022-11-09
		110	Determination of osmolality	ChP2020 Vol III/IV, general rule (0632)		2022-11-09
		111	Pyrogen	ChP 2020 Vol III/IV general rule (1142)		2022-11-09
		112	moisture content (volumetric method)	ChP2020 Vol III/IV, general rule (0832)		2022-11-09
		113	Paptide Mapping	ChP 2020 Vol III general rule (3405)		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			Analysis (Trypsin Cleavage- Reversre Phase HPLC Method)			
		114	in Vitro Relative Potency	ChP 2020 Vol III general rule (3501)		2022-11-09
		115	Test for special toxicity	ChP2020 Vol III, monograph		2022-11-09
		116	sialic acid content	ChP 2020 Vol III/IV general rule, Drug registration standards (3102)		2022-11-09
		117	Appearance	ChP 2020 Vol III monograph		2022-11-09
		118	Host residue DNA	ChP2020 Vol III/IV, general rule (3407)		2022-11-09
		119	The limits of contaminated bacterias	ChP 2020 Vol III/IV general rule (1105),(1106),(1107)		2022-11-09
		120	Thermostability	National Drug Standards WB4-(ZB-070)-2010		2022-11-09
		121	sterility (membrane filtration method)	ChP 2020 Vol III/IV general rule (1101)		2022-11-09
		122	sterility (direct inoculation method)	ChP 2020 Vol III/IV general rule (1101)		2022-11-09
		123	Glutaric dialdehyde content	ChP 2020 Vol III/IV general rule (3204)		2022-11-09
		124	Absorbance (UV-Spectrophotometry)	ChP 2020 Vol III general rule (0401)		2022-11-09
		125	bacterial form and purity	ChP 2020 Vol III		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		126		ChP 2020 Vol III		2022-11-09
		127	Specific toxicity test (pertussis)	ChP2020 Vol III, monograph		2022-11-09
		128	Specific toxicity test (toxoid)	ChP2020 Vol III, monograph		2022-11-09
		129	Test for calf serum	ChP 2020 Vol III general rule (3604)		2022-11-09
		130	serological test for bacteria	ChP 2020 Vol III, monographs		2022-11-09
		131	residual ethanol content	ChP 2020 Vol III/IV general rule (3201)		2022-11-09
		132	Antigen expression	ChP 2020 Vol III general rule (0731)		2022-11-09
		133	Abnormal toxicity	ChP 2020 Vol III/IV general rule (1141)		2022-11-09
		134	free polyscharide content	ChP 2020 Vol III/IV general rule, Drug registration standards, Import drug registration standards (3119)		2022-11-09
		135	Free Formaldehyde (colorimetric method)	ChP 2020 Vol III general rule (3207)		2022-11-09
		136	contaminated bacterias test	ChP 2020 Vol III, monographs		2022-11-09
		137	Thimerosal content	ChP2020 Vol III/IV, general rule (3115)		2022-11-09
		138	Ovalbumin content	ChP2020 Vol III, monographs		2022-11-09
		139	Protein Content (catalysed oxidising pyrolysis and	JS20210014、JS20210015 2.9		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			chemiluminescence)			
140			residual bovine serum albumin	ChP2020 Vol III/IV, general rule (3411)		2022-11-09
141			sucrose content	ChP 2020 Vol IV general rule (0621)		2022-11-09
142			Test for abirritation potency	Registration Standards JS20140093		2022-11-09
143			Test for Mycoplasma	ChP 2020 Vol III general rule (3301)		2022-11-09
144			Filling	ChP2020 Vol III/IV General rule (0100)		2022-11-09
145			Content uniformity	ChP2020 Vol III/IV General rule (0100)		2022-11-09
146			UV spectrum test	ChP 2020 Vol III/IV general rule (0401)		2022-11-09
147			Analysis of ultraviolet absorption spectroscopy	ChP2020 Vol III/IV, general rule (0401)		2022-11-09
148			Test for dextrose concentration (Anthrone method)	ChP2010 Vol III, sup2		2022-11-09
149			Test for minimum filling	ChP2020 Vol III/IV General rule (0942)		2022-11-09
150			Haemagglutinin content	ChP2020 Vol III, monographs		2022-11-09
151			Potency test (animal method)	Human papillomavirus vaccine in vivo potency assay NIFDC-SOP-B-T-0545		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		152	Potency test (Serum antibody)	ChP2020 Vol III, monographs		2022-11-09
		153	Potency test (cell method)	Human papillomavirus neutralization assay NIFDC-SOP-B-T-0568		2022-11-09
		154	Potency test (ELISA)	National Drug Standards YBS01402011		2022-11-09
		155	Potency (in-vitro)	ChP 2020Vol III general rule (3501),(3502)		2022-11-09
		156	Identity test (multi-PCR)	ChP2020 Vol III, monographs		2022-11-09
		157	NACL content Total Chlorines Titration	Imported drug registration standards JS20140105		2022-11-09
		158	Test for the absence of contaminating organisms (phage bacteriolytic test)	ChP2020 Vol III, monographs		2022-11-09
		159	test for Mycobacteria (culture)	ChP2020 Vol III, monographs		2022-11-09
		160	Capillary gel electrophoresis (reduced and none reduced CE-SDS)	ChP2020VolIII/IV General rule (3127)		2022-11-09
		161	Allergen biological activity (UNICAP)	Imported drug registration standards National food and drug administration standards JS20130103 JS20130104 WS4- (S-012)-2010Z		2022-11-09
		162	Allergen biological activity (ELISA Inhibition)	Standard Operating Procedure for the biological activity assy (ELISA inhibition method) of allergens NIFDC-SOP-B-T-5516		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		163	Antibiotic resistance	ChP2015 Vol III, Monographs		2022-11-09
		164	Electron microscopy	ChP2020 Vol III, Monographs		2022-11-09
		165	Expression level	ChP2020 Vol III, Monographs		2022-11-09
		166	Plasmid examination	ChP2020 Vol III, Monographs		2022-11-09
		167	Test for residual virulence	ChP2020 Vol III, Monographs		2022-11-09
		168	Tests for dissociation	ChP2020 Vol III, Monographs		2022-11-09
		169	Serological test	ChP2020 Vol III, Monographs		2022-11-09
		170	Cultural characteristics	ChP2020 Vol III, Monographs		2022-11-09
		171	Microscopic examination of stained smears	ChP2020 Vol III, Monographs		2022-11-09
		172	Determination of residual polysorbate 20 content	Drug registration standards		2022-11-09
		173	Test for virulence	ChP2020 Vol III, Monographs		2022-11-09
		174	sedimentation rate	ChP2020 Vol III, Monographs		2022-11-09
		175	test for viability	ChP2020 Vol III, Monographs		2022-11-09
		176	test for Antitumor activity	ChP2020 Vol III, Monographs		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		177	test for content of CpG	Standard Operation Procedure NIFDC-SOP-B-T-6077		2022-11-09
		178	Stimulus index of spleen	Drug Registration Specification		2022-11-09
		179	Hemagglutination inhibition	ChP 2020 Vol III		2022-11-09
		180	Virus identity(RFLP)	ChP 2020 Vol III		2022-11-09
		181	Antibody Titer Detection(FAMA)	ChP 2020 Vol III		2022-11-09
		182	Antibody Titer Detection(pseudovirus neutralization)	ChP 2020 Vol III		2022-11-09
		183	Antibody Titer Detection(micro plate neutralization)	ChP 2020 Vol III		2022-11-09
		184	Determination of residual exogenous DNA	ChP2020 Vol III, general rule (3407)		2022-11-09
		185	Detection of target antigen expression	ChP2020 Vol III, Monographs		2022-11-09
		186	Detection of RCA	ChP2020 Vol III, Monographs		2022-11-09
		187	Virus Titration (Animal)	ChP2020 Vol III, Monographs, Drug registration standards		2022-11-09
		188	Immunogenicity (Animal)	ChP2020 Vol III, Monographs, Drug registration standards		2022-11-09
		189	Virus inactivated validation (Animal)	ChP2020 Vol III, Monographs, Drug registration standards		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		190	Reverse transcriptase	ChP 2020 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 biological products		2022-11-09
		191	Viral nucleic acid (qPCR)	human immunodeficiency virus type I RNA detection assay NIFDC-SOP-B-T-0564		2022-11-09
		192	Capillary zone electrophoresis (CZE)	ChP 2020 Vol III general rule (0542)		2022-11-09
		193	Hydrophobic chromatography (HIC - HPLC)	ChP 2020 Vol III general rule (0512)		2022-11-09
		194	Ion exchange chromatography (IEC-HPLC)	ChP 2020 Vol III general rule (0512)		2022-11-09
		195	Reversre Phase chromatography (RP-HPLC)	ChP 2015 Vol III general rule (0512)		2022-11-09
		196	Capillary isoelectric focusing electrophoresis (cIEF)	ChP 2020 Vol III general rule (0542)		2022-11-09
		197	imaged Capillary isoelectric focusing electrophoresis (iCIEF)	ChP 2020 Vol III general rule (0542)		2022-11-09
		198	Dissolution time	Dissolution time test of Monoclonal antibody product NIFDC-SOP-B-T-3030		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		199	Color	ChP 2020 Vol III general rule (0901)		2022-11-09
				EP 10.0		2022-11-09
		200	Clarity	ChP 2020 Vol III general rule (0902)		2022-11-09
				EP 10		2022-11-09
		201	N-terminal amino acid sequence	ChP 2020 Vol III general rule		2022-11-09
		202	monocyte activation	General principles of four parts of Chinese Pharmacopoeia 2021 Edition (9301) 9301		2022-11-09
		203		1. Pharmacopoeia of the People's Republic of China 2020, 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. EP10.0,01/2018: 50203 Cell substrates for the production of vaccines for human use 3. Pharmacopoeia General Rule 3429, Immunochemistry, labelling immunochemistry-5 Flow Cytometry 4. Pharmacopoeia General Rule 3429, Immunochemistry, labelling immunochemistry-3 Immunofluorescence Analysis 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	2022-11-09
204		1. Pharmacopoeia of the People's Republic of China 2020, 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. EP10.0, 01/2018:50203 Cell substrates for the production of		2022-11-09		



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				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		
		205		1. Pharmacopoeia of the People's Republic of China 2020, 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.EP10.0, 01/2018:50203 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		2022-11-09
		206		1. Pharmacopoeia of the People's Republic of China 2020, 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 10.0, 01/2018:50203 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		2022-11-09
		207		1. Pharmacopoeia General Rule 3429, Immunochemistry, labelling immunochemistry-5 Flow Cytometry 2. Pharmacopoeia General Rule 3429, Immunochemistry, labelling immunochemistry-3 Immunofluorescence Analysis 3. Pharmacopoeia General Rule 3429, Immunochemistry, labelling		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				immunochemistry-1 enzyme-linked immuno sorbent assay 4. Pharmacopoeia of the People's Republic of China 2020, Part IV, General Principles of Biological Products, Polymerase chain reaction method		
		208		1. Pharmacopoeia General Rule 3429, Immunochemistry, labelling immunochemistry-1 enzyme-linked immuno sorbent assay 2. Pharmacopoeia General Rule 3429, Immunochemistry, labelling immunochemistry-2 Western blotting 3. 2. Pharmacopoeia 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 2020, Part IV, General Principles of Biological Products, Polymerase chain reaction method 6. Detection of markers for cell heredity		2022-11-09
				cell potency assay (in vivo)		2022-11-09
		209		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 biological products 2. EP10.0, 01/2018:50203 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		2022-11-09
		210		Plasmid DNA Isoforms detection (capillary electrophoresis-capillary gel electrophoresis method, CE-CGE method)Pharmacopoeia General Rule 0542 capillary		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				electrophoresis		
		211		Mycoplasma nucleic acid detection (NAT method), EP10.0 01/2008: 20607 Mycoplasmas		2022-11-09
		212		EP10.0, 01/2018:50203 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		2022-11-09
Laboratory Animals						
1	Laboratory Animals	1	Salmonella spp	Laboratory animal-Method for examination of Salmonella sp. GB/T14926.1-2001	only for M、R、H、GP、Rab、D、Mon、treeshrew	2022-11-09
				Defection methods of Salmonella for animal and animal products NY/T 550-2002	only for Pig	2022-11-09
		2	Yersinia sp	Laboratory animal-Method for examination of Yersinia sp GB/T14926.3-2001	only for M、R、H、GP、Rab、D、Mon、	2022-11-09
		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、	2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					Mon、 treeshrew 、 Pig	
		4	Streptobacillus moniliformis	Laboratory animal-Method for examination of Streptobacillus moniliformis GB/T14926.44-2001	only for M、 R、 H、 GP	2022-11-09
		5	Bordetella bronchiseptica	Laboratory animal-Method for examination of Bordetella bronchiseptica GB/T14926.6-2001	only for R、 H、 GP	2022-11-09
		6	Mycoplasma spp	Laboratory animal-Method for examination of Mycoplasma spp GB/T14926.8-2001	only for M、 R、 Pig	2022-11-09
		7	Corynebacterium kutscheri	Laboratory animal-Method for examination of Corynebacterium kutscheri GB/T14926.9-2001	only for M、 R	2022-11-09
		8	Tyzzler's organism	Laboratory animal-Method for examination of Tyzzler's organism GB/T14926.10-2008	only for M、 R、 H、 GP、 Rab	2022-11-09
		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	2022-11-09
		10	Pasteurella pneumotropi-ca	Laboratory animal-Method for examination of Pasteurella pneumotropica GB/T14926.12-2001	only for M、 R、 H、 GP、 Rab	2022-11-09
		11	Klebsiella pneumoniae	Laboratory animal-Method for examination of Klebsiella pneumoniae GB/T14926.13-2001	only for M、 R、 H、 GP、 Rab	2022-11-09
		12	Staphylococcus aureus	Laboratory animal-Method for examination of Staphylococcus aureus GB/T14926.14-2001	only for M、 R、	2022-11-09

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					H、GP、Rab、treeshrew	
		13	Streptococcus pneumoniae	Laboratory animal-Method for examination of Staphylococcus aureus GB/T14926.15-2001	only for M、R、H、GP、Rab、treeshrew	2022-11-09
		14	β-hemolyticstreptococcus	Laboratory animal-Method for examination of β-hemolyticstreptococcus GB/T14926.16-2001	only for M、R、H、GP、Rab、treeshrew	2022-11-09
		15	Pseudomonas aeruginosa	Laboratory animal-Method for examination of Pseudomonas aeruginosa GB/T14926.17-2001	only for M、R、H、GP、Rab、treeshrew	2022-11-09
		16	Pasteurella multocida	Laboratory animal-Method for examination of Pasteurella multocida GB/T14926.5-2001	only for H、GP、Rab	2022-11-09
		17	Brucella spp	Laboratory animal-Method for examination of Brucella spp GB/T14926.45-2001	only for D	2022-11-09
		18	Leptospira spp	Laboratory animal-Method for examination of Leptospira spp GB/T14926.46-2008	only for D、Pig	2022-11-09
		19	Shigella spp	Laboratory animal-Method for examination of Shigella spp GB/T14926.47-2008	only for Mon.	2022-11-09
		20	Mycobacterium tuberculosis	Laboratory animal-Method for examination of Mycobacterium tuberculosis GB/T14926.48-2001	only for Mon.	2022-11-09

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					treeshrew	
		21	Campylobacter jejuni	Laboratory animal-Method for examination of Campylobacter jejuni GB/T14926.49-2001	only for D、Mon、treeshrew	2022-11-09
		22	Detection of germ-free(Bacteria and fungi)	Laboratory animal-Method for examination of Enviroment and faeces for GF animals GB/T14926.41-2001	only for M、R、H、GP、Rab、Gerbil、water、fodder、padding、faeces、environmental sampies	2022-11-09
		23	Lymphocytic Choriomeningitis Virus	Laboratory animal-Method for examination of Lymphocytic Choriomeningitis Virus GB/T14926.18-2001	only for M、R、H、GP、Rab、D、Mon、Gerbil	2022-11-09
		24	Hantavirus	Laboratory animal-Method for examination of Hantavirus GB/T14926.19-2001	only for M、R、Gerbil	2022-11-09
		25	Ectromelia Virus	Laboratory animal-Method for examination of Ectromelia Virus GB/T14926.20-2001	only for M	2022-11-09
		26	Mouse Hepatitis Virus	Laboratory animal-Method for examination of Mouse Hepatitis Virus GB/T14926.22-2001	only for M、	2022-11-09

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					treeshrew 、 Gerbil	
		27	Sendai Virus	Laboratory animal-Method for examination of Sendai Virus GB/T14926.23-2001	only for M、 R、 H、 GP、 Rab、 Gerbil	2022-11-09
		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	2022-11-09
		29	Reovirus type III	Laboratory animal-Method for examination of Reovirus type III GB/T14926.25-2001	only for M、 R、 H、 GP、 Gerbil	2022-11-09
		30	Minute Virus of Mice	Laboratory animal-Method for examination of Minute Virus of Mice GB/T14926.28-2001	only for M、 Gerbil	2022-11-09
		31	Theiler's Mouse Encephalomyelitis Virus	Laboratory animal-Method for examination of Theiler's Mouse Encephalomyelitis Virus GB/T14926.26-2001	only for M	2022-11-09
		32	Mouse Adenovirus	Laboratory animal-Method for examination of Mouse Adenovirus GB/T14926.27-2001	only for M	2022-11-09
		33	Polyoma Virus	Laboratory animal-Method for examination of Polyoma Virus GB/T14926.29-2001	only for M	2022-11-09
		34	Rat Parvovirus (KRV/H-1)	Laboratory animal-Method for examination of Rat Parvovirus(KRV/H-1) GB/T14926.31-2001	only for R	2022-11-09
		35	Rat Coronavirus/Sialodacryoadenitis Virus	Laboratory animal-Method for examination of Rat Coronavirus/Sialodacryoadenitis Virus GB/T14926.32-2001	only for R	2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		36	Rabbit Hemorrhagic Disease Virus	Laboratory animal-Method for examination of Rabbit Hemorrhagic Disease Virus GB/T14926.21-2008	only for Rab	2022-11-09
		37	Rabbit Rotavirus	Laboratory animal-Method for examination of Rabbit Rotavirus GB/T14926.30-2001	only for Rab	2022-11-09
		38	Rabies Virus	Laboratory animal-Method for examination of Rabies Virus GB/T14926.56-2008	only for D	2022-11-09
		39	Canine Parvovirus	Laboratory animal-Method for examination of Canine Parvovirus GB/T14926.57-2008	only for D	2022-11-09
		40	Canine Distemper Virus	Laboratory animal-Method for examination of Canine Distemper Virus GB/T14926.59-2001	only for D	2022-11-09
		41	Infectious Canine Hepatitis Virus	Laboratory animal-Method for examination of Infectious Canine Hepatitis Virus GB/T14926.58-2008	only for D	2022-11-09
		42	Cercopithecine Herpesvirus Type 1	Laboratory animal-Method for examination of Cercopithecine Herpesvirus Type 1 GB/T14926.60-2001	only for Mon	2022-11-09
		43	Simian Retrovirus D	1 Laboratory animal-Method for examination of Simian Retrovirus D GB/T14926.61-2001	only for Mon	2022-11-09
		44	Simian Immunodeficiency Virus	Laboratory animal-Method for examination of Simian Immunodeficiency Virus GB/T14926.62-2001	only for Mon	2022-11-09
		45	Simian Lymphotropic Virus Type 1	Laboratory animal-Method for examination of Simian Lymphotropic Virus Type 1 GB/T14926.63-2001	only for Mon	2022-11-09
		46	Simian Pox Virus	Laboratory animal-Method for examination of Simian Pox Virus GB/T14926.64-2001	only for Mon	2022-11-09
		47	Detection virus from mice	Chinese Pharmacopoeia ,section 3(2020version) General principle 3303 Detection virus from mice Chinese Pharmacopoeia ,section 3(2015version) General principle 3303 Detection virus from mice	Biological products from Mice	2022-11-09
		48	Ectoparasites	Laboratory animal-Method for examination of Ectoparasites GB/T18448.1-2001	only for M、R、	2022-11-09



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		№	Item/ Parameter			
					H、GP、Rab、D、Mon、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	2022-11-09
		50	Encephalitozoon cuniculi	Laboratory animal-Method for examination of Encephalitozoon cuniculi GB/T18448.3-2001	only for M、R、GP、Rab、Gerbil	2022-11-09
		51	Pneumocystis carinii	Laboratory animal-Method for examination of Pneumocystis carinii GB/T18448.4-2001	only for M、R、Rab、Gerbil	2022-11-09
		52	Eimeria spp	Laboratory animal-Method for examination of Eimeria spp GB/T18448.5-2001	only for H、Rab	2022-11-09

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		№	Item/ Parameter			
		53	Helminth	Laboratory animal-Method for examination of Helminth GB/T18448.6-2001	only for M、R、H、GP、Rab、D、Mon、treeshrew、Pig、Gerbil	2022-11-09
		54	Plasmodium spp	Laboratory animal-Method for examination of Plasmodium spp GB/T18448.7-2001	only for Mon	2022-11-09
		55	Dirofilaria immitis	Laboratory animal-Method for examination of Dirofilaria immitis GB/T18448.8-2001	only for D	2022-11-09
		56	Entamoeba histolytica	Laboratory animal-Method for examination of Entamoeba histolytica GB/T18448.9-2001	only for D、Mon	2022-11-09
		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	2022-11-09
		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	2022-11-09
		59	Biochemical markers in	Laboratory animal-Genetic monitoring: methods for biochemical markers of inbred mice and rats GB/T14927.1-2008	only for M、	2022-11-09



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		№	Item/ Parameter			
			experimental mice			
		60	Biochemical markers in experimental rats	Laboratory animal-Genetic monitoring: methods for biochemical markers of inbred mice and rats GB/T14927.1-2008	only for R	2022-11-09
		61	Skin grafting of inbred mice and rats	GB/T14927.2-2008 Laboratory animal-immunological marker of inbred mice and rats GB/T14927.2-2008	only for M、R	2022-11-09
		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	2022-11-09
		63	Laboratory animal physiological biochemistry	National Guide to Clinical Laboratory Procedures (Fourth Edition) blood, body fluid and chemistry analysis (2015)	only for M、R、H、GP、Rab、D、Mon	2022-11-09
		64	Validation of virus inactivation and clearance	The guidelines for the methods and validation of virus inactivation and clearance in blood products (2002)		2022-11-09
				General principles for review of virus safety assessment techniques for biological tissue extracts and eukaryotic expression products (2005)		2022-11-09



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		№	Item/ Parameter				
				Guiding principles for registration information of animal derived medical devices (Revised Edition,2015)		2022-11-09	
				Basic technical requirements of multi component biochemical drug injection (Trial Implementation,2008)		2022-11-09	
				Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin ICH Q5A (R1)		2022-11-09	
		65	Salmonella pullorum	SPF chicken-Microbiological surveillance-Part 4: Serum plate agglutination test for SPF chicken GB/T17999.4-2008	SPF chicken	2022-11-09	
					Diagnostic techniques for fowl typhoid and pullorum disease NY/T 536-2017	only for chicken	2022-11-09
					SPF chicken-Microbiological surveillance-Part 8: Examination of Salmonella pullorum for SPF chicken GB/T17999.8-2008		2022-11-09
					SPF chicken-Microbiological surveillance-Part 9: Tube agglutination test for SPF chicken GB/T17999.9-2008		2022-11-09
		66	Avibacterium paragallinarum	SPF chicken-Microbiological surveillance-Part 4: Serum plate agglutination test for SPF chickenimmunosorbent assay for SPF chicken GB/T17999.4-2008	SPF chicken	2022-11-09	
					SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked GB/T17999.6-2008		2022-11-09
					Diagnostic techniques for infectious coryza of chickens NY/T 538-2015		2022-11-09
		67	Pasteurella multocida	SPF chicken-Microbiological surveillance-Part 5: Agar gel precipitation test for SPF chicken GB/T17999.5-2008	SPF chicken	2022-11-09	
					Diagnostic techniques for fowl cholera (avian pasteurellosis) NY/T 563-2016		2022-11-09
		68	Mycoplasma gallisepticum	SPF chicken-Microbiological surveillance-Part 2: Hemagglutination inhibition test for SPF chicken GB/T17999.2-2008	SPF chicken	2022-11-09	
					SPF chicken-Microbiological surveillance-Part 4: Serum plate agglutination test for SPF chickenimmunosorbent assay for SPF		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				chicken GB/T17999.4-2008		
				GB/T17999.6-2008 SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked GB/T17999.6-2008		2022-11-09
				Detection of avian mycoplasmas by polymerase chain reaction(PCR) NY/T 553-2015	only for poultry	2022-11-09
		69	Mycoplasma synoviae	SPF chicken-Microbiological surveillance-Part 2: Hemagglutination inhibition test for SPF chicken GB/T17999.2-2008	SPF chicken	2022-11-09
				SPF chicken-Microbiological surveillance-Part 4: Serum plate agglutination test for SPF chicken GB/T17999.4-2008		2022-11-09
				SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008		2022-11-09
				Detection of avian mycoplasmas by polymerase chain reaction(PCR) NY/T 553-2015	only for poultry	2022-11-09
		70	Avian Influenza Virus	SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008	SPF chicken	2022-11-09
		71	Newcastle Disease Virus	SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008	SPF chicken	2022-11-09
		72	Infectious Bronchitis Virus	SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008	SPF chicken	2022-11-09
		73	Infectious Laryngotracheitis Virus	SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008	SPF chicken	2022-11-09
		74	Infectious Bursal Disease Virus	SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008	SPF chicken	2022-11-09
		75	Lymphoid Leukosis Virus	SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008	SPF chicken	2022-11-09
		76	Reticuloendotheliosis Virus	SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008	SPF chicken	2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		77	Marek's Disease Virus	SPF chicken-Microbiological surveillance-Part 5: Agar gel precipitation test for SPF chicken GB/T17999.5-2008	SPF chicken	2022-11-09
		78	Chicken Infectious Anaemia Virus	SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008	SPF chicken	2022-11-09
		79	Avian Reovirus	SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008	SPF chicken	2022-11-09
		80	Avian Encephalomyelitis Virus	SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008	SPF chicken	2022-11-09
		81	Avian Adenovirus Group I	SPF chicken-Microbiological surveillance-Part 5: Agar gel precipitation test for SPF chicken GB/T17999.5-2008	SPF chicken	2022-11-09
		82	Avian Adenovirus Group III	SPF chicken-Microbiological surveillance-Part 2: Hemagglutination inhibition test for SPF chicken GB/T17999.2-2008	SPF chicken	2022-11-09
				SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008		2022-11-09
		83	Fowl Pox Virus	SPF chicken-Microbiological surveillance-Part 5: Agar gel precipitation test for SPF chicken GB/T17999.5-2008	SPF chicken	2022-11-09
		84	detection of avian virus	ChP.2020.Vol.III ChP.2020.Vol.III 3308and monographs		2022-11-09
		85	Classical swine fever virus, CSFV	Diagnostic techniques for classical swine fever(hog cholera) GB/T 16551-2020	only for Pig	2022-11-09
		86	Porcine reproductive and respiratory syndrome virus, PRRSV	Diagnostic methods of porcine reproductive and respiratory syndrome; GB/T 18090-2008	only for Pig	2022-11-09
		87	Pseudorabies virus, PrV	Diagnostic method for pseudorabies GB/T 18641-2018	only for Pig	2022-11-09



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		88	Porcine parvovirus, PPV	Indirect ELISA for detection of antibodies against porcine parvovirus NY/T 2840-2015	only for Pig	2022-11-09
		89	Porcine circovirus type2, PCV2	Detecting porcine circovirus with polymerase chain reaction GB/T 21674-2008	only for Pig	2022-11-09
		90	Porcine transmissible gastroenteritis virus, TGEV	Quarantine protocol for transmissible gastroenteritis of swine SN/T 1446-2010	only for Pig	2022-11-09
		91	Swine vesicular disease virus, SVDV	Quarantine protocol for swine vesicular disease SN/T 2702-2010	only for Pig	2022-11-09
		92	Bordetella bronchiseptica	Detection of infectious atrophic rhinitis for swine NY/T 546-2015	only for Pig	2022-11-09
		93	Pasteurella multocida	Detection of infectious atrophic rhinitis for swine NY/T 546-2015	only for Pig	2022-11-09
				NY/T 564-2002 Diagnostic techniques for swine pasteurellosis NY/T 564-2016	only for Pig	2022-11-09
		94	Actinobacillus pleuropneumoniae, APP	Diagnostic techniques for actinobacillus pleuropneumonia NY/T 537-2002	only for Pig	2022-11-09
		95	Streptococcus suis type 2	Procedure of plate and tube agglutination for Streptococcus suis type 2 GB/T 19915.1-2005	only for Pig	2022-11-09
				Methods for detection of Streptococcus suis type 2 GB/T 19915.2-2005		2022-11-09
				Method for detection Streptococcus suis type 2 by PCR GB/T 19915.3-2005		2022-11-09
				Method of the real-time PCR for the detection of Streptococcus suis type 2 GB/T 19915.7-2005		2022-11-09
		96	coccidium	Diagnostic techniques for animal coccidiosis GB/T 18647-2020	only for Pig	2022-11-09



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		№	Item/ Parameter			
		97	Vibrio cholerae	National Specification for Food Safety: Microbiological Test Examination of Vibrio cholerae GB 4789.7-2013	only for fish	2022-11-09
		98	Aeromonas hydrophila	Rules for quaranting bacterial diseases of fish Part3: Diagnostic method for bacterial enteritis SC/T 7201.3-2006	only for fish	2022-11-09
		99	Streptococcus iniae	Method for examination of Streptococcus pneumonia GB/T 14926.15-2001	only for fish	2022-11-09
		100	Flavobacterium columnare	Rules for quaranting bacterial diseases of fish Part:2: Diagnostic method for gill-rot disease SC/T 7201.2-2006	only for fish	2022-11-09
		101	Aeromonas veronii	Methods for detection of pathogenic aeromonas hydrophila GB/T 18652-2002	only for fish	2022-11-09
		102	Aeromonas jandaei	Methods for detection of pathogenic aeromonas hydrophila GB/T 18652-2002	only for fish	2022-11-09
		103	Saprolegnia spp.	National Specification for Food Safety: Microbiological Test Enumeration of moulds and yeasts GB 4789.15-2016	only for fish	2022-11-09
		104	Branchiomyces spp.	Protocol of quarantine for branchiomycosis of fish SN/T 2439-2010	only for fish	2022-11-09
		105	Flavobacterium branchiophilum	Diagnostic method for gill-rot disease SC/T 7201.2-2006	only for fish	2022-11-09
		106	Flavobacterium psychrophilum	Diagnostic method for gill-rot disease SC/T 7201.2-2006	only for fish	2022-11-09
		107	Pseudomonas spp.	Diagnostic method for Red-skin disease SC/T 7201.4-2006	only for fish	2022-11-09
		108	Aeromonas sobri	Methods for detection of pathogenic aeromonas hydrophila GB/T 18652-2002	only for fish	2022-11-09
		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	2022-11-09
		110	Erysipelothrix rhusiopathiae	Diagnostic techniques for swine erysipelas NY/T 566-2019	only for Pig	2022-11-09



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		111	Haemophilus parasuis	Detection methods for haemophilus parasuis GB/T 34750-2017	only for Pig	2022-11-09
		112	Coxiella burnetii	PCR detection methods for tick borne encephalitis virus, borrelia burgdorferi, coxiella burnetii SN/T 3395-2012	only for sheep and goat	2022-11-09
		113	Bacillus anthracis	Diagnostic techniques for animal anthrax NY/T 561-2015	only for sheep and goat	2022-11-09
		114	trichinella	Diagnostic techniques for trichinella spp. GB/T 18642-2021	only for Pig	2022-11-09
		115	cysticercus	Diagnostic techniques for cysticercosis cellulosae GB/T 18644-2020	only for Pig	2022-11-09
		116	echinococcus	Diagnostic techniques for animal echinococcosis NY/T 1466-2018	only for sheep and goat	2022-11-09
		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	only for pig	2022-11-09
		118	SV40 (Simian vacuolating virus)	Pharmacopoeia of the People's Republic of China (2020 edition, part III), general rule 3304	Biological products derived from animal	2022-11-09
		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	2022-11-09
				Diagnostic techniques for foot-and-mouth disease GB/T 18935-2018	only for pig	2022-11-09
		120	Peste des petits	Diagnostic techniques for peste des petits ruminants GB/T 27982-	only for	2022-11-09

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			ruminantsvirus	2011	sheep and goat	
		121	Sheep/ goat pox virus	Clinical diagnostic technology for sheep pox and goat pox NY/T 576-2015	only for sheep and goat	2022-11-09
		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	2022-11-09
				Sterilization of health care products — Biological indicators — Part 1: General requirements Sterilization of health care products — Biological indicators — Part 1: General requirements		2022-11-09
				Sterilization of medical devices — Microbiological methods—Part 1: Determination of a population of microorganisms on products Sterilization of medical devices — Microbiological methods—Part 1: Determination of a population of microorganisms on products		2022-11-09
		123	Helicobacter pylori	Determination of Helicobacter pylori in food for export SN/T 3724-2013	only for M、Gerbil	2022-11-09
		124	Klebsiellaoxytoca	Microbiological examination method for milk an milk products hygiene-Part 9: Detection of Klebsiella spp. SN/T 2552.9-2010	only for M、Gerbil	2022-11-09
		125	DNA barcode	Laboratory animal-Quality control of laboratory fish GB/T 39649-2020 4	Except for 4.2.3.3	2022-11-09
		126	microsatellite markers	Laboratory animal-Methods for microsatellite markers of laboratory mice & rats T/CALAS 21-2017	Except for 4.4.6	2022-11-09
		127	Helicobacter spp.	Laboratory animal- PCR Method for the detection of Helicobacter T/CALAS 24-2017	only for Mouse	2022-11-09
		128	Corynebacterium bovis	Laboratory animal-Method for examination of Corynebacterium bovis T/CALAS 20-2017	only for Mouse	2022-11-09



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		129	Mycobacterium tuberculosis	Real-time PCR method for the detection of tuberculosis pathogenic organisms GB/T 27639-2011	only for Harmster, monkey	2022-11-09
		130	Burkholderia mallei	OIE Terrestrial Manual 2018 Chapter 3.5.11-Glanders and Melioidosis	only for Equine	2022-11-09
		131	Salmonella abortus equi	Diagnostic techniques for equine abortus salmonellosis NY/T 570-2002	only for Equine	2022-11-09
				Defection methods of salmonella for animal and animal products NY/T 550-2002	only for Equine	2022-11-09
		132	Edwardsiella tarda	Detection methods for Edwardsiella from fish—Part 1:Edwardsiella tarda SC/T 7214.1-2011	only for Fish	2022-11-09
		133	Vibrio vulnificus	National food safety standards, microbiology detection, inspection of Vibrio vulnificus GB 4789.44-2020	only for Fish	2022-11-09
				GB/T 39649-2020 6	Only for Fish	2022-11-09
		134	Mycobacterium marinum	Laboratory animal-Quality control of laboratory fish GB/T 39649-2020 6	only for Fish	2022-11-09
		135	Mycoplasma hyopneumoniae	Diagnostic techniques for mycoplasmal pneumonia of swine NY/T 1186-2017	only for Pig	2022-11-09
		136	Avian mycoplasmas(Mycoplasma gallisepticum, Mycoplasma synoviae)	Detection of avian mycoplasmas by polymerase chain reaction(PCR) NY/T 553-2015	only for poultry	2022-11-09
		137	Serpul-Mahydysenteriae	Quarantine protocol for swine dysentery NY/T 545-2002	only for Pig	2022-11-09
				Quarantine protocol for swine dysentery SN/T 1207-2011	only for Pig	2022-11-09



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		138	Brucella spp.	Diagnostic techniques for animal brucellosis GB/T 18646-2018	only for dog, pig, sheep or goat, equine	2022-11-09
		139	Japanese encephalitis virus, JEV	Diagnostic techniques for Japanese encephalitis GB/T 18638-2021	only for Pig	2022-11-09
		140	murine norovirus	Laboratory animal-Methods for murine norovirus T/CALAS 22-2017	only for Mouse	2022-11-09
		141	porcine parvovirus	Quarantine protocol for porcine parvovirus infection SN/T 1919-2016	only for Pig	2022-11-09
		142	Genotype	Genotype of genetically modifying mouse model T/CALAS79-2020		2022-11-09
Packaging materials						
1	Packaging materials	1	Test for Skin Sensitization	National standards for pharmaceutical packaging materials Test for Skin Sensitization YBB00052003-2015		2022-11-09
		2	Test for Acute Systemic Toxicity	National standards for pharmaceutical packaging materials Test for Acute Systemic Toxicity YBB00042003-2015		2022-11-09
		3	Test for Pyrogen	National standards for pharmaceutical packaging materials Test for Pyrogen YBB00022003-2015		2022-11-09
		4	Test for Hemolysis	National standards for pharmaceutical packaging materials Test for Hemolysis YBB00032003-2015		2022-11-09
		5	Test for eye Irritation	National standards for pharmaceutical packaging materials Test for eye Irritation YBB00062002-2015, YBB00072002-2015		2022-11-09
		6	Test for Cytotoxicity	National standards for pharmaceutical packaging materials Test for Cytotoxicity YBB00012003-2015		2022-11-09
		7	Test for Intracutaneous	National standards for pharmaceutical packaging materials Test for Intracutaneous Irritation YBB00062003-2015		2022-11-09



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		№	Item/ Parameter			
			Irritation			
		8	Test for Primary Skin Irritation	National standards for pharmaceutical packaging materials Test for Primary Skin Irritation YBB00072003-2015		2022-11-09
Non-active medical device						
1	Allogeneic bone grafts	1	All items	Allogeneic bone grafts Part3: Demineralized allogeneic bone grafts YY/T 0513.3-2009		2022-11-09
2	medical devices	1	Pyrogen Test	ChP 2020 年版四部 通则 (1142)		2022-11-09
		2	Bacterial Endotoxins Test	ChP 2020 年版四部 通则 (1143)		2022-11-09
		3	Sterility Test Technology	ChP 2020 年版四部 通则 (1101)		2022-11-09
		4	Protein content determination method	ChP 2020 年版四部 通则 (0731)		2022-11-09
		5	molecular-exclusion chromatography method	ChP 2020 年版四部 通则 (0514)		2022-11-09
		6	transformation temperature	Standard test method for transformation temperature of nickel-Titanium alloys by thermal analysis YY/T 0641-2008		2022-11-09
		7	Vickers hardness test	Metallic materials--Vickers hardness test—Part1: Test method GB/T 4340.1-2009		2022-11-09
		8	corrosion resistance	Medical instruments of stain less steel-Test methods of corrosion resistance YY/T 0149-2006		2022-11-09
		9	corrosion resistance	Standard test method for conducting cyclic potentiodynamic polarization measurements to determine the corrosion susceptibility of small Implant devices YY/T 0695-2008		2022-11-09



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		10	MS	ChP 2020 年版四部 通则 (0431)		2022-11-09
		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		2022-11-09
		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		2022-11-09
		13	pH measurement method	ChP 2020 年版四部 通则 (0631)		2022-11-09
		14	Heavy metal inspection method	ChP 2020 年版四部 通则 (0821)		2022-11-09
		15	Infrared spectrophotometry method	ChP 2020 年版四部 通则 (0402)		2022-11-09
		16	ultraviolet-visible spectrophotometry method	ChP 2020 年版四部 通则 (0401)		2022-11-09
		17	Clarity	ChP 2020 年版四部 通则 (0902)		2022-11-09
		18	Color	ChP 2020 年版四部 通则 (0901)		2022-11-09
		19	Residue on Ignition	ChP 2020 年版四部 通则 (0841)		2022-11-09
		20	Residual solvents	ChP 2020 年版四部 通则 (0861)		2022-11-09
		21	Atomic absorption spectrophotometry method	ChP 2020 年版四部 通则 (0406)		2022-11-09
		22	High Performance Liquid Chromatography	ChP 2020 年版四部 通则 (0512)	不做多维液相色谱法	2022-11-09

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		№	Item/ Parameter			
		23	Gas Chromatography	ChP 2020 年版四部 通则 (0521)		2022-11-09
		24	Microbial limits test	ChP 2020 年版四部 通则 (1105), (1106)		2022-11-09
		25	characterizaiton of hydrogels	Tissue engineering medical products-Standard guide for characterizaiton of hydrogels YY/T 1435-2016		2022-11-09
		26	Determination of silver contents in biological samples	Nanotechnology—Determination of silver contents in biological samples — Inductively coupled plasma mass spectrometry GB/T 38261-2019		2022-11-09
		27	Method to measure cell miagration in porous materials	Tissue engineering medical products-Bioactive ceramics-Method to measure cell miagration in porous materials YY/T 1744-2020		2022-11-09
3	Heart valve substitutes implanted by transcatheter techniques	1	All items	Cardiovascular implants—Cardiac valve prostheses—Part 3:Heart valve substitutes implanted by transcatheter techniques YY/T1449.3-2016		2022-11-09
4	vascular stents	1	All items	Standard test methods for in vitro pulsatile durability testing of vascular stents YY/T 0808-2010		2022-11-09
5	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		2022-11-09
6	Stainless Steel Needles for Prefilled Syringes	1	All items	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015		2022-11-09
7	Tissue	1	Characterization of	Tissue engineering medical device products-Methods for		2022-11-09

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		№	Item/ Parameter			
	engineering medical device		type I collagen	determination of type I collagen YY/T 1453-2016		
		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		2022-11-09
		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		2022-11-09
8	Tissue engineering medical devices		remnant DNA quantification	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	non	2022-11-09
9	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		2022-11-09
10	Medical devices	1	immunological evaluation	Biological evaluation of medical devices—Part 20:Principles and methods for immunotoxicology testing of medical devices GB/T 16886.20-2015		2022-11-09
11	Medical devices	1	pyrogen	Pyrogen test for medical devices— Monocyte-activation test Human whole bloodELISA method YY/T 1500-2016		2022-11-09
12	Tissue engineering medical devices	1	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		2022-11-09
13	Medical devices utilizing	1	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;		2022-11-09



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	animal tissues and their derivatives or allogeneic medical device		2、 Kinetics of virus inactivated	YY/T 0771.3-2009		
				2020 Revision		2022-11-09
				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		2022-11-09
		2	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		2022-11-09
		3	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		2022-11-09
14	Medical devices utilizing animal tissues and their derivatives	1	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		2022-11-09
15	Artificial heart Valve	1	All items	Artificial heart Valve GB12279-2008 (ISO5840: 1996,IDT)		2022-11-09
16	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts	1	All items	Tubular vascular prostheses YY/T 0500-2021		2022-11-09



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	and vascular patches					
17	Silicon gel breast implant prostheses	1	All items	Silicon gel breast implant prostheses YY 0647-2008/ISO 14607:2007		2022-11-09
18	Hip joint prostheses		All items	Hip joint prostheses YY0118-2016		2022-11-09
19	Artificial Knee joint Implants	1	All items	Joint replacement implants- Knee joint prostheses YY0502-2016		2022-11-09
20	Metallic bone screws	1	All items	Implants for osteosynthesis-Metallic bone screws YY 0018—2016		2022-11-09
21	Metallic intramedullary nailing systems	1	All items	Implants for surgery-Intramedullary nailing systems - Part 2: Medullary pins YY/T0019.2-2011		2022-11-09
22	Metal correctional nail	1	All items	Spinal implants-Components used in the surgical fixation of the spinal skeletal system-Part2:Metallic spinal screws YY/T0119.2-2014		2022-11-09
23	Metal correctional stick	1	All items	Spinal implants-Components used in the surgical fixation of the spinal skeletal system-Part4:Metallic spinal rods YY/T0119.4-2014		2022-11-09
24	Metal bone pins	1	All items	Implant for osteosynthesis- Metal bone pins YY/T 0345.1-2020,YY/T 0345.2-2014,YY/T 0345.3-2014		2022-11-09
25	Metallic bone plates	1	All items	Implant for osteosynthesis- Metallic bone plates YY0017-2016		2022-11-09
26	Metal nail for neck fixation of femur	1	All items	Implant for osteosynthesis-Metal nail for neck fixation of femur YY0346-2002		2022-11-09
27	Forgings, castings for bone joint	1	All items	Implants for surgery-Forgings, castings for bone joint prostheses-TC4 titanium alloy forgings YY0117.1-2005		2022-11-09



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	prostheses-TC4 titanium alloy forgings					
28	Forgings, castings for bone joint prostheses-Ti6Al4V titanium alloy castings	1	All items	Implants for surgery-Forgings, castings for bone joint prostheses-Ti6Al4V titanium alloy castings YY0117.2-2005		2022-11-09
29	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 YY0117.3-2005		2022-11-09
30	The principle of surgery implants	1	All items	The principle of surgery implants YY0340-2009		2022-11-09
31	General technological requirements for non-active metallic surgery implants of osteosynthesis	1	All items	General technological requirements for non-active metallic surgery implants of osteosynthesis YY0341-2009		2022-11-09
32	Disposable	1	All items	Disposable intrauterine device inserter YY/T0470-2004		2022-11-09



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	intrauterine device inserter					
33	Disposable intrauterine device inserter	1	All items	Disposable intrauterine device inserter GB 11234-2006		2022-11-09
34	OCu intra-uterine devices	1	All items	OCu intra-uterine devices GB 3156-2006		2022-11-09
35	Vcu intra-Uterine device	1	All items	Vcu intra-Uterine device GB 11235-2006		2022-11-09
36	TCu intrauterine devices	1	All items	TCu intrauterine devices GB 11236-2006		2022-11-09
37	Stents	1	All items	Cardiovascular implant—Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016		2022-11-09
38	Biological evaluation of medical devices	1	Tests for genotoxicity, carcinogenicity and reproductive toxicity	Biological evaluation of medical devices-Part3:Tests for genotoxocoty,carcinogenicity and reproductive toxicity GB/T 16886.3-2019		2022-11-09
		2	Selection of tests for interactions with blood	Biological evaluation of medical devices-Part4:Selection of tests fou interactions with biood GB/T 16886.4-2003		2022-11-09
		3	Test for in vitro cytotoxicity	Biological evaluation of medical devices-Part5:Test for in vitro cytotoxicity GB/T 16886.5-2017		2022-11-09
		4	Tests for local effects after implantation	Biological evaluation of medical devices-Part6:Tests for local effects after implantation GB/T 16886.6-2015		2022-11-09
		5	Ethylene oxide sterilization residuals	Biological evaluation of medical devices-Part7:Ethylene oxide sterilization residuals GB/T 16886.7-2015		2022-11-09



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		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/T 16886.9-2017		2022-11-09
		7	Tests for irritation and delayed-type hypersensitivity	Biological evaluation of medical devices-Part10:Tests for irritation and delayed-type hypersensitivity GB/T 16886.10-2017		2022-11-09
		8	Tests for systemic toxicity	Biological evaluation of medical devices-Part11:Tests for systemic toxicity GB/T 16886.11-2011		2022-11-09
		9	Sample preparation and reference materials	Biological evaluation of medical devices-Part12:Sample preparation and reference materials GB/T 16886.12-2017		2022-11-09
		10	Identification and quantification of degradation products from polymeric medical devices	Biological evaluation of medical devices-Part13:Identification and quantification of degradation products from polymeric medical devices GB/T 16886.13-2017		2022-11-09
		11	Identification and quantification of degradation products from ceramics	Biological evaluation of medical devices-Part14:Identification and quantification of degradation products from ceramics GB/T 16886.14-2003		2022-11-09
		12	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/T 16886.15-2003		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
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		13	Toxicokinetic study design for degradation products and leachables	Biological evaluation of medical devices-Part16:Toxicokinetic study design for degradation products and leachables GB/T 16886.16-2013		2022-11-09
		14	Establishment of allowable limits for leachable substances	Biological evaluation of medical devices-Part17:Establishment of allowable limits for leachable substances GB/T 16886.17-2005		2022-11-09
		15	Chemical characterization of materials	Biological evaluation of medical devices-Part18:Chemical characterization of materials GB/T 16886.18-2011		2022-11-09
		16	Physico-chemical, morphological and topographical characterization of materials	Biological evaluation of medical devices-Part19:Physico-chemical,morphological and topographical characterization of materials GB/T 16886.19-2011		2022-11-09
		17	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		2022-11-09
		18	Brain in situ implantation test	Evaluation of neurotoxicity of medical devices—Part 1:Standard guide for selecting tests to evaluate potential neurotoxicity YY/T 1670.1-2019		2022-11-09
		19	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		2022-11-09
		20	Toxicokinetic study	Biological evaluation of medical devices—Part 16:Toxicokinetic study design for degradation products and leachables GB/T 16886.16-2021		2022-11-09



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		21	Biological evaluation of absorbable medical devices	Biological evaluation of absorbable medical devices—Part 1:Guidance for absorbable implants YY/T 1775.1-2021		2022-11-09
		22	implantation assessment of absorbable medical products	Tissue engineering medical products-Standard practice for implantation assessment of absorbable/resorbable biomaterials YY/T 1576-2017		2022-11-09
		23		Test for genotoxicity of medical devices—Part 1:Bacterial reverse mutation test YY/T 0870.1-2013		2022-11-09
		24		Biological evaluation of medical devices—Part 11:Tests for systemic toxicity GB/T 16886.11-2021		2022-11-09
		25		Tests for hemolysis of medical devices—Part 1: Material induced hemolysis assay YY/T 1651.1-2019		2022-11-09
		26		Immunogenic evaluation method of medical devices--Part 6: Determination of animal spleen lymphocyte subsets by flow cytometry YY/T 1465.6-2019		2022-11-09
		27		Immunogenic evaluation method of medical devices--Part 7: Liquid phase multiplex protein quantification technique by flow cytometry YY/T 1465.7-2021		2022-11-09
		28	In Vitro skin irritation test for medical devices	In Vitro skin irritation test for medical devices YY/T 1808-2021		2022-11-09
39	Sterile, single-use intravascular catheters-Part 1: General requirements	1	All items	Sterile, single-use intravascular catheters-Part 1: General requirements YY 0285.1—2017		2022-11-09



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40	Sterile, single-use intravascular catheters-Angiographic catheters	1	Partial items	Sterile, single-use intravascular catheters-Angiographic catheters YY 0285.2-1999	Except for: X ray detection	2022-11-09
41	Sterile, single-use intravascular catheters-Central venous catheters	1	Partial items	Sterile, single-use intravascular catheters-Central venous catheters YY 0285.3-2017	Except for X-ray detection	2022-11-09
42	Sterile, single-use intravascular catheters-Balloon dilatation catheters	1	Partial items	Sterile, single-use intravascular catheters-Balloon dilatation catheters YY 0285.4-2017	Except for X-ray detection	2022-11-09
43	Sterile, single-use intravascular catheters-Over-needle peripheral catheters	1	Partial items	Sterile, single-use intravascular catheters-Over-needle peripheral catheters YY 0285.5-2018	Except for X-ray detection	2022-11-09
44	Accessory devices for sterile single-use intravascular	1	Partial items	Accessory devices for sterile single-use intravascular catheters-Introducers YY0450.1-2020	Except for X-ray detection	2022-11-09



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	catheters- Introducers					
45	Accessory devices for sterile single-use intravascular catheters- Obturator for over-needle peripheral catheters	1	All items	Accessory devices for sterile single-use intravascular catheters- Obturator for over-needle peripheral catheters YY0450.2-2003		2022-11-09
46	Infusion sets for single use	1	All items	Infusion sets for single use GB 8368-2018		2022-11-09
47	Transfusion set for single use	1	All items	Transfusion set for single use GB 8369.1-2019		2022-11-09
48	Infusion sets with precision filters for single use	1	All items	Infusion sets with precision filters for single use YY 0286.1-2019		2022-11-09
49	Burette-type infusion sets for single use	1	All items	Burette-type infusion sets for single use YY 0286.2-2006		2022-11-09
50	Single use blood-taking set for blood processing equipment	1	All items	A.V.fistula needle sets for single use YY/T 0328-2015		2022-11-09
51	Conventional blood	1	All items	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB14232.1-2004		2022-11-09



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	containers					
52	Plunger of sterile syringes for single use	1	All items	Plunger seal of syringes for single use YY/T 0243-2016		2022-11-09
53	Blood flow products for single use-General specification	1	All items	Blood flow products for single use-General specification GB19335-2003		2022-11-09
54	Single-use containers for venous blood specimen collection	1	All items	Single-use containers for venous blood specimen collection YY 0314 -2007		2022-11-09
55	Infusion sets for single use,gravity feed	1	All items	Infusion sets for single use,gravity feed GB 8368-2018		2022-11-09
56	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		2022-11-09
57	Implantable drug-supplying device	1	All items	Implantable drug-supplying device YY0332-2011		2022-11-09
58	Soft tissue expander device	1	All items	Soft tissue expander device YY 0333-2010		2022-11-09

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59	Silicone rubber for surgery application	1	All items	General requirements of Silicone rubber implants YY0334-2002、XG1-2013		2022-11-09
60	Cervix expander	1	All items	cervix expander YY 0091-2013		2022-11-09
61	Sterile vagina dilator for single use	1	All items	Sterile vagina dilator for single use YY 0336-2013		2022-11-09
62	Commonly-used tubes and connectors	1	All items	Tracheal tubes Part 1:- Commonly-used tubes and connectors YY0337.1-2002		2022-11-09
63	Cole type tube	1	All items	Tracheal tubes-Part2: Cole type tube YY0337.2-2002		2022-11-09
64	Anaesthetic and respiratory equipment: Breathing tubes	1	All items	Anaesthetic and respiratory equipment—Conical connectors—Part 1:Cones and sockets YY 1040.1-2015		2022-11-09
65	Single-use injectors for continuous ambulatory administration of medicinal products by parenteral route	1	All items	Single-use injectors for continuous ambulatory administration of medicinal products by parenteral route YY0451-2010		2022-11-09
66	Sterile urethral catheter for single use	1	All items	Sterile urethral catheter for single use YY0325-2016		2022-11-09



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67	polyethylene for Infusion, transfusion ,Injection equipment	1	Partial items	polyethylene for Infusion, transfusion ,Injection equipment YY/T 0114-2008	Tensile yield stress, flexural modulus, notched izod impact	2022-11-09
68	Polypropylene for transfusion (infusion) equipment	1	Partial items	Plasticized polyvinyl chloride (PVC) compounds for transfusion (infusion) equipment GB/T 15593-2020	Except for Aluminum, Mercury	2022-11-09
69	Polypropylene for transfusion (infusion) equipment	1	Partial items	polypropylene for transfusion (infusion) equipment YY0242-2007	Tensile yield stress, flexural modulus, notched izod impact, fog scale	2022-11-09
70	Rubber condoms	1	All items	Natural latex rubber condoms—Requirements and test methods GB/T 7544-2019		2022-11-09
71	Silicone elastomer pump tubs	1	All items	Cardiopulmonary bypass systems—Extracorporeal blood circuit YY 1048-2016		2022-11-09
72	Silicone elastomer infusion (transfusion) tubes	1	All items	Silicone elastomer infusion (transfusion) tubes YY/T 0031-2008		2022-11-09
73	Dimethiconum	1	All items	Dimethiconum ChP 2020 Vol II		2022-11-09



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74	Hydroxypropyl Methyl Cellulose (HPMC)	1	All items	Hydroxypropyl Methyl Cellulose (HPMC) ChP 2020 Vol IV		2022-11-09
75	Infusion, transfusion, injection equipment for medical use	1	All items	Infusion, transfusion, injection equipment for medical use GB/T 14233.1-2008		2022-11-09
76	Test methods for infusion, transfusion, injection equipment for medical use	1	All items	Test methods for infusion, transfusion, injection equipment for medical use GB/T 14233.2-2005		2022-11-09
77	Conical fittings with a 6% taper for syringes, needles and certain other medical equipment	1	All items	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment-Part1: General requirement、Part2: Lock fittings GB/T1962.1-2015、GB/T1962.2-2001		2022-11-09
78	Medical purified cotton	1	All items	Medical absorbent cotton YY 0330-2015		2022-11-09
79	Medical purified gauze	1	All items	Medical purified gauze YY 0331-2006		2022-11-09
80	Primary wound dressing	1	All items	Primary wound dressing YY/T 0471.1~6-2004		2022-11-09
81	Medical suture	1	All items	Medical suture needle YY/T 0043-2016		2022-11-09

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	needle(without thread)					
82	Non-absorbable surgical suture	1	All items	Non-absorbable surgical suture YY0167-2020		2022-11-09
83	Absorbable surgical suture		All items	Absorbable surgical suture YY1116-2020		2022-11-09
84	Suture forceps	1	All items	Suture forceps YY/T 0245-2008		2022-11-09
85	Single-use puncture set for local anaesthesia	1	All items	Single-use puncture set for local anaesthesia YY 0321.1-2009		2022-11-09
86	Single-use needle for anaesthesia	1	All items	Single-use needle for anaesthesia YY 0321.2-2009		2022-11-09
87	Single-use filter for anaesthesia	1	All items	Single-use filter for anaesthesia YY 0321.3-2009		2022-11-09
88	Intravenous needles for single use	1	All items	Intravenous needles for single use GB18671-2009		2022-11-09
89	Sterile hypodermic needles for single use	1	All items	Sterile hypodermic needles for single use GB 15811- 2016		2022-11-09
90	Sterile hypodermic syringes for single use	1	All items	Sterile hypodermic syringes for single use GB 15810-2019		2022-11-09



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91	Needles	1	All items	Needles YY/T 0282-2009		2022-11-09
92	Hydroxyapatite powder for medical applications	1	All items	Hydroxyapatite powder for medical applications YY 0303-1998		2022-11-09
93	plasma sprayed hydroxyapatite coated titanium implants	1	All items	plasma sprayed hydroxyapatite coated titanium implants YY 0304—2009		2022-11-09
94	wrought titanium and titanium implant	1	All items	wrought titanium and titanium dental implant YY 0315-2016		2022-11-09
95	Dentistry.Dental enamel bonding resin	1	All items	Dentistry.Dental enamel bonding resin YY 0269-2009Dentistry.Dental enamel bonding resin		2022-11-09
96	Dentistry—Ceramic denture teeth	1	All items	Dentistry—Ceramic denture teeth YY 0716-2009		2022-11-09
97	Synthetic Resin Teeth	1	All items	Synthetic Resin Teeth YY 0300-2009		2022-11-09
98	Biological evaluation of dental materials	1	Acute oral toxicity test	Biological evaluation of medical devices used in dentistry-Part 2:Test method-Acute oral toxicity test YY/T0127.14-2009		2022-11-09
		2	Subacute and subchronic systemic toxicity test:oral route	Biological evaluation of medical devices used in dentistry Part 2:Test method Subacute and subchronic systemic toxicity test:oral route YY/T0127.15-2018		2022-11-09
		3	Mouse lymphoma cells(TK)gene	Biological evaluation of medical devices used in dentistry-Part 17:Mouse lymphoma cells(TK)gene mutation test YY/T0127.17-		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			mutation test	2014		
		4	Micronucleus test	Dentistry-Biological evaluation of medical devices used in dentistry-Part 2:Test method-Micronucleus test YY/T0127.12-2008		2022-11-09
		5	Oral mucous membrane irritation test	Biological evaluation of medical devices used in dentistry-Part 2: Test method-Oral mucous membrane irritation test YY/T 0127.13-2018		2022-11-09
		6	hemolysis test, intravenous injection of acute systemic toxicity test	Biological test methods of dental materials hemolysis test biological oral material test method of intravenous injection of acute systemic toxicity test YY/T0127.1-1993		2022-11-09
		7	Test method-Acute systemic toxicity:intravenous path	Biological evaluation of medical devices used in dentistry-Part 2: Test method-Acute systemic toxicity:intravenous path YY/T0127.2-2009		2022-11-09
		8	Subcutaneous implant test	Biological evaluation of dental materials-Part 2:Biological evaluation test method of dental materials-Subcutaneous implant test YY/T0127.8-2001		2022-11-09
		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/T0127.10-2009		2022-11-09
99	dental elevator	1	All items	dental elevator YY/T 0170-2011		2022-11-09
100	Dental scalers instruments Excavators	1	All items	Dental scalers instruments Excavators YY/T 0274-2011		2022-11-09



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		№	Item/ Parameter			
101	Apical elevator	1	All items	Apical elevator YY/T 0277-1995		2022-11-09
102	Dental pluggers	1	All items	Dental pluggers YY/T 0275-2011		2022-11-09
103	T shape dental elevator	1	All items	T shape dental elevator YY/T 0170-2011		2022-11-09
104	Centrifuge bowl	1	All items	Centrifuge bowl YY/T 0326-2017		2022-11-09
105	Plasma tubing	1	All items	Plasma tubing YY/T 0326-2017		2022-11-09
106	Leukocyte removal filters for single use	1	All items	Leukocyte removal filters for single use YY 0329-2009		2022-11-09
107	Single use hemoperfueor	1	All items	Single use hemoperfueor YY/T 0464-2019		2022-11-09
108	Single use membrane plasmaseparator	1	All items	Single use membrane plasmaseparator YY 0465-2019		2022-11-09
109	Single use blood-taking set for blood processing equipment	1	All items	A.V.fistula needle sets for single use YY/T 0328-2015		2022-11-09
110	Cardiovascular implants and artificial organs— Blood-gas exchangers(oxygenators)	1	All items	Cardiopulmonary bypass systems—Blood-gas exchangers(oxygenators) YY 0604-2016		2022-11-09



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		№	Item/ Parameter			
111	Artificial heart-lung machine-extracorporeal blood circuit	1	All items	Cardiopulmonary bypass systems—Extracorporeal blood circuit YY1048-2016		2022-11-09
112	Artificial heart-lung machine—Water heating/cooling system	1	All items	Artificial heart-lung machine—Water heating/cooling system GB 12263-2017		2022-11-09
113	Cardiovascular implants and artificial organs—Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators	1	All items	Hemodialysis and relevant therapies—Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators YY 0053-2016		2022-11-09
114	Cardiovascular implants and artificial organs—Extracorporeal blood circuit for blood purification devices	1	All items	Hemodialysis and related therapies—Extracorporeal blood circuit for blood purification devices YY 0267-2016		2022-11-09



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		№	Item/ Parameter			
115	Cardiovascular implants and artificial organs— Haemodialysers haemodiafilters haemofilters and haemoconcentrators	1	All items	Hemodialysis and relevant therapies— Haemodialysers, haemodiafilters, haemofilters haemoconcentrators YY 0053-2016		2022-11-09
116	Water for haemodialysis and related therapies	1	All items	Water for haemodialysis and related therapies、 Concentrates for haemodialysis and related therapies YY 0572-2005 YY0598-2015		2022-11-09
117	Haemostatic forceps with box joint- General specifications	1	All items	Haemostatic forceps with box joint-General specifications GB/T2766-2006		2022-11-09
118	General specifications for needle holders	1	All items	General specifications for needle holders YY/T 0687-2008		2022-11-09
119	Scalpel blade	1	All items	Scalpel blade YY 0174-2019		2022-11-09
120	Surgical Scissors— General specifications	1	All items	Surgical Scissors—General specifications YY/T0176-2006		2022-11-09



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		№	Item/ Parameter			
121	General specification for medical forceps	1	All items	General specification for medical forceps YY/T0295.1-2005		2022-11-09
122	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		2022-11-09
123	Cardiac pacemakers-Part 1: Implantable pacemakers	1	All items	Implants for surgery-Active implantable medical devices-Part2: Cardiac pacemakers、 Disposable ECG electrodes GB 16174.2-2015, YY/T 0196-2005		2022-11-09
124	Medical ultrasonic couplant	1	All items	Medical ultrasonic couplant YY0299-2022		2022-11-09
125	heat radiation therapy equipment	1	All items	heat radiation therapy equipment YY 0060-2018		2022-11-09
126	Harmful residual of medical electronical materials	1	All items	Harmful residual of medical electronical materials SJ-T11365-2006		2022-11-09
127	Intraocular lens	1	All items	Intraocular lens YY 0290.1-2008、YY 0290.2-2009、YY 0290.2-2021、YY 0290.3-2018、YY 0290.4-2008、YY 0290.5-2008、YY 0290.6-2009、YY 0290.8-2008、YY 0290.9-2010		2022-11-09



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		№	Item/ Parameter			
128	Rigid contact lens	1	All items	Rigid contact lens GB11417.2 -2012		2022-11-09
129	Hydrophilic contact lens	1	All items	Hydrophilic contact lens GB11417.3 -2012		2022-11-09
130	Medical sodium hyaluronate gel	1	All items	Medical sodium hyaluronate gel YY/T0308-2015		2022-11-09
131	General specification for medical oxygen generator with molecular sieve	1	All items	General specification for medical oxygen generator with molecular sieve YY/T0298-1998		2022-11-09
132	CAPSULAR TENSION RINGS	1	All items	CAPSULAR TENSION RINGS YY 0762-2017		2022-11-09
133	Endovascular prostheses	1	All items	Cardiovascular implant—Endovascular devices—Part 1:Endovascular prostheses YY/T0663.1-2014		2022-11-09
134	Vena cava filters	1	All items	Cardiovascular implant—Endovascular devices—Part 3:Vena cava filters YY/T0663.3-2016		2022-11-09
135	Cardiac occluder	1	All items	Cardiovascular implant—Cardiac occluder YY/T1553-2017		2022-11-09
136	Cross-linked sodium hyaluronate gel	1	All items	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2014		2022-11-09
137	Medical devices for human in vitro assisted	1	All items	Medical devices for human in vitro assisted reproductive technology-In vitro mouse embryo assay YY/T1434-2016		2022-11-09



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		№	Item/ Parameter			
	reproductive technology					
138	Rigid gas permeable contact lenses for orthokeratology	1	All items	Rigid gas permeable contact lenses for orthokeratology YY0477-2016		2022-11-09
139	Medical devices	1	T lymphocyte transformation test in vitro	T lymphocyte transformation test in vitro YY/T 1465.1—2016		2022-11-09
140	Medical devices utilizing animal tissues and their derivatives	1	Material specific antibody detection	Material specific antibody detection for medical devices utilizing animal tissues and their derivatives Non-standard method non		2022-11-09
141	Biological evaluation of medical devices	1	All items	Biological evaluation of medical devices-Part5:Test for in vitro cytotoxicity GB/T 16886.5-2017		2022-11-09
		2	All items	Biological evaluation of medical devices-Part9:Framework for identification and quantification of potential degradation products GB/T 16886.9-2017		2022-11-09
		3	All items	Biological evaluation of medical devices-Part10:Tests for irritation and delayed-type hypersensitivity GB/T16886.10-2017		2022-11-09
		4	All items	Biological evaluation of medical devices-Part12:Sample preparation and reference materials GB/T 16886.12-2017		2022-11-09
		5	All items	Biological evaluation of medical devices-Part13:Identification and quantification of degradation products from polymeric medical devices GB/T16886.13-2017		2022-11-09



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142	Sterile, single-use intravascular catheters-Part 1: General requirements	1	All items	Intravascular catheters-Sterile and single-use catheters- Part 1: General requirements YY 0285.1—2017		2022-11-09
143	Sterile, single-use intravascular catheters-Central venous catheters	1	Partial items	Intravascular catheters-Sterile and single-use catheters- Part 3:Central venous catheters YY 0285.3-2017		2022-11-09
144	Sterile, single-use intravascular catheters-Balloon dilatation catheters	1	Partial items	Intravascular catheters-Sterile and single-use catheters- Part 4:Balloon dilatation catheters YY 0285.4-2017		2022-11-09
145	Sterile, single-use intravascular catheters-Over-needle peripheral catheters	1	Partial items	Intravascular catheters-Sterile and single-use catheters- Part 5:Over-needle peripheral catheters YY 0285.5—2018		2022-11-09
146	Single use blood-taking set for blood processing equipment	1	All items	A.V.fistula needle sets for single use YY/T 0328-2015		2022-11-09
		2	All items	Biological evaluation of medical devices used in dentistry- Part 15: Subacute and subchronic systemic toxicity test: oral route YY/T0127.15-2018		2022-11-09



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147	Centrifuge bowl	1	All items	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017		2022-11-09
148	Plasma tubing	1	All items	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017		2022-11-09
149	Single use blood-taking set for blood processing equipment	1	All items	A.V.fistulneedle sets for single use YY/T 0328-2015		2022-11-09
150	CAPSULAR TENSION RINGS	1	All items	Ophthalmic optical-Capsular tension ring YY 0762-2017		2022-11-09
151	Immunogenic evaluation method of medical devices-Part 4: Phagocytosis of mouse peritoneal macrophages on chicken erythrocytes-Ex-vivo method	1		Immunogenic evaluation method of medical devices-Part 4: Phagocytosis of mouse peritoneal macrophages on chicken erythrocytes-Ex-vivo method YY/T 1465.4-2017		2022-11-09
152	Medical devices for human assisted reproductive technology-A	1		Medical devices for human assisted reproductive technology-A method for blastocyst cell staining and counting YY/T 1688-2021		2022-11-09



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		№	Item/ Parameter			
	method for blastocyst cell staining and counting					
153	Test for reproductive and developmental toxicity of medical devices -Part 2:Prenatal developmental toxicity test	1		Test for reproductive and developmental toxicity of medical devices -Part 2:Prenatal developmental toxicity test YY/T 1292.2-2015		2022-11-09
154	Cardiovascular implants-Cardiac valve repair devices and delivery system	1		Cardiovascular implants-Cardiac valve repair devices and delivery system YY/T 1787-2021		2022-11-09
155	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		2022-11-09

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156		1	All Items	Additive manufacturing medical product-3D printing titanium alloy implant metal ion precipitation evaluation method YY/T 1802-2021		2022-11-09
157	Sterilization of medical devices- Microbiological methods-Part 1:Determination of a population of microorganisms on products	1	All Items	Sterilization of medical devices-Microbiological methods-Part 1:Determination of a population of microorganisms on products GB/T 19973.1-2015		2022-11-09
Active medical device						
1	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 YY0505-2012		2022-11-09
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014		2022-11-09
				Electromagnetic compatibility (EMC) -- Part 3-2: Limits -- Limits for harmonic current emissions (equipment input current ≤ 16 A per phase GB 17625.1-2012	Except for: three-phase product	2022-11-09
				Electromagnetic compatibility (EMC) -- Part 3-2: Limits -- Limits for harmonic current emissions (equipment input current ≤ 16 A per phase IEC 61000-3-2:2014,I	Except for: three-phase product	2022-11-09
		2	voltage fluctuations and flicker	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY0505-2012		2022-11-09



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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		2022-11-09
				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	Except for: three-phase product	2022-11-09
				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	Except for: three-phase product	2022-11-09
		3	Electrostatic discharge immunity test	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY0505-2012		2022-11-09
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014		2022-11-09
				Testing and measuring techniques - Electrostatic discharge immunity test GB/T 17626.2-2018		2022-11-09
				Testing and measuring techniques - Electrostatic discharge immunity test IEC 61000-4-2:2008		2022-11-09
				Testing and measuring techniques - Electrostatic discharge immunity test IEC 61000-4-2-2001		2022-11-09
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2022-11-09
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2:		2022-11-09



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		№	Item/ Parameter			
				Immunity CISPR 14-2:2015		
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2022-11-09
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2022-11-09
		4	Electrical fast transient/burst immunity test	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY0505-2012		2022-11-09
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014		2022-11-09
				Testing and measurement techniques -- Electrical fast transient/burst immunity test GB/T 17626.4-2018		2022-11-09
				Testing and measurement techniques -- Electrical fast transient/burst immunity test IEC 61000-4-4:2012		2022-11-09
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2022-11-09
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity CISPR 14-2:2015		2022-11-09
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2022-11-09
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2022-11-09
		5	Surge immunity test	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY0505-2012		2022-11-09



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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		2022-11-09	
				Testing and measurement techniques - Surge immunity test GB/T 17626.5-2019		2022-11-09	
				Testing and measurement techniques - Surge immunity test IEC 61000-4-5:2014		2022-11-09	
				Testing and measurement techniques - Surge immunity test IEC 61000-4-5:2005		2022-11-09	
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2022-11-09	
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity CISPR 14-2:2015		2022-11-09	
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2022-11-09	
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2022-11-09	
		6	conducted disturbances, induced by radio-frequency fields		Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY0505-2012		2022-11-09
					Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014		2022-11-09
					Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields GB/T 17626.6-2017		2022-11-09
					Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields IEC 61000-4-		2022-11-09



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		№	Item/ Parameter			
				6:2013		
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2022-11-09
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity CISPR 14-2:2015		2022-11-09
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2022-11-09
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2022-11-09
		7	Voltage dips, short interruptions and voltage variations	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY0505-2012		2022-11-09
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014		2022-11-09
				Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests GB/T 17626.11-2008		2022-11-09
				Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests IEC 61000-4-11: 2004		2022-11-09
				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		2022-11-09
				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		2022-11-09



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		№	Item/ Parameter				
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2022-11-09	
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity CISPR 14-2:2015		2022-11-09	
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2022-11-09	
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2022-11-09	
		8	Power frequency magnetic field immunity		Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY0505-2012		2022-11-09
					Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014		2022-11-09
					Testing and measurement techniques - Power frequency magnetic field immunity test GB/T 17626.8-2006		2022-11-09
					Testing and measurement techniques - Power frequency magnetic field immunity test IEC 61000-4-8:2009		2022-11-09
					Testing and measurement techniques - Power frequency magnetic field immunity test IEC 61000-4-8-2001		2022-11-09
					Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2022-11-09
					Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2022-11-09
		9	CE		Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY0505-2012		2022-11-09



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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		2022-11-09
				Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emissio GB 4343.1-2018		2022-11-09
				Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emissio CISPR 14-1:2011		2022-11-09
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement GB 4824-2019		2022-11-09
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement CISPR 11:2016		2022-11-09
				Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement GB/T 9254.1-2021		2022-11-09
				Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement CISPR 32:2015		2022-11-09
				Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment GB/T 17743-2021		2022-11-09
				Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment CISPR 15: 2018		2022-11-09
		10	RE (1GHz~18GHz)	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY0505-2012		2022-11-09



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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		2022-11-09		
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement GB 4824-2019		2022-11-09		
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement CISPR 11:2016		2022-11-09		
				Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement GB/T 9254.1-2021		2022-11-09		
				Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement CISPR 32:2015		2022-11-09		
		11	RE (30MHz~1GHz)			Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY0505-2012		2022-11-09
						Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014		2022-11-09
						Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement GB 4824-2019		2022-11-09
						Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement CISPR 11:2016		2022-11-09
						Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement GB/T 9254.1-2021		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement CISPR32:2015		2022-11-09
				Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emissio GB 4343.1-2018		2022-11-09
				Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emissio CISPR 14-1:2011		2022-11-09
				Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment GB/T 17743-2021		2022-11-09
				Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment CISPR 15: 2018		2022-11-09
		12	RE (9kHz~31MHz)	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY0505-2012		2022-11-09
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014		2022-11-09
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement GB 4824-2019		2022-11-09
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement CISPR 11:2016		2022-11-09
				Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment GB/T 17743-2021		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment CISPR 15: 2018		2022-11-09
		13	click	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY0505-2012		2022-11-09
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014		2022-11-09
				Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emissio GB 4343.1-2018		2022-11-09
				Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emissio CISPR 14-1:2011		2022-11-09
		14	distrubance power	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY0505-2012		2022-11-09
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014		2022-11-09
				Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emissio GB 4343.1-2018		2022-11-09
				Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emissio CISPR 14-1:2011		2022-11-09
		15	RS	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY0505-2012		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014		2022-11-09
				Electromagnetic compatibility (EMC) -- Part 4-3: Testing and measurement techniques -- Radiated, radio-frequency, electromagnetic field immunity test - GB/T 17626.3-2016		2022-11-09
				Electromagnetic compatibility (EMC) -- Part 4-4: Testing and measurement techniques -- Radiated, radio-frequency, electromagnetic field immunity test IEC 61000-4-3:2010		2022-11-09
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2022-11-09
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 3: Immunity CISPR 14-2:2015		2022-11-09
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2022-11-09
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2022-11-09
				2	Measurement control and laboratory use—EMC	1
Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements IEC 61326-1:2005(第1版)		2022-11-09				
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		2022-11-09				
Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 2-6: Particular requirements -- In		2022-11-09				



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				vitro diagnostic (IVD) medical equipment IEC 61326-2-6:2005		
				Electromagnetic compatibility (EMC) -- Part 3-2: Limits -- Limits for harmonic current emissions (equipment input current ≤ 16 A per phase GB 17625.1-2012	Except for: three-phase product	2022-11-09
				Electromagnetic compatibility (EMC) -- Part 3-2: Limits -- Limits for harmonic current emissions (equipment input current ≤ 16 A per phase IEC 61000-3-2:2014	Except for: three-phase product	2022-11-09
		2	voltage fluctuations and flicker	Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 1: General requirements GB/T 18268.1-2010		2022-11-09
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 1: General requirements IEC 61326-1:2005(第1版)		2022-11-09
				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		2022-11-09
				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		2022-11-09
				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	Except for: three-phase product	2022-11-09
				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	Except for: three-phase product	2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
3			Electrostatic discharge immunity test	Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 1: General requirements GB/T 18268.1-2010		2022-11-09
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 1: General requirements IEC 61326-1:2005(第1版)		2022-11-09
				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		2022-11-09
				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		2022-11-09
				Testing and measuring techniques - Electrostatic discharge immunity test GB/T 17626.2-2018		2022-11-09
				Testing and measuring techniques - Electrostatic discharge immunity test IEC 61000-4-2:2008		2022-11-09
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2022-11-09
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity CISPR 14-2:2015		2022-11-09
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2022-11-09
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2022-11-09
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		2022-11-09	



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 1: General requirements IEC 61326-1:2005(第 1 版)		2022-11-09
				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		2022-11-09
				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		2022-11-09
				Testing and measurement techniques -- Electrical fast transient/burst immunity test GB/T 17626.4-2018		2022-11-09
				Testing and measurement techniques -- Electrical fast transient/burst immunity test IEC 61000-4-4:2012		2022-11-09
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2022-11-09
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity CISPR 14-2:2015		2022-11-09
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2022-11-09
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2022-11-09
		5	Surge immunity test	Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 1: General requirements GB/T 18268.1-2010		2022-11-09
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 1: General requirements IEC 61326-1:2005(第 1 版)		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				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		2022-11-09
				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		2022-11-09
				Testing and measurement techniques - Surge immunity test GB/T 17626.5-2019		2022-11-09
				Testing and measurement techniques - Surge immunity test IEC 61000-4-5:2014		2022-11-09
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2022-11-09
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity CISPR 14-2:2015		2022-11-09
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2022-11-09
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2022-11-09
		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		2022-11-09
				Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements IEC 61326-1:2005(第1版)		2022-11-09
				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		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				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		2022-11-09
				Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields GB/T 17626.6-2017		2022-11-09
				Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields IEC 61000-4-6:2013		2022-11-09
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2022-11-09
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity CISPR 14-2:2015		2022-11-09
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2022-11-09
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2022-11-09
				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
		Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements IEC 61326-1:2005(第1版)		2022-11-09		
		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		2022-11-09		
		Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 2-6: Particular requirements -- In		2022-11-09		



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				vitro diagnostic (IVD) medical equipment IEC 61326-2-6:2005		
				Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests GB/T 17626.11-2008		2022-11-09
				Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests IEC 61000-4-11: 2004		2022-11-09
				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		2022-11-09
				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		2022-11-09
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2022-11-09
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity CISPR 14-2:2015		2022-11-09
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2022-11-09
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2022-11-09
		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		2022-11-09
				Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements IEC 61326-1:2005(第 1 版)		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				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		2022-11-09
				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		2022-11-09
				Testing and measurement techniques - Power frequency magnetic field immunity test GB/T 17626.8-2006		2022-11-09
				Testing and measurement techniques - Power frequency magnetic field immunity test IEC 61000-4-8:2009		2022-11-09
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2022-11-09
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2022-11-09
3	Medical electrical equipment	1	Partial items	Medical electrical equipment Part1:General requirements for safety GB 9706.1-2007	Except for 39-41	2022-11-09
				Medical electrical equipment Part1:General requirements for safety IEC 60601-1:1988	Except for 39-41	2022-11-09
				Medical electrical equipment Part1:General requirements for safety IEC 60601-1: 2012	Except for 39-41	2022-11-09
		2	All items	Medical electrical equipment Part1:General requirements for safety-1.Collateral standard:Safety requirements for medical electrical systems GB 9706.15-2008		2022-11-09
				Medical electrical equipment Part1:General requirements for safety-1.Collateral standard:Safety requirements for medical electrical systems IEC 60601-1-1:2000		2022-11-09
		3	All items	Medical electrical equipment-Recurrent test and test after repair of medical electrical equipment YY/T 0841-2011		2022-11-09
		4	All items	The environmental requirements and test methods for medical electrical equipment GB/T 14710-2009		2022-11-09



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		№	Item/ Parameter			
		5	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		2022-11-09
				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		2022-11-09
		6	All items	Electric apparatus for gastric lavage YY 1105-2008		2022-11-09
		7	Partial items	General Specifications for medical foot switch YY 1057-2016		2022-11-09
		8	All items	fire hazard testing for electric and electronic products-part21:abnormal heat-ball pressure test GB/T 5169.21-2017		2022-11-09
		9	All items	Flammability of solid non-metallic materials when exposed to flame sources-list of test methods GB/T 11020-2005		2022-11-09
		10	All items	Method for determining the comparative and the proof trackin indices of solid insulating materials under moist conditionis GB/T 4207-2012		2022-11-09
		11	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		2022-11-09
4	Monitoring equipment	1	All items	Medical electrical equipment part2:particular requirements for the safety of electrocardiographic monitoring equipment GB 9706.25-2005		2022-11-09
				Medical electrical equipment part2:particular requirements for the safety of electrocardiographic monitoring equipment IEC 60601-2-27:1994		2022-11-09
		2	All items	Medical electrical equipment-Particular requirements for basic safety and essential performance of respiratory gas monitors YY0601-2009		2022-11-09



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		№	Item/ Parameter			
		3	All items	Medical electrical equipment—part2-49:Particular requirement for the safety of multifunction patient monitoring equipment YY 0668-2008		2022-11-09
		4	All items	Electrocardiographic monitors YY 1079-2008		2022-11-09
		5	All items	ECG cables and leadwires YY 0828-2011		2022-11-09
5	Physiological parameters analysis and measurement equipment	1	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		2022-11-09
		2	All items	Non-invasive Automatic measurement Blood Pressure Monitor YY 0670-2008		2022-11-09
		3	All items	Medical electrical equipment—part2-30:particular requirements for the safety,inclusing essential performance,of automatic cycling non-invasive blood pressure monitoring equipment YY0667-2008		2022-11-09
		4	All items	Clinical electronic thermometer GB/T 21416-2008		2022-11-09
		5	All items	Clinical thermometers—Performance of electrical thermometers for continuous measurement YY 0785-2010		2022-11-09
		6	All items	Medical electrical equipment. Part 2: Particular requiremetns for the safety of electromyograohs and evoked response equipment YY 0896-2013		2022-11-09
		7	All items	Temperature biofeedback equipment YY/T 1096-2007		2022-11-09
		8	All items	Bridge type impedance blood flow recorder YY/T 1143-2008		2022-11-09
		9	All items	Direct impedance blood flow recorder YY/T 1078-2008		2022-11-09
		10	All items	Myoelectric biofeedback equipment YY/T 1095-2015		2022-11-09



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		11	All items	Electroencephalographic biofeedback equipment YY/T 0903-2013		2022-11-09
		12	All items	Medical Electrical equipment—Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY 0784-2010		2022-11-09
		13	All items	Medical electrical equipment - Part 2-26: Particular requirements for the safety of electroencephalographs GB9706.26-2005		2022-11-09
				Medical electrical equipment - Part 2-26: Particular requirements for the safety of electroencephalographs IEC 60601-2-26: 2003		2022-11-09
6	electrocardiograph	1	All items	single and multichannel electrocardiograph YY 1139-2013		2022-11-09
		2	All items	Medical electrical equipment-Part2:Particular requirement for the safety of electrocardiographs GB10793-2000		2022-11-09
		3	All items	Medical electrical equipment-Part 2-51: Particular requirements for safety,inclusing essential performance,of recording and analysing single channel and multichannel ofelectrocardiographs YY 0782-2010		2022-11-09
		4	All items	Medical electrical equipment-part 2: Particular requirements for the safety,inclusing essential performance of ambulatory electrocardiographic systems YY 0885-2013		2022-11-09
		5	All items	Disposable ECG electrodes YY/T 0196-2005		2022-11-09
7	Optical equipment and appliances	1	All items	ophthalmic instruments-Trial case lenses GB 17342-2009		2022-11-09
		2	All items	Ophthalmic instruments-Perimeters YY 0676-2008		2022-11-09
		3	All items	ophthalmic instruments-Refractor heads YY 0674-2008		2022-11-09



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		4	All items	Ophthalmic instruments-Fundus camera YY 0634-2022		2022-11-09
				Ophthalmic instruments-Fundus camera ISO 10940:1998		2022-11-09
		5	All items	Ophthalmic instruments-Fundus camera ISO 10940:2009		2022-11-09
				Ophthalmic instruments-Endoilluminators-Part 1: Requirements and test methods YY 0792.1-2016		2022-11-09
		6	All items	Ophthalmic instruments-Endoilluminators-Part 2: Fundamental requirements and test methods for optical radiation safety YY 0792.2-2010		2022-11-09
		7	All items	Ophthalmic optics and instruments-Optical devices for enhancing low vision GB 23719-2009		2022-11-09
		8	All items	Ophthalmic instruments—Synoptophores YY 0675-2008		2022-11-09
				Ophthalmic instruments—Synoptophores ISO 10944:1998		2022-11-09
				Ophthalmic instruments—Synoptophores ISO 10944:2009		2022-11-09
		9	All items	Ophthalmic instruments-Eye refractometers YY 0673-2008		2022-11-09
		10	All items	Ophthalmic instruments — Fundamental requirements and test methods —Part 1: General requirements applicable to all ophthalmic instruments ISO 15004-1: 2006		2022-11-09
		11	All items	Ophthalmic instruments-Fundamental requirements and test methods-Part 2: Light hazard protection ISO 15004-2: 2007		2022-11-09
		12	All items	Ophthalmic instruments-Microkeratome YY 0788-2010		2022-11-09
13	All items	standard for logarithmic visual acuity charts GB 11533-2011		2022-11-09		



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		№	Item/ Parameter				
8	Ophthalmic measurement diagnostic equipment and apparatus	14	All items	Measurement methods of illuminance for medical optical instruments YY/T 1146-2016		2022-11-09	
		15	All items	pupil distance meters JIG 952-2014		2022-11-09	
		16	Partial items	assembled spectacles-Part 1: single-vision and multifocal GB 13511.1-2011	except 5.4	2022-11-09	
		17	All items	Optics and optical instruments—Focimeters GB/T 17341-1998		2022-11-09	
		18	All items	Ophthalmometers GB 38455-2019			2022-11-09
				Ophthalmometers ISO 10343:2009			2022-11-09
		1	All items	Ophthalmic instruments-Retinoscopes YY/T0718-2009			2022-11-09
		2	All items	Ophthalmic instruments-Direct ophthalmoscopes YY 1080-2009			2022-11-09
3	All items	Ophthalmic instruments- Indirect ophthalmoscope YY 0633-2008			2022-11-09		
		Ophthalmic instruments- Indirect ophthalmoscope ISO 10943:1998			2022-11-09		
4	All items	Ophthalmic instruments—Corneal topographers YY 0787-2010			2022-11-09		
5	All items	ophthalmic instruments-slit-lamp microscopes YY 0065-2016			2022-11-09		
6	All items	ophthalmic instruments-Chart projectors YY/T 0764-2009			2022-11-09		
		ophthalmic instruments-Chart projectors ISO 10938: 1998			2022-11-09		
7	All items	Ophthalmic instruments -Instrumentsto measure axial distance in the eye YY/T 1484—2016			2022-11-09		
8	All items	Lens ultrasonic removal and vitrectomy devices for ophthalmic surgery YY 0766-2009			2022-11-09		

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
9	Diagnostic X-ray generators	1	All items	Medical electrical equipment—Part 2-43:Particular requirements for the safety of X-ray equipment for interventional procedures GB 9706.23-2005		2022-11-09
				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		2022-11-09
		2	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		2022-11-09
				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		2022-11-09
		3	All items	Particular specifications for mammographic X-ray equipment YY/T 0706-2017		2022-11-09
		4	All items	Particular specifications for medical X-ray angiography equipment YY/T 0740-2009		2022-11-09
		5	All items	Particular specifications for mini medical diagnostic X-ray equipment YY/T 0347-2009		2022-11-09
		6	All items	Particular specifications for gastrointestinal diagnostic X-ray equipment YY/T 0742-2021		2022-11-09
		7	All items	Particular specifications for mobile C-arm X-ray equipment YY/T0744-2018		2022-11-09
		8	All items	Particular specifications for mobile radiography X-ray equipment YY/T 0707-2020		2022-11-09
		9	All items	Particular specifications for X-ray equipment installed on the vehicle YY/T 0746-2021		2022-11-09
10	All items	Particular specifications for X-ray unit for oral cavity YY/T 0010-2020		2022-11-09		
11	All items	Particular specification for oral cavity X-ray equipment for digital tomography YY/T 0795-2010		2022-11-09		



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		12	All items	General specifications for medical diagnostic X-ray equipment YY/T 0106-2021		2022-11-09
		13	All items	General specifications for digital medical X-ray radiography system YY/T 0741-2018		2022-11-09
		14	All items	Environmental requirements and test methods for medical X-ray equipment YY/T 0291-2016		2022-11-09
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		2022-11-09
				Medical electrical equipment Part 2: particular requirements for the safety of associated equipment of X-ray equipment IEC 60601-2-32:1994		2022-11-09
		2	All items	Particular specifications for medical X-ray radiographic table YY/T 0737-2009		2022-11-09
		3	All items	Particular specifications for wall stand of medical X-ray equipment YY/T 0739-2009		2022-11-09
		4	All items	General specification for medical diagnostic X-ray adjustable beam limiting devices YY/T 0129-2007		2022-11-09
		5	All items	Particular specifications for cardiovascular table YY/T 0738-2009		2022-11-09
		6	All items	General specifications for X-ray image intensifier TV system for medical diagnosis YY/T 0608-2013		2022-11-09
		7	All items	Particular specifications for angiographic injector YY/T0891-2013		2022-11-09
		8	All items	Particular specifications for X-ray gastrointestinal diagnostic table YY/T 0743-2009		2022-11-09
11	X-ray equipment for computed tomography	1	All items	Medical electrical equipment-Part 2:Particular requirements for the safety of X-ray equipment for computed tomography GB 9706.18-2006		2022-11-09



№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Medical electrical equipment-Part 2:Particular requirements for the safety of X-ray equipment for computed tomography IEC 60601-2-44:2002		2022-11-09
		2	All items	General specifications of X-ray equipment for computed tomography YY/T 0310-2015		2022-11-09
		3	All items	specifications of X-ray equipment for 64 slice helical computed tomography YY/T 1417-2016		2022-11-09
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		2022-11-09
				Medical electrical equipment-Part 2:Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators IEC 60601-2-7-1998		2022-11-09
		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 9706.11-1997		2022-11-09
				Medical electrical equipment Part 2:Particular requirements for the safety ofX-ray source assemblies and X-ray tube assembliesfor medical diagnosis IEC 601-2-28-1993		2022-11-09
13	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		2022-11-09
				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		2022-11-09
14	Phototherapy apparatus	1	All items	Red light therapy equipment YY/T 1496-2016		2022-11-09
		2	All items	Ultraviolet therapy equipment YY 0901-2013		2022-11-09



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		№	Item/ Parameter			
		3	All items	Particular requirements for the safety of infrared therapy equipment YY 0323-2018		2022-11-09
		4	All items	Medical electrical equipment-Part 2:Particular requirements for the safety of infant phototherapy equipment YY 0669-2008		2022-11-09
				Medical electrical equipment-Part 2:Particular requirements for the safety of infant phototherapy equipment IEC 60601-2-50:2005		2022-11-09
15	Laser products	1	All items	Safety of laser product-Part1: Equipment classification and requirements GB 7247.1-2012		2022-11-09
				Safety of laser product-Part1: Equipment classification and requirements IEC 60825-1:2007		2022-11-09
		2	All items	Medical electrical equipment--Part 2:Particular requirements for the safety of diagnostic and therapeutic laser equipment GB 9706.20-2000		2022-11-09
				Medical electrical equipment--Part 2:Particular requirements for the safety of diagnostic and therapeutic laser equipment IEC 60601-2-22: 1995		2022-11-09
		3	All items	Test methods for laser beam widths,divergence angle and transverse mode GB/T 13739-2011		2022-11-09
		4	All items	Laser confocal scanner YY/T 1154-2009		2022-11-09
		5	All items	Test methods for laser radiation power and its instability GB/T 13863-2011		2022-11-09
		6	All items	Evaluation and test for beam quality of high energy laser GB/T 32831-2016		2022-11-09
		7	All items	Therapeutic Laser Equipment—Pulsed Nd:YAG LaserEquipment for Therapy YY 1300-2016		2022-11-09
8	All items	Therapeutic Laser Equipment—RubyLaserEquipment for Therapy YY 0983-2016		2022-11-09		



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		№	Item/ Parameter					
		9	All items	Laser treating equipment—Ophthalmic semiconductor laser photocoagulators YY 1289-2016		2022-11-09		
		10	All items	Carbon dioxide laser treating instrument GB 11748-2005		2022-11-09		
		11	All items	General specification of He-Ne laser medical equipment GB 12257-2000		2022-11-09		
		12	All items	General specification of Nd:YAG laser medical instrument with continuous wave (CW) YY 0307-2011		2022-11-09		
		13	All items	Therapeutic laser equipment—Ho:YAG laser equipment YY 0846-2011		2022-11-09		
		14	All items	Laser therapeutic equipment-Pulsed carbon dioxide laser treating instrument YY 0844-2011		2022-11-09		
		15	All items	Laser therapeutic equipment—Diode laser equipment for photodynamic therapy YY 0845-2011		2022-11-09		
		16	All items	Laser therapeutic equipment Q-Switched Nd:YAG laser equipment YY 1475-2016		2022-11-09		
		17	All items	Treating laser equipment Excimer laser cornea ametropia cure system YY 0599-2015		2022-11-09		
		18	All items	Q-Switched Nd:YAG Laser Ophthalmic System YY 0789-2010		2022-11-09		
		19	All items	General requirements for therapeutic laser fiber YY/T 0758-2021		2022-11-09		
		20	All items	Tracheal tubes designed for laser surgery — Requirements for marking and accompanying information YY/T 0486—2016		2022-11-09		
		16	Optical imaging diagnostic equipment	1	All items	Operation microscopes-Part 1:Requirements and test methods GB 11239.1-2005		2022-11-09
				2	All items	Stereomicroscopes-Part 1 :Stereomicroscopes for general use GB/T 19864.1-2013		2022-11-09
						Stereomicroscopes-Part 2:High performance stereomicroscope GB/T 19864.2-2013		2022-11-09



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		№	Item/ Parameter			
				Testing of stereomicroscope GB/T 19863-2005		2022-11-09
		3	All items	Biological microscope GB/T 2985-2008		2022-11-09
		4	All items	Micro-circulation microscopes YY/T 0067-2007		2022-11-09
		5	All items	Microscope-Objectives GB/T 2609-2015		2022-11-09
		6	All items	Microscope-Oculars(eyepieces) GB/T 9246-2008		2022-11-09
		7	All items	Microscopes-Condensers GB/T 9247-2008		2022-11-09
		8	All items	Microscopes-Marking of objectives and eyepieces GB/T 22056-2018		2022-11-09
		9	All items	Microscopes-Imaging distances related to mechanical reference planes—Part 1:Tube length 160mm GB/T 22057.1-2008		2022-11-09
		10	All items	Microscopes-Imaging distances related to mechanical reference planes—Part 2:Infinity-corrected optical systems GB/T 22057.2-2008		2022-11-09
		11	All items	Microscopes-Dimensions and positions of holes for stage clips and attachable mechanical stage on microscope stage JB/T 8230.7-1999		2022-11-09
		12	All items	Microscopes-connecting dimensions of dismountable condenser and colour filter JB/T 8230.8-1999		2022-11-09
		13	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		2022-11-09
		14	All items	Medical luminaires—Medical head-mounted luminaires YY/T 0932-2014		2022-11-09



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		№	Item/ Parameter			
		15	All items	Infrared examining equipment for mammary gland YY/T 0324-2019		2022-11-09
17	Lung ventilator	1	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		2022-11-09
		2	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		2022-11-09
		3	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		2022-11-09
		4	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		2022-11-09
		5	All items	Medical suture needle YY 0042-2018		2022-11-09
		6	All items	Breathing tubes intended for use with anaesthetic apparatus and ventilators YY 0461-2003		2022-11-09
18	Anaesthetic systems	1	All items	Medical electrical equipment-Part2:Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006		2022-11-09
				Medical electrical equipment-Part3:Particular requirements for the safety and essential performance of anaesthetic systems IEC 60601-2-13:2003		2022-11-09
		2	All items	Inhalational anaesthesia system-Part 1:Anaesthetic breathing system for adults YY0635.1-2013		2022-11-09
		3	All items	Inhalational anaesthesia system-Part 2:Anaesthetic gas scavenging systems transfer and receiving systems YY0635.2-2009		2022-11-09



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		№	Item/ Parameter				
		4	All items	Inhalational anaesthesia system-Part 3:Anaesthetic vapour delivery devices YY0635.3-2009		2022-11-09	
		5	All items	Inhalational anaesthesia system-Part 4:Requirements for anaesthetic ventilators YY0635.4-2009		2022-11-09	
19	Breathing, anaesthesia, first aid equipment	1	All items	Anaesthetic reservoir bags YY/T 0978-216		2022-11-09	
		2	All items	Gas mixers for medical use-Stand-alone gas mixers YY 0893-2013		2022-11-09	
		3	All items	Suction catheter for use in the respiratory tract YY 0339-2019		2022-11-09	
		4	Partial items	Oxygen concentrators for medical use-Safety requirements YY 9706.269-2021	except 50.4,50.5	2022-11-09	
		5	All items	Respiratory tract humidifiers for medical use-Particular requirements for respiratory humidification systems YY0786-2010		2022-11-09	
		6	All items	Medical suction equipment-Part1: Electrically powered suction equipment-Safety requirements YY 0636.1-2008		2022-11-09	
		7	All items	Medical suction equipment-Part2: Manually powered suction equipment YY 0636.2-2008		2022-11-09	
		8	All items	Medical suction equipment—Part3:Suction equipment powered a vacuum or pressure source YY 0636.3-2008		2022-11-09	
		9	All items		Semi-Automatic External Defibrillato GB9706.8-2009		2022-11-09
					Semi-Automatic External Defibrillato IEC 60601-2-4:2002		2022-11-09
					Semi-Automatic External Defibrillato IEC 60601-2-4:2003		2022-11-09
10	All items	Sleep apnoea breathing therapy-Part 1: Sleep apnoea breathing therapy devices YY 0671.1-2009		2022-11-09			
11	All items	Sleep apnoea breathing therapy-Part 1: Sleep apnoea breathing		2022-11-09			



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		№	Item/ Parameter			
				therapy devices YY 0671.2-2011		
		12	All items	Buoy type oxygen inhalator YY 1107-2003		2022-11-09
20	Anaesthetic equipment	1	All items	Breathing tubes intended for use with anaesthetic apparatus and ventilators YY/T 1040.1-2015		2022-11-09
		2	All items	Anaesthetic and respiratory equipment—Conical connectors—Part 2:Screw-threaded weight-bearing connectors YY/T 1040.2-2008		2022-11-09
		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		2022-11-09
		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		2022-11-09
		5	All items	Anaesthetic vaporizers—Agent-specific filling systems YY/T 0755-2009		2022-11-09
		6	All items	Breathing system filters for anaesthetic and respiratory use—Part2:Non-filtration aspects YY/T 0753.2-2009		2022-11-09
		7	All items	Anaesthetic and respiratory equipment-Supralaryngeal airways and connectors YY/T 0985—2016		2022-11-09
21	Medical oxygen production equipment	1	Partial items	Medical oxygen generator with molecular sieve YY/T0298-1998	except 5.2	2022-11-09
		2	All items	Oxygen concentrator supply systems for use with medical gas pipeline systems YY 1468-2016		2022-11-09
		3	All items	Oxygen supplies for medicine and aircraft breathing GB/T 8982-2009		2022-11-09
22	Surgical Instruments	1	All items	Surgical Instruments—Gill shaft,Bolt and Rivet YY/T 0173-2010		2022-11-09
		2	All items	Rectosigmoid biopsy forceps YY/T 0178-2010		2022-11-09



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		№	Item/ Parameter					
		3	All items	Naso-pharyngeal biopsy forceps YY/T 0246-2010		2022-11-09		
		4	All items	Ophthalmic scissors YY/T 0176.9-2011		2022-11-09		
		5	All items	General specification for ophthalmic knives YY/T 0072-2010		2022-11-09		
		6	All items	Ophthalmic Forceps YY/T 0819-2010		2022-11-09		
		7	All items	Electric surgical equipment for osseous tissue YY/T 0752-2016		2022-11-09		
		8	All items	Battery power supply surgical equipment for osseous tissue YY/T 0904-2013		2022-11-09		
		9	All items	Abdominal suction tube YY/T 0191-2011		2022-11-09		
		10	All items	Plasma surgical equipment YY/T 1409—2016		2022-11-09		
		11	All items	Cardiopulmonary bypass systems—Centrifugal pump YY 1412-2016		2022-11-09		
		12	All items	Metal plating classification technology condition of parts YY/T 0076-1992		2022-11-09		
		23	Electrical acoustic measurement and analysis equipment	1	All items	Audiometers Part2:Equipment for speech audiometry GB/T 7341.2-1998		2022-11-09
				2	All items	Audiometers Part4:Equipment for extended high-frequency audiometry GB/T 7341.4-1998		2022-11-09
3	All items			Electroacoustics-Audiological equipment-Part 1:Pure-tone audiometers GB 7341.1-2011		2022-11-09		
4	All items			Instruments for the measurement of aural acoustic impedance/admittance GB/T 7341.5-2018		2022-11-09		
24	Hearing Aids	1	All items	Measurement of performance characteristics of hearing aids for quality inspection for delivery purposes SJ 10862-1996 SJ 10862-1996		2022-11-09		



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		№	Item/ Parameter					
		2	All items	Electroacoustics-General specification for hearing aids GB/T 14199-2010		2022-11-09		
		3	All items	Electroacoustics-Hearing aids-Part1:Hearing aids with induction pick-up coil input GB/T 25102.1-2010		2022-11-09		
				Electroacoustics-Hearing aids-Part1:Hearing aids with induction pick-up coil input IEC 60118-1:1999		2022-11-09		
		4	All items	Electroacoustics-hearing aids-Part 2:Hearing aids with automatic gain control circuits GB/T 25102.2-2010		2022-11-09		
				Electroacoustics-hearing aids-Part 2:Hearing aids with automatic gain control circuits IEC60118-2:1983		2022-11-09		
		5	All items	Electroacoustics-Hearing aids-Part 0:Measurement of electroacoustical characteristics GB/T 25102.100-2010		2022-11-09		
				Electroacoustics-Hearing aids-Part 0:Measurement of electroacoustical characteristics IEC 60118-0:1983		2022-11-09		
		6	All items	Electroacoustics - Hearing aids - Part13:Electromagnetic compatibility(EMC) GB/T 25102.13 -2010		2022-11-09		
				Electroacoustics - Hearing aids - Part13:Electromagnetic compatibility(EMC) IEC60118-13:2016		2022-11-09		
		25	Medical endoscope	1	All items	Medical electrical equipment- Part2 :Particular requirements for the safety of endoscopic equipment GB 9706.19-2000		2022-11-09
						Medical electrical equipment- Part3 :Particular requirements for the safety of endoscopic equipment IEC 60601-2-18: 1996		2022-11-09
				2	All items	General requirements for the medical endoscope and endoscope accessories GB 11244-2005		2022-11-09
3	All items			Medical endoscopes Fiber optical cable for lighting YY/T 0763-2009		2022-11-09		
4	All items			Endoscopic washing station YY 0992-2016		2022-11-09		
5	Partial items			Medical Endoscopes—Capsule Endoscopes YY 1298-2016	except 4.5.1、4.5.2	2022-11-09		



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		№	Item/ Parameter			
		6	All items	Medical Endoscopes-Rigid Endoscope-Part 1:Optical properties and test methods YY 0068.1-2008		2022-11-09
		7	All items	Medical endoscopes-Rigid endoscope-Part 2:Mechanical properties and test methods YY 0068.2-2008		2022-11-09
		8	All items	Medical endoscopes-Rigid endoscope-Part 3:Marking and instruction manual YY/T 0068.3-2008		2022-11-09
		9	All items	Medical Endoscopes —Rigid endoscope —part 4:Fundamental requirement YY 0068.4-2009 YY 0068.4-2009		2022-11-09
		10	All items	Medical endoscopes—Rigid resectoscope YY/T 0619—2017		2022-11-09
		11	All items	General specification of medical rigid trachea endoscope YY 0069-2009		2022-11-09
		12	All items	Rigid hysteroscope YY 1075-2007		2022-11-09
		13	All items	Rigid arthroscope YY 1082-2007		2022-11-09
		14	All items	Esophagoscope YY/T 0070-2018		2022-11-09
		15	All items	Sigmoidos-copy and rectoscope set YY/T 0071-2018		2022-11-09
		16	All items	Large intestine fiber endoscope YY/T 0283-2007		2022-11-09
		17	All items	Anoscope YY/T 0190-2008		2022-11-09
		18	All items	Upper gastro intestinal fiberscope YY 1028-2008		2022-11-09
		19	All items	General specification for anaesthetic laryngoscope YY0499-2004		2022-11-09
		20	All items	Nasal specula YY/T 0189-2008		2022-11-09
26	Roller irrigation and	1	All items	Medical endoscopes--Endoscope functional supply units--Roller irrigation and suction equipment YY/T 0863-2011		2022-11-09

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	suction equipment	2	All items	Medical endoscopes--Endoscope functional supply units--Irrigation pump YY/T 0864-2011		2022-11-09
		3	All items	Medical Endoscopes-Endoscope supply units-insufflators YY 0843-2011		2022-11-09
		4	All items	Medical Endoscopes—Endoscope supply units—cold light sources YY 1081-2011		2022-11-09
		5	All items	Medical endoscopes--Endoscope surgical equipment--Shaver YY/T 0955-2014		2022-11-09
27	Medical Endoscope endoscope accessories	1	All items	Medical Endoscope endoscope accessories cytology brush YY/T 0930-2014		2022-11-09
		2	All items	Medical Endoscopes — Endotherapy Device — Palmate Retractor YY/T 1446—2016		2022-11-09
		3	All items	Medical endoscopes-Endoscope device-Curette YY/T 1297—2015		2022-11-09
		4	All items	Medical endoscopes -Endotherapy device -Needle forceps YY/T 0943-2014		2022-11-09
		5	All items	Medical endoscopes — Endotherapy device — Grasping forceps YY/T 0940-2014		2022-11-09
		6	All items	Medical endoscopes — Endotherapy device — Separating forceps YY/T 0944-2014		2022-11-09
		7	All items	Medical endoscopes — Endotherapy device — Punch forceps YY/T 0941-2014		2022-11-09
		8	All items	Medical Endoscope endoscope device loop ligature YY/T 0931-2014		2022-11-09
		9	All items	Medical Endoscopes — endotherapy device — stone retrieval forceps YY 0847-2011		2022-11-09
		10	All items	Medical endoscopes--endoscope accessories--bridges YY/T 0922-2014		2022-11-09
		11	All items	Medical endoscopes--Endoscope accessories--Sheaths YY/T 0842-2011		2022-11-09



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		№	Item/ Parameter				
		12	All items	Hose biopsy sampling forceps used with endoscope-General specifications YY/T 1076-2004		2022-11-09	
		13	All items	Endoscopic instruments-Part1:Trocars for laparoscope use YY/T 1783-2021		2022-11-09	
		14	All items	Endoscopy instruments--Part 2: Laparoscopy scissors YY 0672.2-2011		2022-11-09	
		15	All items	Laryngoscopic fittings-Part 1:Conventional hook-on type handle-blade fittings YY 0498.1-2004		2022-11-09	
		16	All items	Laryngoscopic fittings-Part 2:Miniature electric lamps-Screw threads and sockets for conventional blades YY0498.2-2004		2022-11-09	
28	Ultrasonic physiological parameters measurement and analysis equipment	1	All items	Ultrasonics-Hand-held probe Doppler foetal heartbeat detectors-Performance requirements and methods of measurement and reporting YY/T 0749-2009		2022-11-09	
		2	All items	Ultrasonic Doppler fetal monitor YY/T 0449-2018		2022-11-09	
		3	All items	Ultrasonic Doppler foetal heartbeat detector YY/T 0448-2019		2022-11-09	
		4	All items	Ultrasound Bone Sonometers YY/T 0774-2019		2022-11-09	
		5	All items	Ultrasound transcranial Doppler system YY 0593-2015		2022-11-09	
		6	All items	Medical electrical equipment Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment GB 9706.9-2009			2022-11-09
				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			2022-11-09
		7	All items	Methods of measuring the frequency of medical diagnostic and monitoring ultrasonic equipment YY/T 1142-2013			2022-11-09
8	All items	Requirement for the declaration of the acoustic output of medical diagnostic ultrasonic equipment GB/T 16846-2008			2022-11-09		



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		№	Item/ Parameter			
		9	All items	Testing methods for M-mode of ultrasonic diagnostic equipment YY/T 0108-2008		2022-11-09
		10	All items	Measurement methods of output power for medical diagnostic ultrasonic equipments YY/T 1084-2015		2022-11-09
		11	All items	Ultrasonics - Field characterization -Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields YY/T 0642-2014		2022-11-09
		12	Part of Items	Measuring methods for beam area of medical ultrasound equipment transducer YY/T 1278-2015	Except for 4.3	2022-11-09
		13	All items	Ultrasound - Test methods of performance for quasi-static strain sonoelasticity YY/T 1419-2016		2022-11-09
		14	All items	Environmental requirement and test methods for medical ultrasonic equipment YY/T 1420-2016		2022-11-09
		15	All items	B mode ultrasonic diagnostic equipment GB 10152-2009		2022-11-09
		16	All items	Medical ultrasound equipment class series-Part 1: B mode ultrasound diagnostic equipment YY/T 0162.1-2009		2022-11-09
29	Ultrasonic imaging diagnostic equipment	1	All items	Test method for performance of three-dimensional ultrasonography YY/T 1279-2015		2022-11-09
		2	All items	Ultrasonic colour flow imaging systems YY 0767-2009		2022-11-09
30	Ultrasonic physiotherapy equipment	1	All items	Medical electrical equipment Part 2-5: GB Particular requirements for the safety of ultrasonic physiotherapy equipmen GB 9706.7-2008		2022-11-09
				Medical electrical equipment Part 2-5: GB Particular requirements for the safety of ultrasonic physiotherapy equipmen IEC 60601-2-5:2000		2022-11-09
		2	All items	Ultrasonic Therapy Equipment for Superficial Tissue YY 0830-2011		2022-11-09



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		№	Item/ Parameter			
		3	Part of Items	Ultrasonics-surgical systems-Measurement and declaration of the basic output characteristics YY/T 0644-2008	Except for 6.5、6.6	2022-11-09
		4	All items	Ultrasonic physiotherapy equipment YY/T 1090-2018		2022-11-09
31	Ultrasonic biometer for ophthalmology	1	All items	A mode ultrasonic biometer for ophthalmology YY/T 0107-2015		2022-11-09
		2	All items	Ophthalmic high frequency ultrasound scanner YY 0849-2011		2022-11-09
		3	All items	General technical requirements for ophthalmic ultrasound B-mode scan YY 0773-2010		2022-11-09
32	Ultrasonic imaging diagnostic accessory equipment	1	All items	Test methods for B mode ultrasonic diagnostic equipment :connect the Intracavity probe YY/T 0906-2013		2022-11-09
		2	All items	Medical ultrasonic nebulizer YY 0109-2013		2022-11-09
		3	All items	Medical ultrasonic couplant YY 0299-2022		2022-11-09
33	High frequency surgical equipment	1	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	2022-11-09
				Medical electrical equipment Part2-3:Particular requirements for the safety of high frequency surgical equipment IEC 60601-2-2:2007	Except for 39	2022-11-09
		2	All items	High frequency electrocautery therapy equipmen YY 0322-2018		2022-11-09
		3	All items	Medical electrical equipment-Part 2:Particular requirements for the safety of microwave therapy equipment GB 9706.6-2007		2022-11-09
				Medical electrical equipment-Part 2:Particular requirements for the safety of microwave therapy equipment IEC 60601-2-6:1984		2022-11-09
4	All items	Accessories of Microwave equipmentin medical parctices YY 0899-2013		2022-11-09		



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		№	Item/ Parameter			
		5	All items	Microwave ablation/coagulation equipment YY 0838-2011		2022-11-09
		6	All items	Microwave hyperthermia equipment YY 0839-2011		2022-11-09
		7	All items	Millimeter wave therapy equipment YY 0898-2013		2022-11-09
		8	All items	Specified electromagnetic wave therapy equipment YY/T 0061-2021		2022-11-09
34	Radio-frequency ablation equipment	1	All items	Radio-frequency ablation equipment for ear, nose and throat YY 0897-2013		2022-11-09
		2	All items	Radio frequency ablation catheter YY 0778-2018		2022-11-09
		3	All items	Radio frequency ablation instrument for liver YY 0776-2010		2022-11-09
		4	All items	Radio frequency hyperthermia equipment YY 0777-2010		2022-11-09
		5	All items	Radio frequency ablation instrument for cardiac application YY 0860-2011		2022-11-09
		6	All items	Gynecological radio frequency therapy instrument YY 0650-2008		2022-11-09
35	Oral treatment equipment	1	All items	Ultrasonics dental descaler equipment YY 0460-2009		2022-11-09
		2	All items	Ultrasonics—Dental descaler systems—Measurement and declaration of the output characteristics YY/T 0751-2009		2022-11-09
		3	All items	dentistry—powered polymerization activators YY 0055-2018		2022-11-09
		4	All items	dental units YY/T 1043.1-2016		2022-11-09
		5	All items	dentistry—dental units—part 2:water and air supply YY/T 1043.2-2018		2022-11-09
		6	All items	Dentistry - Patient chair YY 0058-2015		2022-11-09



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		№	Item/ Parameter			
		7	All items	Dental handpieces.Dental low-voltage electrical motor YY 0836-2011		2022-11-09
		8	All items	Dental handpieces.Dental air-motors YY 0837-2011		2022-11-09
		9	All items	Dental handpiece No.4 dental handpiece YY 0059.1-1991		2022-11-09
		10	All items	Dental handpiece No.7 dental handpiece YY 0059.2-1991		2022-11-09
		11	All items	Dental handpiece No.4 and No.7 dental curve handpiece YY 0059.3-1991		2022-11-09
		12	All items	dental handpieces—part 1:high-speed air turbine handpieces YY 1045.1-2009		2022-11-09
		13	All items	Dental handpieces-Part 2:Straight and geared angle handpieces YY 1045.2-2010		2022-11-09
		14	All items	dental hand pieces -- coupling dimensions YY/T 1012-2021		2022-11-09
		15	All items	Dental Rotary instruments - Nominal diameters and designation code number YY/T 1011-2014		2022-11-09
		16	All items	Dentistry— Dental implant unit YY/T 1485-2016		2022-11-09
		17	All items	high-speed dental air turbine unit YY/T 1044-2018		2022-11-09
		18	All items	general technology condition for electric dental engine YY/T 1147-2004		2022-11-09
		19	All items	Dentistry - Dental rubber dam technique - Part 1: Hole punch YY/T 1487.1-2016		2022-11-09
		20	All items	Dentistry— Whitening Accelerator YY/T 1401—2016		2022-11-09
36	Electronic equipment	1	All items	Medical electrical equipment—part2:--Particular requirements for the safety of nerve and muscle stimulators YY0607-2007		2022-11-09



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		№	Item/ Parameter			
				Medical electrical equipment—part2:--Particular requirements for the safety of nerve and muscle stimulators IEC 60601-2-10:1987		2022-11-09
				Medical electrical equipment—part2:--Particular requirements for the safety of nerve and muscle stimulators IEC 60601-2-10:2012		2022-11-09
		2	All items	Test method for measuring output characteristics of the nerve and muscle stimulators YY/T 0696-2021		2022-11-09
		3	All items	Electrodes for nerve and muscle stimulators YY/T 0868-2021		2022-11-09
		4	All items	Interferential current therapy instrument YY 0951-2015		2022-11-09
		5	All items	Electroacupuncture therapy device YY 0780-2018		2022-11-09
37	Heat treatment equipment	1	All items	Standard performance and safety specification for cryosurgical medical instruments YY 0678-2008	except 6.3.2	2022-11-09
		2	All items	Liquid nitrogen cryosurgical equipment YY/T 0677-2008		2022-11-09
		3	All items	Semiconductor heating and/or cooling therapy equipment YY/T 0998-2015		2022-11-09
		4	Partial items	Temperature control blanket for medical use YY 0952-2015	Except for 5.2.4	2022-11-09
		5	All items	Steam Therapy Apparatus YY/T 1306—2016		2022-11-09
		6	All items	Heating and Magnetic Vibrator Therapeutic Equipment YY/T 0982-2016		2022-11-09
		7	All items	medical electrical equipment-Part 2: particular requirements for the safety of infant radiant warmers YY 9706.221-2021		2022-11-09
		8	All items	Particular requirements for the safety of heat radiation therapy equipment YY 0306-2018		2022-11-09
		9	Partial items	Contacting far infrared physiotherapy equipment YY/T 0902-2013	Except for 4.2	2022-11-09



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		10	All items	Medical heating pad therapy equipment YY/T 0165-2016		2022-11-09
38	Magnetic stimulation equipment	1	All items	Magnetic stimulation equipment YY/T 0994-2015		2022-11-09
39	Force therapy equipment	1	All items	Air-bag type sequential external counter-pulsation device GB 10035-2017		2022-11-09
		2	All items	Compression physiotherapy equipment for limbs YY 0833-2020		2022-11-09
		3	All items	Elbow,knee joints passive motion equipment YY/T 0997-2015		2022-11-09
		4	All items	Balance evaluation& exercise systems YY/T 1410-2016		2022-11-09
		5	All items	Walk training platform with suspension YY 0900-2013		2022-11-09
		6	All items	Electric cervical and lumbar traction therapy device YY/T 0697—2016		2022-11-09
		7	All items	Table, chair and accessories used for electric cervical and lumbar traction therapy device YY/T 1491—2016		2022-11-09
40	Photobiological safety	1	All items	Photobiological safety of lamps and lamp systems GB/T 20145-2006		2022-11-09
		2	All items	Optics and photonics — Operation microscopes — Light hazard from operation microscopes used in ocular surgery YY 1296-2016		2022-11-09
		3	All items	Safety of laser products-Part9: Compilation of maximum permissible exposure to incoherent optical radiation GB/T 7247.9-2016		2022-11-09
		4	All items	Measuring methods for optical radiation safety classification of medical LED equipment YY/T 1534—2017		2022-11-09
	Medical Optical	1	All items	Medical Light Radiation Protective Eyewears-Evaluation Method-Part1:Decrease of Light Hazard YY/T 0968.1-2014		2022-11-09



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	Radiation Protective Eyewears	2	All items	Medical Optical Radiation Protective Eyewears-Evaluation Method-Part2:Vision and Color Vision YY/T 0968.2-2014		2022-11-09
42	Medical device software	1	All items (User document level requirements, Product quality)	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		2022-11-09
		2		Medical electrical equipment--Part 1-4:General requirements for safety--collateral standard:programmable electrical medical systems YY/T 0708-2009 6,52		2022-11-09
		3	All items	Medical device software--Software life cycle processes YY/T 0664-2020		2022-11-09
43	Surgical luminaries and luminaries for diagnosis	1	All items	Medical electrical equipment—Part 2-41:Particular requirements for the safety of surgical luminaries and luminaries for diagnosis YY 0627-2008		2022-11-09
44	Operating tables	1	All items	Medical electrical equipment-Part 2-46: Particular requirements for the safety of operating tables YY 0570-2013		2022-11-09
				Medical electrical equipment-Part 2-46: Particular requirements for the safety of operating tables IEC60601-2-46:1998		2022-11-09
		2	All items	Electrically powered operating table YY/T 1106-2008		2022-11-09
45	Medical bed	1	All items	Medical electrical equipment -Part2 : Particular requirements for the safety ofelectrically operated hospital beds YY 0571-2013		2022-11-09
				Medical electrical equipment -Part2 : Particular requirements for the safety ofelectrically operated hospital beds IEC60601-2-38:1996		2022-11-09



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		№	Item/ Parameter			
		2	All items	Dynamoelectric traction-table YY/T 0697-2016		2022-11-09
		3	All items	General maternity beds YY 0045-2013		2022-11-09
		4	All items	Blankets,pads and mattresses,intended for heating in medical use YY 0834-2011		2022-11-09
46	Infusion pumps	1	All items	Medical electrical equipment -- Part 2-24:Particular requirements for the safety ofinfusion pumps and controller GB 9706.27-2005		2022-11-09
				Medical electrical equipment -- Part 2-24:Particular requirements for the safety ofinfusion pumps and controller IEC 60601-2-24:1998		2022-11-09
				Medical electrical equipment -- Part 2-24:Particular requirements for the safety ofinfusion pumps and controller IEC 60601-2-24:2012		2022-11-09
		2	All items	Electrical Infusion Pump for Ambulatory Use YY/T 1469—2016		2022-11-09
47	Active implantable medical device	1	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		2022-11-09
				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		2022-11-09
				ISO 14708.1-2014		2022-11-09
		2	All items	Implants for surgery -- Active implantable medical devices -- Part 2 Cardiac pacemakers GB 16174.2-2015		2022-11-09
				Implants for surgery -- Active implantable medical devices -- Part 2 Cardiac pacemakers ISO 14708.2-2005		2022-11-09
		3	All items	ISO 14708-7 2013 Implants for surgery — Active implantable		2022-11-09

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48	Electrical equipment for measurement, control, and laboratory use			medical devices --Part 7 Particular requirements for cochlear implant systems YY0989.7-2017						
						ISO 14708-7 2013 Implants for surgery — Active implantable medical devices --Part 7 Particular requirements for cochlear implant systems ISO 14708.7-2013		2022-11-09		
				4	All items	Implants for surgery - Active implantable medical devices - Part 3: Implantable neurostimulators ISO 14708.3-2007		2022-11-09		
		1	All items			Safety requirements for electrical equipment for measurement, control, and laboratory use-Part 1: General requirements GB4793.1-2007		2022-11-09		
								Electrical equipment for measurement, control, and laboratory use IEC 61010-1: 2001		2022-11-09
								Electrical equipment for measurement, control, and laboratory use IEC 61010-1: 2010		2022-11-09
				2	All items			Safety requirements for electrical equipment for measurement, control and laboratory use—Part 9: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes GB 4793.9-2013		2022-11-09
										Safety requirements for electrical equipment for measurement, control and laboratory use—Part 9: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes IEC 61010-2-081:2009
				3	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		2022-11-09
										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
4	All items			Safety requirements for electrical equipment for measurement control and laboratory use - Part 3: Particular requirements for		2022-11-09				



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				laboratory equipment for mixing and stirring GB 4793.3-2008		
				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		2022-11-09
		5	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		2022-11-09
		6	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		2022-11-09
		7	All items	General requirements for in vitro diagnostic medical for self-testing YY/T 1454—2016		2022-11-09
49	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		2022-11-09
		2	All items	Low temperature steam and formaldehyde sterilizers for medical purposes YY/T 0679—2016		2022-11-09
		3	Partial items	Portable Mode Steam Sterilizers YY 0504-2016	Except for 5.18	2022-11-09
		4	Partial items	Steam sterilizer - the performance requirements of biosafety YY 1277—2016	Except for 4.1	2022-11-09
		5	All items	Steam generators for medical use YY/T 0791-2018		2022-11-09
50	Dry Heat Sterilized equipment	1	All items	Safety requirements for electrical equipment for measurement control and laboratory use - Part 2-043:Particular requirements for dry heat sterilizers using either hot air or hot inert gas YY 0602-2007		2022-11-09

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		2	All items	Dry heat (heated air) sterilizers YY 1275-2016		2022-11-09
51	Chemical disinfection sterilized equipment	1	Partial items	Ethylene oxide sterilizer YY 0503-2016	Except for 5.17.1	2022-11-09
52	Urine analyzer equipment	1	All items	Urine analyzer YY/T 0475-2011		2022-11-09
		2	All items	Dry chemistry analyzer YY/T 0655-2008		2022-11-09
		3	All items	Urine formed element analyzer(digital imaging automatic identification) YY/T 0996-2015		2022-11-09
53	Medical Centrifuge	1	All items	Medical centrifuge YY/T 0657-2017		2022-11-09
54	Blood analysis equipment	1	All items	automatic blood coagulation analytical nstrument YY/T 0659-2017		2022-11-09
		2	All items	Blood rheometer YY/T 1460—2016		2022-11-09
		3	All items	Hematology analyzer YY/T0653-2017		2022-11-09
		4	All items	Erythrocyte sedimentation rate tester YY/T 1251-2014		2022-11-09
		5	All items	Flow cytometer YY/T 0588-2017		2022-11-09
		6	All items	Centrifugal blood components separation device YY 1413—2016		2022-11-09
		7	All items	Automatic blood analyzer YY/T 1245-2014		2022-11-09
		8	All items	Glycosylated hemoglobin analyzer YY/T 1246-2014		2022-11-09
		9	All items	Heamoglobin instrument YY/T0032-2004		2022-11-09



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		№	Item/ Parameter			
		10	All items	General technical requirements for hemoglobin dry chemistry testing systems YY/T 1150-2009		2022-11-09
		11	All items	Dry Hematology Analyzer(centrifuge method) YY/T 1452—2016		2022-11-09
55	Biochemical analysis equipment	1	All items	Automatic chemistry analyzer YY/T 0654-2017		2022-11-09
		2	All items	Semiautomatic biochemistry analyzer YY/T0014-2005		2022-11-09
		3	All items	In vitro diagnostic test systems- General technical requirements for blood-glucose monitoring systems for self-testing GB/T 19634-2021		2022-11-09
56	Electrolyte analyzer	1	Partial items	Electrolyte analyzer YY/T 0589—2016		2022-11-09
57	Immunoassay Analysis equipment	1	All items	Automatic Time-resolved Fluorescence Counter YY/T 1533-2017		2022-11-09
		2	All items	Detection system of time-resolved fluoroimmunoassay—Part 1:Semi-auto time-resolved fluoroimmunoassay analyser YY/T 1304.1-2015		2022-11-09
		3	All items	Automatic Luminescence Immunoassay Analyzer YY/T 1155-2019		2022-11-09
		4	All items	Semi-automatic chemiluminescence immunoassay analyzer YY/T 1174-2010		2022-11-09
		5	All items	Polymerase Chain Reaction Analyzer YY/T1173-2010		2022-11-09
		6	All items	Enzyme-linked immunity analyzer YY/T 1529—2017		2022-11-09
58	Medical endoscope	1	Contact materials with patient	Medical endoscopes-Video endoscopes YY/T 1587-2018		2022-11-09
		2	Field angle	Medical endoscopes-Video endoscopes YY/T 1587-2018		2022-11-09



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		3	Relative self-effect of illumination light luminosity	Medical endoscopes-Video endoscopes YY/T 1587-2018		2022-11-09
		4	Brightness response characteristics	Medical endoscopes-Video endoscopes YY/T 1587-2018		2022-11-09
		5	SNR	Medical endoscopes-Video endoscopes YY/T 1587-2018		2022-11-09
		6	SFR	Medical endoscopes-Video endoscopes YY/T 1587-2018		2022-11-09
		7	Static image tolerance	Medical endoscopes-Video endoscopes YY/T 1587-2018		2022-11-09
		8	mechanical character	Medical endoscopes-Video endoscopes YY/T 1587-2018		2022-11-09
59	Roller irrigation and suction equipment	1	MTF	Medical endoscopes- Endoscope supply units-Video camera system YY/T 1603-2018		2022-11-09
		2	focal length	Medical endoscopes- Endoscope supply units-Video camera system YY/T 1603-2018		2022-11-09
		3	Brightness response characteristics	Medical endoscopes- Endoscope supply units-Video camera system YY/T 1603-2018		2022-11-09
		4	SNR	Medical endoscopes- Endoscope supply units-Video camera system YY/T 1603-2018		2022-11-09
		5	SFR	Medical endoscopes- Endoscope supply units-Video camera system YY/T 1603-2018		2022-11-09
		6	Static image tolerance	Medical endoscopes- Endoscope supply units-Video camera system YY/T 1603-2018		2022-11-09
60	Active implantable medical device	1	electrode catheter connector	Cardiac Pacemakers-Low-Profile Implantable Pacemakers YY/T 0491-2004 Connectors(IS-1)for		2022-11-09
		2	connector cavity	Cardiac Pacemakers-Low-Profile Implantable Pacemakers YY/T 0491-2004 Connectors(IS-1)for		2022-11-09
		3	Physical dimensions	Implantable cardiac pacing lead YY/T 0492-2017		2022-11-09

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date		
		№	Item/ Parameter					
		4	Appearance	Implantable cardiac pacing lead YY/T 0492-2017		2022-11-09		
		5	Measurement of Electrical Characteristic of Electrode Conductor	Implantable cardiac pacing lead YY/T 0492-2017		2022-11-09		
		6	Protection against mechanical damage	Implantable cardiac pacing lead YY/T 0492-2017		2022-11-09		
		7	Protection against mechanical damage	Implantable cardiac pacing lead YY/T 0492-2017		2022-11-09		
		8	X-ray detectability	Implantable cardiac pacing lead YY/T 0492-2017		2022-11-09		
		9	Accelerated Aging Life Experiments	Implantable cardiac pacing lead YY/T 0492-2017		2022-11-09		
		10	Chemical performance requirements	Implantable cardiac pacing lead YY/T 0492-2017		2022-11-09		
		11	sterilization	Implantable cardiac pacing lead YY/T 0492-2017		2022-11-09		
		12	Protection against biological effects	Implantable cardiac pacing lead YY/T 0492-2017		2022-11-09		
		13	Packaging and marking	Implantable cardiac pacing lead YY/T 0492-2017		2022-11-09		
		14	Random files	Implantable cardiac pacing lead YY/T 0492-2017		2022-11-09		
		61	Mass Spectrometric Analysis Equipment	1	appearance	General specification for mass spectrometers GB/T 33864-2017		2022-11-09
				2	mass range	General specification for mass spectrometers GB/T 33864-2017		2022-11-09
				3	mass accuracy	General specification for mass spectrometers GB/T 33864-2017		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	mass stability	General specification for mass spectrometers GB/T 33864-2017		2022-11-09
		5	mass resolution	General specification for mass spectrometers GB/T 33864-2017		2022-11-09
		6	limit of detection	General specification for mass spectrometers GB/T 33864-2017		2022-11-09
		7	reproducibility	General specification for mass spectrometers GB/T 33864-2017		2022-11-09
		8	safety	General specification for mass spectrometers GB/T 33864-2017		2022-11-09
		9	transport and transportation storage	General specification for mass spectrometers GB/T 33864-2017		2022-11-09
		10	environmental suitability	General specification for mass spectrometers GB/T 33864-2017		2022-11-09
		11	resolution	Method of performance testing for liquid chromatography-tandem quadrupole mass spectrometry GB/T 35410-2017		2022-11-09
		12	mass range	Method of performance testing for liquid chromatography-tandem quadrupole mass spectrometry GB/T 35410-2017		2022-11-09
		13	灵敏度	Method of performance testing for liquid chromatography-tandem quadrupole mass spectrometry GB/T 35410-2017		2022-11-09
		14	linear correlation coefficient	Method of performance testing for liquid chromatography-tandem quadrupole mass spectrometry GB/T 35410-2017		2022-11-09
		15	mass stability	Method of performance testing for liquid chromatography-tandem quadrupole mass spectrometry GB/T 35410-2017		2022-11-09
		16	mass accuracy	Method of performance testing for liquid chromatography-tandem quadrupole mass spectrometry GB/T 35410-2017		2022-11-09
		17	Area repeatability	Method of performance testing for liquid chromatography-tandem quadrupole mass spectrometry GB/T 35410-2017		2022-11-09
		18	Qualitative repeatability	Method of performance testing for liquid chromatography-tandem quadrupole mass spectrometry GB/T 35410-2017		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		19	Retention time repeatability	Method of performance testing for liquid chromatography-tandem quadrupole mass spectrometry GB/T 35410-2017		2022-11-09
		20	scanning speed	Method of performance testing for liquid chromatography-tandem quadrupole mass spectrometry GB/T 35410-2017		2022-11-09
62	Other medical analysis equipment	1	essential function	Technical requirement of area fluorescent imaging microarray scanner GB/T 33806-2017		2022-11-09
		2	stability	Technical requirement of area fluorescent imaging microarray scanner GB/T 33806-2017		2022-11-09
		3	Resolution	Technical requirement of area fluorescent imaging microarray scanner GB/T 33806-2017		2022-11-09
		4	Lowest limit of detection	Technical requirement of area fluorescent imaging microarray scanner GB/T 33806-2017		2022-11-09
		5	linearity	Technical requirement of area fluorescent imaging microarray scanner GB/T 33806-2017		2022-11-09
		6	Location Variation	Technical requirement of area fluorescent imaging microarray scanner GB/T 33806-2017		2022-11-09
		7	Dynamic Range	Technical requirement of area fluorescent imaging microarray scanner GB/T 33806-2017		2022-11-09
		8	safety	Technical requirement of area fluorescent imaging microarray scanner GB/T 33806-2017		2022-11-09
		9	environment test	Technical requirement of area fluorescent imaging microarray scanner GB/T 33806-2017		2022-11-09
		10	appearance	Technical requirement of area fluorescent imaging microarray scanner GB/T 33806-2017		2022-11-09
63	Oral treatment equipment	1	Design	Dental equipment-High-and medium-volume suction systems YY/T 0629-2021		2022-11-09
		2	Max Suction Pressure	Dental equipment-High-and medium-volume suction systems YY/T 0629-2021		2022-11-09
		3	Filter of Bacteria	Dental equipment-High-and medium-volume suction systems YY/T 0629-2021		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	Breif information of manufacture	Dental equipment-High-and medium-volume suction systems YY/T 0629-2021		2022-11-09
		5	Instruction Manual	Dental equipment-High-and medium-volume suction systems YY/T 0629-2021		2022-11-09
		6	Technical Instruction	Dental equipment-High-and medium-volume suction systems YY/T 0629-2021		2022-11-09
		7	External mark of electronic central suction equipment	Dental equipment-High-and medium-volume suction systems YY/T 0629-2021		2022-11-09
		8	Joints of pipe	Dental equipment-High-and medium-volume suction systems YY/T 0629-2021		2022-11-09
		9	Package	Dental equipment-High-and medium-volume suction systems YY/T 0629-2021		2022-11-09
64	Surgical Instruments	1	Structure and size	Cutting tools for electric osseous tissue surgical equipment-Part 2:Cranial perforator YY/T 1629.2-2018		2022-11-09
		2	Appearance	Cutting tools for electric osseous tissue surgical equipment-Part 2:Cranial perforator YY/T 1629.2-2018		2022-11-09
		3	Requirement	Cutting tools for electric osseous tissue surgical equipment-Part 2:Cranial perforator YY/T 1629.2-2018		2022-11-09
		4	Surface roughness	Cutting tools for electric osseous tissue surgical equipment-Part 2:Cranial perforator YY/T 1629.2-2018		2022-11-09
		5	Hardness	Cutting tools for electric osseous tissue surgical equipment-Part 2:Cranial perforator YY/T 1629.2-2018		2022-11-09
		6	Interface strength	Cutting tools for electric osseous tissue surgical equipment-Part 2:Cranial perforator YY/T 1629.2-2018		2022-11-09
		7	Adaptability	Cutting tools for electric osseous tissue surgical equipment-Part 2:Cranial perforator YY/T 1629.2-2018		2022-11-09
		8	Corrosion resistance	Cutting tools for electric osseous tissue surgical equipment-Part 2:Cranial perforator YY/T 1629.2-2018		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Cleaning, disinfection or sterilization	Cutting tools for electric osseous tissue surgical equipment-Part 2:Cranial perforator YY/T 1629.2-2018		2022-11-09
		10	Sterile products should be sterile	Cutting tools for electric osseous tissue surgical equipment-Part 2:Cranial perforator YY/T 1629.2-2018		2022-11-09
		11	Structure and size	Cutting tools for electric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2022-11-09
		12	Edge size	Cutting tools for electric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2022-11-09
		13	Surface roughness	Cutting tools for electric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2022-11-09
		14	Rod straightness	Cutting tools for electric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2022-11-09
		15	Radial circular runout of edge	Cutting tools for electric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2022-11-09
		16	Hardness	Cutting tools for electric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2022-11-09
		17	Connecting Strength	Cutting tools for electric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2022-11-09
		18	Edge strength	Cutting tools for electric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2022-11-09
		19	Permanent deformation	Cutting tools for electric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2022-11-09
		20	Corrosion resistance	Cutting tools for electric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2022-11-09
		21	Tolerance to disinfection or sterilization	Cutting tools for electric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2022-11-09
		22	Aseptic requirements	Cutting tools for electric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		23	Ethylene oxide residue	Cutting tools for electric osseous tissue surgical equipment-Part 1: Burs YY/T 1629.1-2018		2022-11-09
		24	Adaptability	Cutting tools for electric osseous tissue surgical equipment-Part 1: Burs YY/T 1629.1-2018		2022-11-09
		25	Appearance and structure	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2022-11-09
		26	Display and Control	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2022-11-09
		27	Tip main amplitude	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2022-11-09
		28	Tip transverse amplitude	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2022-11-09
		29	Excitation frequency	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2022-11-09
		30	Tip vibration frequency	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2022-11-09
		31	Derived Output Sound Power	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2022-11-09
		32	Duty cycle	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2022-11-09
		33	Static (no-load) power	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2022-11-09
		34	Maximum electric power	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2022-11-09
		35	Power reserve index	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2022-11-09
		36	Main Sound Output Area	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2022-11-09
		37	Acoustic output area of secondary	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			transverse vibration			
		38	Liquid flow rate	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2022-11-09
		39	Noise	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2022-11-09
		40	Characteristics to be published in the specification	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2022-11-09
65	Industrial, scientific and medical robots	1	Electrostatic discharge immunity test	Industrial, scientific and medical robots—Electromagnetic compatibility—Immunity tests GB/T 38326-2019		2022-11-09
		2	Electrical fast transient/burst immunity test	Industrial, scientific and medical robots—Electromagnetic compatibility—Immunity tests GB/T 38326-2019		2022-11-09
		3	Surge immunity test	Industrial, scientific and medical robots—Electromagnetic compatibility—Immunity tests GB/T 38326-2019		2022-11-09
		4	conducted disturbances, induced by radio-frequency fields	Industrial, scientific and medical robots—Electromagnetic compatibility—Immunity tests GB/T 38326-2019		2022-11-09
		5	conducted disturbances, induced by radio-frequency fields	Industrial, scientific and medical robots—Electromagnetic compatibility—Immunity tests GB/T 38326-2019		2022-11-09
		6	Power frequency magnetic field immunity	Industrial, scientific and medical robots—Electromagnetic compatibility—Immunity tests GB/T 38326-2019		2022-11-09
		7	Voltage dips, short interruptions and	Industrial, scientific and medical robots—Electromagnetic compatibility—Immunity tests GB/T 38326-2019		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			voltage variations			
		8	CE	Industrial,scientific and medical robots—Electromagnetic compatibility—Emission methods of measurement and limits GB/T 38336-2019		2022-11-09
		9	RE (30MHz~1GHz)	Industrial,scientific and medical robots—Electromagnetic compatibility—Emission methods of measurement and limits GB/T 38336-2019		2022-11-09
		10	RE (1GHz~18GHz)	Industrial,scientific and medical robots—Electromagnetic compatibility—Emission methods of measurement and limits GB/T 38336-2019		2022-11-09
		11	harmonic current	Industrial,scientific and medical robots—Electromagnetic compatibility—Emission methods of measurement and limits GB/T 38336-2019		2022-11-09
		12	voltage fluctuations and flicker	Industrial,scientific and medical robots—Electromagnetic compatibility—Emission methods of measurement and limits GB/T 38336-2019		2022-11-09
66		1	All items	Blood refrigerator YY/T 0086-2020		2022-11-09
		2	All items	Automated blood culture system YY/T 0656-2008		2022-11-09
		3	All items	Electrophoresis device YY0087-2004		2022-11-09
67	Medical electrical equipment	1	General requirements	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 4.1		2022-11-09
		2	secondary tip vibration excursion	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 4.2		2022-11-09
		3	drive frequency	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 4.3		2022-11-09
		4	drived output acoustic power	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 4.4		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	quiescent electrical power	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 4.5		2022-11-09
		6	maximum electrical power	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 4.6		2022-11-09
		7	clamping force	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 4.7		2022-11-09
		8	grasping force	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 4.8		2022-11-09
		9	Appearance and structure	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 4.9		2022-11-09
		10	power supply	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 4.10		2022-11-09
		11	power input	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 4.11		2022-11-09
		12	type tests	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 5.1		2022-11-09
		13	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		2022-11-09
		14	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		2022-11-09
		15	humidity preconditioning treatment	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 5.7		2022-11-09
		16	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		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		17	protection against electric shock	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 6.2		2022-11-09
		18	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		2022-11-09
		19	methods of sterilization	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 6.4		2022-11-09
		20	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		2022-11-09
		21	mode of operation	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 6.6		2022-11-09
		22	General	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 7.1		2022-11-09
		23	marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 7.2		2022-11-09
		24	marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 7.3		2022-11-09
		25	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		2022-11-09
		26	safety signs	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 7.5		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		27	symbols	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 7.6		2022-11-09
		28	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		2022-11-09
		29	indicator lights and controls	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 7.8		2022-11-09
		30	accompanying documents	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 7.9		2022-11-09
		31	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		2022-11-09
		32	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		2022-11-09
		33	Classification of APPLIED PARTS	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 8.3		2022-11-09
		34	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		2022-11-09
		35	Separation of parts	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 8.5		2022-11-09
		36	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		2022-11-09
		37	LEAKAGE CURRENTS and PATIENT	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 8.7		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			AUXILIARY CURRENTS			
		38	Insulation	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 8.8		2022-11-09
		39	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		2022-11-09
		40	Components and wiring	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 8.10		2022-11-09
		41	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		2022-11-09
		42	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		2022-11-09
		43	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		2022-11-09
		44	Instability HAZARDS	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 9.4		2022-11-09
		45	Expelled parts HAZARD	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 9.5		2022-11-09
		46	Acoustic energy (including infra- and ultrasound) and vibration 281	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 9.6		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		47	9.7 * 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		2022-11-09
		48	9.8 * HAZARDS associated with support systems 291	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 9.8		2022-11-09
		49	X-Radiation	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 10.1		2022-11-09
		50	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		2022-11-09
		51	Microwave radiation	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 10.3		2022-11-09
		52	Lasers	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 10.4		2022-11-09
		53	Other visible electromagnetic radiation	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 10.5		2022-11-09
		54	Infrared radiation	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 10.6		2022-11-09
		55	Ultraviolet radiation	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 10.7		2022-11-09
		56	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		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		57	Fire prevention	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 11.2		2022-11-09
		58	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		2022-11-09
		59	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		2022-11-09
		60	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		2022-11-09
		61	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT...	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 11.6		2022-11-09
		62	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		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		63	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		2022-11-09
		64	USABILITY	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 12.2		2022-11-09
		65	Alarm systems	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 12.3		2022-11-09
		66	Protection against hazardous output....	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 12.4		2022-11-09
		67	Specific HAZARDOUS SITUATIONS	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 13.1		2022-11-09
		68	SINGLE FAULT CONDITIONS	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 13.2		2022-11-09
		69	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 14		2022-11-09
		70	Arrangements of controls and indicators of ME EQUIPMENT	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 15.1		2022-11-09
		71	Serviceability	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 15.2		2022-11-09
		72	Mechanical strength	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 15.3		2022-11-09
		73	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		2022-11-09



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		74	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		2022-11-09
		75	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		2022-11-09
		76	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		2022-11-09
		77	Power supply .	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 16.3		2022-11-09
		78	ENCLOSURES	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 16.4		2022-11-09
		79	SEPARATION DEVICES.....	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 16.5		2022-11-09
		80	LEAKAGE CURRENTS.	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 16.6		2022-11-09
		81	Protection against MECHANICAL HAZARDS	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 16.7		2022-11-09
		82	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		2022-11-09



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		83	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		2022-11-09
		84	General requirement	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		2022-11-09
		85	ME EQUIPMENT indentification 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		2022-11-09
		86		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 5.1		2022-11-09
		87	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		2022-11-09
		88	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		2022-11-09



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		№	Item/ Parameter			
		89	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		2022-11-09
		90	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		2022-11-09
		91	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		2022-11-09
		92	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		2022-11-09
		93	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		2022-11-09
		94	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		2022-11-09



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				medical electrical equipment and medical electrical systems YY/T 9706.108-2021 6.7		
		95	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		2022-11-09
		96	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		2022-11-09
		97	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 medical electrical equipment and medical electrical systems YY/T 9706.108-2021 6.10		2022-11-09
		98	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		2022-11-09
		99	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		2022-11-09
68	Medical electrical	1	Additional requirements for	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral		2022-11-09



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	equipment used in the home healthcare environment		supply mains for ME equipment and ME systems	standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 4.1		
		2	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		2022-11-09
		3	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		2022-11-09
		4	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		2022-11-09
		5	General requirments for testing 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 5		2022-11-09
		6	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		2022-11-09
		7	usability of the accompanying	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
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			documents	standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 7.1		
		8	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		2022-11-09
		9	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		2022-11-09
		10	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		2022-11-09
		11	technical description	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 7.5		2022-11-09
		12	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		2022-11-09
		13	additional	Medical electrical equipment Part 1-11: General requirements for		2022-11-09

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			requirements for sterilization of ME equipment and ME systems	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		
		14	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		2022-11-09
		15	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		2022-11-09
		16	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 medical electrical systems used in the home healthcare environment YY 9706.111-2021 8.5.1		2022-11-09
		17	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		2022-11-09
		18	accuracy of controls and instruments and protection against	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and		2022-11-09



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			hazardous outputs	medical electrical systems used in the home healthcare environment YY 9706.111-2021 9		
		19	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		2022-11-09
		20	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		2022-11-09
		21	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		2022-11-09
		22	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 medical electrical systems used in the home healthcare environment YY 9706.111-2021 11		2022-11-09
		23	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		2022-11-09
		24	additional requirements for	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral		2022-11-09



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			generation of alarm signals	standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 13.1		
		25	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		2022-11-09
69	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 9706.102-2021		2022-11-09
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014		2022-11-09
				Electromagnetic compatibility (EMC) -- Part 3-2: Limits -- Limits for harmonic current emissions (equipment input current ≤ 16 A per phase GB 17625.1-2012		2022-11-09
				Electromagnetic compatibility (EMC) -- Part 3-2: Limits -- Limits for harmonic current emissions (equipment input current ≤ 17 A per phase IEC 61000-3-2:2014,I		2022-11-09
		2	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		2022-11-09
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014		2022-11-09
				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		2022-11-09



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				GB/T 17625.2-2007		
				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		2022-11-09
		3	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		2022-11-09
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014		2022-11-09
				Testing and measuring techniques - Electrostatic discharge immunity test GB/T 17626.2-2018		2022-11-09
				Testing and measuring techniques - Electrostatic discharge immunity test IEC 61000-4-2:2008		2022-11-09
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2022-11-09
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity CISPR 14-2:2015		2022-11-09
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2022-11-09
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2022-11-09
		4	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		2022-11-09



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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		2022-11-09		
				Testing and measurement techniques -- Electrical fast transient/burst immunity test GB/T 17626.4-2018		2022-11-09		
				Testing and measurement techniques -- Electrical fast transient/burst immunity test IEC 61000-4-4:2012		2022-11-09		
				Testing and measurement techniques -- Electrical fast transient/burst immunity test IEC 61000-4-4:2004		2022-11-09		
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2022-11-09		
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity CISPR 14-2:2015		2022-11-09		
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2022-11-09		
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2022-11-09		
		5	Surge immunity test			Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2022-11-09
						Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014		2022-11-09
						Testing and measurement techniques - Surge immunity test GB/T 17626.5-2019		2022-11-09
						Testing and measurement techniques - Surge immunity test IEC 61000-4-5:2014		2022-11-09



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				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2022-11-09
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity CISPR 14-2:2015		2022-11-09
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2022-11-09
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2022-11-09
		6	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		2022-11-09
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014		2022-11-09
				Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields GB/T 17626.6-2017		2022-11-09
				Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields IEC 61000-4-6:2013		2022-11-09
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2022-11-09
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity CISPR 14-2:2015		2022-11-09



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				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2022-11-09
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2022-11-09
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2022-11-09
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014		2022-11-09
				Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests GB/T 17626.11-2008		2022-11-09
				Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests IEC 61000-4-11: 2004		2022-11-09
		7	Voltage dips, short interruptions and voltage variations	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		2022-11-09
				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		2022-11-09
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2022-11-09
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity CISPR 14-2:2015		2022-11-09
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2022-11-09



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				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2022-11-09
		8	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		2022-11-09
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014		2022-11-09
				Testing and measurement techniques - Power frequency magnetic field immunity test GB/T 17626.8-2006		2022-11-09
				Testing and measurement techniques - Power frequency magnetic field immunity test IEC 61000-4-8:2009		2022-11-09
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2022-11-09
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2022-11-09
		9	CE	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2022-11-09
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014		2022-11-09
				Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emissio GB 4343.1-2018		2022-11-09
				Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emissio CISPR 14-1:2011		2022-11-09
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of		2022-11-09



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				measurement GB 4824-2019		
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement CISPR 11:2016		2022-11-09
				Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement GB/T 9254.1-2021		2022-11-09
				Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement CISPR 32:2015		2022-11-09
				Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment GB/T 17743-2021		2022-11-09
				Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment CISPR 15: 2018		2022-11-09
		10	RE (1GHz~18GHz)	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2022-11-09
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014		2022-11-09
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement GB 4824-2019		2022-11-09
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement CISPR 11:2016		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
11				Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement GB/T 9254.1-2021		2022-11-09
				Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement CISPR 32:2015		2022-11-09
		RE (30MHz~1GHz)		Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2022-11-09
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014		2022-11-09
				Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emissio GB 4343.1-2018		2022-11-09
				Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emissio CISPR 14-1:2011		2022-11-09
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement GB 4824-2019		2022-11-09
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement CISPR 11:2016		2022-11-09
				Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement GB/T 9254.1-2021		2022-11-09
Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement CISPR 32:2015		2022-11-09				



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment GB/T 17743-2021		2022-11-09
				Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment CISPR 15: 2018		2022-11-09
		12	RE (9kHz~30MHz)	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2022-11-09
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014		2022-11-09
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement GB 4824-2019		2022-11-09
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement CISPR 11:2016		2022-11-09
				Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment GB/T 17743-2021		2022-11-09
				Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment CISPR 15: 2018		2022-11-09
		13	click	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2022-11-09
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date	
		№	Item/ Parameter				
				Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emissio GB 4343.1-2018		2022-11-09	
				Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emissio CISPR 14-1:2011		2022-11-09	
		14	distrubance power		Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2022-11-09
					Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014		2022-11-09
					Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emissio GB 4343.1-2018		2022-11-09
					Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emissio CISPR 14-1:2011		2022-11-09
		15	RS		Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2022-11-09
					Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014		2022-11-09
					Electromagnetic compatibility (EMC) -- Part 4-3: Testing and measurement techniques -- Radiated, radio-frequency, electromagnetic field immunity test GB/T 17626.3-2016		2022-11-09
					Electromagnetic compatibility (EMC) -- Part 4-4: Testing and measurement techniques -- Radiated, radio-frequency, electromagnetic field immunity test IEC 61000-4-3:2010		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
70	Electromagnetic compatibility of electrically powered wheelchairs			Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2022-11-09
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 3: Immunity CISPR 14-2:2015		2022-11-09
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2022-11-09
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2022-11-09
		1	CE	GB/T 18029.21-2012 5.3.1、 5.4.1		2022-11-09
		2	RE (30MHz~1GHz)	GB/T 18029.21-2012 5.2.1、 5.3.2、 5.4.2		2022-11-09
		3	harmonic current	GB/T 18029.21-2012 5.3.3、 5.4.3		2022-11-09
		4	voltage fluctuations and flicker	GB/T 18029.21-2012 5.3.4、 5.4.4		2022-11-09
5	Electrostatic discharge immunity test	GB/T 18029.21-2012 5.2.2、 5.3.5、 5.4.5		2022-11-09		
6	RS	Electromagnetic compatibility (EMC) -- Part 4-3: Testing and measurement techniques -- Radiated, radio-frequency, electromagnetic field immunity test GB/T 18029.21-2012 5.2.3、 5.3.6、 5.4.6		2022-11-09		
7	Electrical fast transientburst immunity test	Testing and measurement techniques -- Electrical fast transientburst immunity test GB/T 18029.21-2012 5.3.7、 5.4.7		2022-11-09		
8	Surge immunity test	GB/T 18029.21-2012 5.3.8、 5.4.8		2022-11-09		



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		№	Item/ Parameter			
		9	conducted disturbances, induced by radio-frequency fields	GB/T 18029.21-2012 5.3.9、5.4.9		2022-11-09
		10	Voltage dips, short interruptions and voltage variations	GB/T 18029.21-2012 5.3.10、5.4.10		2022-11-09
		11	Power frequency magnetic field immunity	Testing and measurement techniques - Power frequency magnetic field immunity test GB/T 18029.21-2012 5.2.4		2022-11-09
71	Ultrasonic physiological parameters measurement and analysis equipment	1	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		2022-11-09
		2	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		2022-11-09
		3	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		2022-11-09
		4	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		2022-11-09
		5	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		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	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		2022-11-09
		7	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		2022-11-09
		8	acoustic working frequency	General technical requirements for intravascular ultrasound (IVUS) diagnostic equipment YY/T 1659-2019 4.1		2022-11-09
		9	radius of imaging	General technical requirements for intravascular ultrasound (IVUS) diagnostic equipment YY/T 1659-2019 4.2		2022-11-09
		10	axial resolution	General technical requirements for intravascular ultrasound (IVUS) diagnostic equipment YY/T 1659-2019 4.3		2022-11-09
		11	lateral resolution	General technical requirements for intravascular ultrasound (IVUS) diagnostic equipment YY/T 1659-2019 4.4		2022-11-09
		12	pullback resolution	General technical requirements for intravascular ultrasound (IVUS) diagnostic equipment YY/T 1659-2019 4.5		2022-11-09
		13	Longitudinal geometric position accuracy	General technical requirements for intravascular ultrasound (IVUS) diagnostic equipment YY/T 1659-2019 4.6		2022-11-09
		14	Horizontal geometric position accuracy	General technical requirements for intravascular ultrasound (IVUS) diagnostic equipment YY/T 1659-2019 4.7		2022-11-09
		15	Geometric position accuracy of retraction direction	General technical requirements for intravascular ultrasound (IVUS) diagnostic equipment YY/T 1659-2019 4.8		2022-11-09
		16	Image geometric distortion	General technical requirements for intravascular ultrasound (IVUS) diagnostic equipment YY/T 1659-2019 4.9		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		17	Appearance and structure	General technical requirements for intravascular ultrasound (IVUS) diagnostic equipment YY/T 1659-2019 4.10		2022-11-09
		18	Use function	General technical requirements for intravascular ultrasound (IVUS) diagnostic equipment YY/T 1659-2019 4.11		2022-11-09
72	Ultrasonic physiotherapy equipment	1	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		2022-11-09
		2	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		2022-11-09
		3	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		2022-11-09
		4	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		2022-11-09
		5	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		2022-11-09
		6	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		2022-11-09
		7	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		2022-11-09
		8	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		2022-11-09
		9	primary tip vibration excursion	Ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T 1750-2020 4.1		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		10	secondary tip vibration excursion	Ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T 1750-2020 4.2		2022-11-09
		11	drive frequency	Ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T 1750-2020 4.3		2022-11-09
		12	drived output acoustic power	Ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T 1750-2020 4.4		2022-11-09
		13	quiescent electrical power	Ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T 1750-2020 4.5		2022-11-09
		14	maximum electrical power	Ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T 1750-2020 4.6		2022-11-09
		15	clamping force	Ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T 1750-2020 4.7		2022-11-09
		16	grasping force	Ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T 1750-2020 4.8		2022-11-09
		17	Appearance and structure	Ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T 1750-2020 4.9		2022-11-09
		18	Use function	Ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T 1750-2020 4.10		2022-11-09
73	Optical equipment and appliances	1	General	Medical endoscopes-Video endoscopes GB 38455-2019 4.1		2022-11-09
		2	Radius of curvation measurements	Medical endoscopes-Video endoscopes GB 38455-2019 4.2		2022-11-09
		3	Measurement of direction of principal meridians	Medical endoscopes-Video endoscopes GB 38455-2019 4.3		2022-11-09
		4	Eyes adjustment	Medical endoscopes-Video endoscopes GB 38455-2019 4.4		2022-11-09
		5	General	Ophthalmic instruments — Fundamental requirements and test methods —Part 1:General requirements applicable to all ophthalmic instruments ISO 15004-1:2020 4.1		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	Design	Ophthalmic instruments — Fundamental requirements and test methods —Part 1:General requirements applicable to all ophthalmic instruments ISO 15004-1:2020 4.2		2022-11-09
		7	Performance	Ophthalmic instruments — Fundamental requirements and test methods —Part 1:General requirements applicable to all ophthalmic instruments ISO 15004-1:2020 4.3		2022-11-09
		8	Combination of different devices	Ophthalmic instruments — Fundamental requirements and test methods —Part 1:General requirements applicable to all ophthalmic instruments ISO 15004-1:2020 4.4		2022-11-09
		9	Materials	Ophthalmic instruments — Fundamental requirements and test methods —Part 1:General requirements applicable to all ophthalmic instruments ISO 15004-1:2020 4.5		2022-11-09
		10	Protection against contaminants	Ophthalmic instruments — Fundamental requirements and test methods —Part 2:General requirements applicable to all ophthalmic instruments ISO 15004-1:2020 4.6		2022-11-09
		11	Scales and displays	Ophthalmic instruments — Fundamental requirements and test methods —Part 3:General requirements applicable to all ophthalmic instruments ISO 15004-1:2020 4.7		2022-11-09
		12	Thermal hazards	Ophthalmic instruments — Fundamental requirements and test methods —Part 4:General requirements applicable to all ophthalmic instruments ISO 15004-1:2020 4.8		2022-11-09
		13	Mechanical hazards	Ophthalmic instruments — Fundamental requirements and test methods —Part 5:General requirements applicable to all ophthalmic instruments ISO 15004-1:2020 4.9		2022-11-09
		14	Environmental conditions	Ophthalmic instruments — Fundamental requirements and test methods —Part 6:General requirements applicable to all ophthalmic instruments ISO 15004-1:2020 5		2022-11-09
74	Laser products	1	Laser output performance of therapeutic	Therapeutic laser equipment-Laser diode irradiation therapeutic equipment for nasal cavity YY/T 1751-2020 4.2		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			equipment			
		2	Light guide parts	Therapeutic laser equipment-Laser diode irradiation therapeutic equipment for nasal cavity YY/T 1751-2020 4.3		2022-11-09
		3	Over voltage indication performance	Therapeutic laser equipment-Laser diode irradiation therapeutic equipment for nasal cavity YY/T 1751-2020 4.4		2022-11-09
		4	appearance	Therapeutic laser equipment-Laser diode irradiation therapeutic equipment for nasal cavity YY/T 1751-2020 4.6		2022-11-09
		5	laser wavelength	Therapeutic laser equipment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.1		2022-11-09
		6	laser mode	Therapeutic laser equipment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.2		2022-11-09
		7	laser pulse duration	Therapeutic laser equipment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.3		2022-11-09
		8	laser pulse train duration	Therapeutic laser equipment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.4		2022-11-09
		9	maximum laser pulse power	Therapeutic laser equipment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.5		2022-11-09
		10	maximum average power	Therapeutic laser equipment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.6		2022-11-09
		11	maximum single pulse energy and duration	Therapeutic laser equipment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.7		2022-11-09
		12	laser pulse energy	Therapeutic laser equipment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.8		2022-11-09
		13	laser treatment area size	Therapeutic laser equipment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.9		2022-11-09
		14	laser treatment speckle	Therapeutic laser equipment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.10		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			energypower density			
		15	laser divergence angle	Therapeutic laser equipment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.11		2022-11-09
		16	laser energy instability	Therapeutic laser equipment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.12		2022-11-09
		17	laser energy repeatability	Therapeutic laser equipment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.13		2022-11-09
		18	aiming beam wavelength	Therapeutic laser equipment-Er:YAG laser equipment for therapy YY 1301-2016 5.3.1		2022-11-09
		19	aiming beam power	Therapeutic laser equipment-Er:YAG laser equipment for therapy YY 1301-2016 5.3.2		2022-11-09
		20	laser goggle	Therapeutic laser equipment-Er:YAG laser equipment for therapy YY 1301-2016 5.6		2022-11-09
75	dental equipment	1	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		2022-11-09
		2	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		2022-11-09
		3	Protection of ME equipment against electric shock hazard	Medical electrical equipment - Part 2-60: Particular requirements for basic safety and essential performance of dental equipment GB 9706.260-2020 201.8		2022-11-09
		4	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		2022-11-09



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		5	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		2022-11-09
76	Immunoassay equipment	1	Appearance Requirements	High-throughput gene sequencer YY/T 1723-2020 4.1		2022-11-09
		2	Sequence read length and throughput	High-throughput gene sequencer YY/T 1723-2020 4.2		2022-11-09
		3	Percentage of base recognition mass	High-throughput gene sequencer YY/T 1723-2020 4.3		2022-11-09
		4	Performance Index	High-throughput gene sequencer YY/T 1723-2020 4.4		2022-11-09
		5	Software function	High-throughput gene sequencer YY/T 1723-2020 4.5		2022-11-09
		6	Safety requirements	High-throughput gene sequencer YY/T 1723-2020 4.6		2022-11-09
		7	EMC requirements	High-throughput gene sequencer YY/T 1723-2020 4.7		2022-11-09
		8	appearance	Colloidal gold immunochromatographic reader YY/T 1582-2018 3.1		2022-11-09
		9	resolution ratio	Colloidal gold immunochromatographic reader YY/T 1582-2018 3.2		2022-11-09
		10	accuracy	Colloidal gold immunochromatographic reader YY/T 1582-2018 3.3		2022-11-09
		11	repeatability	Colloidal gold immunochromatographic reader YY/T 1582-2018 3.4		2022-11-09
		12	linearity	Colloidal gold immunochromatographic reader YY/T 1582-2018 3.5		2022-11-09
		13	channel consistency (if applicable)	Colloidal gold immunochromatographic reader YY/T 1582-2018 3.6		2022-11-09



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		14	stability	Colloidal gold immunochromatographic reader YY/T 1582-2018 3.7		2022-11-09
		15	function	Colloidal gold immunochromatographic reader YY/T 1582-2018 3.8		2022-11-09
77	X-ray accessory and auxiliary equipment	1	Size and type of plug and socket	specification for high coltage cable assemblies and sockets of Mammographic X-ray equipment YY/T 1541-2017 5.1		2022-11-09
		2	Physical properties of plug and socket	specification for high coltage cable assemblies and sockets of Mammographic X-ray equipment YY/T 1541-2017 5.2		2022-11-09
		3	contact resistance	specification for high coltage cable assemblies and sockets of Mammographic X-ray equipment YY/T 1541-2017 5.3		2022-11-09
		4	DC withstand voltage	specification for high coltage cable assemblies and sockets of Mammographic X-ray equipment YY/T 1541-2017 5.4		2022-11-09
		5	Electrical reliability	specification for high coltage cable assemblies and sockets of Mammographic X-ray equipment YY/T 1541-2017 5.5		2022-11-09
		6	Sealing performance	specification for high coltage cable assemblies and sockets of Mammographic X-ray equipment YY/T 1541-2017 5.6		2022-11-09
		7	Pin firmness of plug	specification for high coltage cable assemblies and sockets of Mammographic X-ray equipment YY/T 1541-2017 5.7		2022-11-09
		8	Connection firmness	specification for high coltage cable assemblies and sockets of Mammographic X-ray equipment YY/T 1541-2017 5.8		2022-11-09
		9	mechanical strength	specification for high coltage cable assemblies and sockets of Mammographic X-ray equipment YY/T 1541-2017 5.9		2022-11-09
		10	Resistance to mechanical stress	specification for high coltage cable assemblies and sockets of Mammographic X-ray equipment YY/T 1541-2017 5.10		2022-11-09
		11	Requirements for high voltage cable assemblies	specification for high coltage cable assemblies and sockets of Mammographic X-ray equipment YY/T 1541-2017 5.11		2022-11-09
		12	Image noise	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.2.1		2022-11-09



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		№	Item/ Parameter			
		13	Uniformity of CT value	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.2.2		2022-11-09
		14	Accuracy of CT value	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.2.3		2022-11-09
		15	spatial resolution	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.2.4		2022-11-09
		16	Low contrast resolution	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.2.5		2022-11-09
		17	Running noise	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.2.6		2022-11-09
		18	Artifact	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.2.7		2022-11-09
		19	Slice thickness	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.2.8		2022-11-09
		20	Scanning frame	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.3		2022-11-09
		21	Patient stent	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.4		2022-11-09
		22	Mobile performance	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.5		2022-11-09
		23	X-ray generator	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.6		2022-11-09
		24	Internal power supply	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.8		2022-11-09
		25	Protection against stray radiation	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.9		2022-11-09
		26	appearance	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.11		2022-11-09
		27	Compatibility	Basic requirements of communication and conformance for medical diagnostic X-ray image equipment Part1: general		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				requirements YY/T 1708.1-2020 4.1		
		28	Reliability	Basic requirements of communication and conformance for medical diagnostic X-ray image equipment Part1: general requirements YY/T 1708.1-2020 4.2		2022-11-09
		29	Cybersecurity	Basic requirements of communication and conformance for medical diagnostic X-ray image equipment Part1: general requirements YY/T 1708.1-2020 4.3		2022-11-09
		30	Maintainability	Basic requirements of communication and conformance for medical diagnostic X-ray image equipment Part1: general requirements YY/T 1708.1-2020 4.4		2022-11-09
		31	Portability	Basic requirements of communication and conformance for medical diagnostic X-ray image equipment Part1: general requirements YY/T 1708.1-2020 4.5		2022-11-09
78	Electronic equipment	1	Treatment temperature	Electric heating moxibustion equipment YY/T 1490-2016 5.1		2022-11-09
		2	Timing function	Electric heating moxibustion equipment YY/T 1490-2016 5.2		2022-11-09
		3	Noise	Electric heating moxibustion equipment YY/T 1490-2016 5.3		2022-11-09
		4	Noise	Electric heating moxibustion equipment YY/T 1490-2016 5.4		2022-11-09
		5	size of moxibustion head and pad	Electric heating moxibustion equipment YY/T 1490-2016 5.5		2022-11-09
		6	Other requirements of moxibustion pad	Electric heating moxibustion equipment YY/T 1490-2016 5.6		2022-11-09
		7	Manual	Electric heating moxibustion equipment YY/T 1490-2016 5.8		2022-11-09
		8	appearance	Electric heating moxibustion equipment YY/T 1490-2016 5.9		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
79	Cardiopulmonary bypass systems	1	Appearance and structure of blood pump	Cardiopulmonary bypass systems-Roller blood pump GB 12260-2017 5.2		2022-11-09
		2	Constant current performance	Cardiopulmonary bypass systems-Roller blood pump GB 12260-2017 5.3		2022-11-09
		3	Pulsatility	Cardiopulmonary bypass systems-Roller blood pump GB 12260-2017 5.4		2022-11-09
		4	Mechanical properties	Cardiopulmonary bypass systems-Roller blood pump GB 12260-2017 5.5		2022-11-09
		5	Reflux performance	Cardiopulmonary bypass systems-Roller blood pump GB 12260-2017 5.6		2022-11-09
		6	Safety monitoring function	Cardiopulmonary bypass systems-Roller blood pump GB 12260-2017 5.7		2022-11-09
		7	Noise	Cardiopulmonary bypass systems-Roller blood pump GB 12260-2017 5.8		2022-11-09
		8	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		2022-11-09
80	surgical luminaires	1	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		2022-11-09
		2	ME equipment identification, marking and documentation	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 201.7		2022-11-09



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		№	Item/ Parameter					
		3	Protection of me equipment against electric shock hazard (source)	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 201.8		2022-11-09		
		4	Protection of ME equipment and me system against mechanical hazards	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 201.9		2022-11-09		
		5	Protection against unnecessary or excessive radiation hazards (sources)	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 201.10		2022-11-09		
		6	Protection against stray radiation	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 201.11		2022-11-09		
		7	Accuracy of controller and instrument and protection of dangerous output	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 201.12		2022-11-09		
		8	Dangerous situation and fault status of ME equipment	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 201.13		2022-11-09		
		81	Usability test of medical devices	1	General requirements	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 4.1		2022-11-09
		2		Usability engineering file	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 4.2		2022-11-09	



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		№	Item/ Parameter			
				Medical devices-Application of usability engineering to medical devices IEC 62366-1:2005 4.2		2022-11-09
		3	Scaling of the Usability Engineering effort	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 4.3		2022-11-09
				Medical devices-Application of usability engineering to medical devices IEC 62366-1:2005 4.3		2022-11-09
		4	Application specification	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 5.1		2022-11-09
		5	Frequently used functions	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 5.2		2022-11-09
		6	Identification of hazards and hazardous situations related to usability	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 5.3		2022-11-09
				Medical devices-Application of usability engineering to medical devices IEC 62366-1:2005 5.3		2022-11-09
		7	Primary operating function	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 5.4		2022-11-09
		8	Usability specification	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 5.5		2022-11-09
		9	Availability validation plan	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 5.6		2022-11-09
		10	User interface design and implementation	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 5.7		2022-11-09
		11	Usability verification	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 5.8		2022-11-09
		12	Usability validation	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 5.9		2022-11-09
		13	accompanying document	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 6		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		14	Training and materials for training	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 7		2022-11-09
		15	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		2022-11-09
		16	USABILITY ENGINEERING PROCESS for ME EQUIPMENT	Medical electrical equipment-Part1-6: General equipments for basic safety and essential performance-Collateral standard: Usability IEC 60601-1-6:2010 4.2		2022-11-09
		17	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		2022-11-09
		18	General equipments	Medical devices-Part 1:Application of usability engineering to medical devices IEC 62366-1:2015 4.1		2022-11-09
		19	Prepare use specification	Medical devices-Part 1:Application of usability engineering to medical devices IEC 62366-1:2015 5.1		2022-11-09
		20	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		2022-11-09
		21	Identify and describe hazard-related use scenarios	Medical devices-Part 1:Application of usability engineering to medical devices IEC 62366-1:2015 5.4		2022-11-09
		22	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		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		23	Establish user interface specification	Medical devices-Part 1:Application of usability engineering to medical devices IEC 62366-1:2015 5.6		2022-11-09
		24	Establish user interface evaluation plan	Medical devices-Part 1:Application of usability engineering to medical devices IEC 62366-1:2015 5.7		2022-11-09
		25	Perform user intrrface design,implementati on and formative	Medical devices-Part 1:Application of usability engineering to medical devices IEC 62366-1:2015 5.8		2022-11-09
		26	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		2022-11-09
		27	User interface of unknown provenance	Medical devices-Part 1:Application of usability engineering to medical devices IEC 62366-1:2015 5.10		2022-11-09
		28	Conditions for application to ME EQUIPMENT	Medical electrical equipment-Part1-6: General requipments for basic safety and essential performance-Collateral standard: Usability YY/T 9706.106-2021 4.1		2022-11-09
		29	USABILITY ENGINEERING PROCESS for ME EQUIPMENT	Medical electrical equipment-Part1-6: General requipments for basic safety and essential performance-Collateral standard: Usability YY/T 9706.106-2021 4.2		2022-11-09
		30	Replacement of requirement given inYY/T 1474-2016	Medical electrical equipment-Part1-6: General requipments for basic safety and essential performance-Collateral standard: Usability YY/T 9706.106-2021 5		2022-11-09
82	ventilators	1	Additional requirements for ESSENTIAL	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.4.3.101		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			PERFORMANCE	Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.4.3.101		2022-11-09
		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		2022-11-09
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.4.6		2022-11-09
		3	Overpressure requirement	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.4.11.101		2022-11-09
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.4.11.101		2022-11-09
		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		2022-11-09
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.5.101		2022-11-09
		5	Consult ACCOMPANYING DOCUMENTS	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.7.2.3		2022-11-09
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.7.2.3		2022-11-09
		6	Additional requirements for marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.7.2.101		2022-11-09
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.7.2.101		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		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		2022-11-09
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.7.2.4.101		2022-11-09
		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		2022-11-09
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.7.2.13.101		2022-11-09
		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		2022-11-09
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.7.2.17.101		2022-11-09
		10	Unit of measure	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.7.4.3		2022-11-09
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.7.4.3		2022-11-09
		11	Additional general requirements	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.7.9.1		2022-11-09
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.7.9.1		2022-11-09
		12	Additional requirements for warnings and safety notices	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.9.6.2.1.101		2022-11-09
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.9.6.2.1.101		2022-11-09
		13	Additional	Particular requirements for basic safety and essential performance		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			requirements for suction procedures	of critical care ventilators GB 9706.212-2020 201.9.101		
			Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.9.101		2022-11-09	
		14	Leakage	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.11.6.4		2022-11-09
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.11.6.4		2022-11-09
		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		2022-11-09
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.11.6.5.101		2022-11-09
		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		2022-11-09
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.11.6.6		2022-11-09
		17	Additional requirements for interruption of the power supply SUPPLY MAINS to ME EQUIPMENT	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.11.8.101		2022-11-09
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.11.8.101		2022-11-09
		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		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.12.1.101		2022-11-09
		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		2022-11-09
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.12.1.102		2022-11-09
		20	DELIVERED VOLUME MONITORING	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.12.1.103		2022-11-09
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.12.1.103		2022-11-09
		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		2022-11-09
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.12.1.104		2022-11-09
		22	Protection against hazardous output	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.12.4		2022-11-09
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.12.4		2022-11-09
		23	Protection against accidental adjustments	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.12.101		2022-11-09
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.12.101		2022-11-09
		24	HAZARDOUS SITUATIONS and	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.13		2022-11-09



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			fault conditions	Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.13		2022-11-09
		25	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.14		2022-11-09
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.14		2022-11-09
		26	Construction of ME EQUIPMENT	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.15		2022-11-09
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.15		2022-11-09
		27	ME SYSTEMS	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.16		2022-11-09
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.16		2022-11-09
		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		2022-11-09
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.17		2022-11-09
		29	Gas connections	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.101		2022-11-09
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.101		2022-11-09
		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		2022-11-09
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.102		2022-11-09
		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		2022-11-09



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		№	Item/ Parameter			
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.103		2022-11-09
		32	Training	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.104		2022-11-09
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.104		2022-11-09
		33	Indication of duration of operation	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.105		2022-11-09
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.105		2022-11-09
		34	SIGNAL INPUTOUTPUT PART	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.106		2022-11-09
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.106		2022-11-09
		35	Display loops	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.107		2022-11-09
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.107		2022-11-09
		36	Timed ventilatory pause	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.108		2022-11-09
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 201.108		2022-11-09
		37	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance –	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 206		2022-11-09
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12: 2011 206		2022-11-09



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			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		2022-11-09 2022-11-09
83	Magnetic resonance equipment	1	ACCOMPANYING DOCUMENTS	Medical Electrical Equipment-Part 2-33:Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis YY 0319-2008 6.8		2022-11-09
		2	Vibration and noise	Medical Electrical Equipment-Part 2-33:Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis YY 0319-2008 26		2022-11-09
		3	Pressure vessels and parts subject to pressure	Medical Electrical Equipment-Part 2-33:Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis YY 0319-2008 45.101		2022-11-09
		4	Emergency field shut-down unit	Medical Electrical Equipment-Part 2-33:Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis YY 0319-2008 49.101		2022-11-09



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		№	Item/ Parameter			
		5	Scan interruption	Medical Electrical Equipment-Part 2-33:Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis YY 0319-2008 49.102		2022-11-09
		6	Operating modes	Medical Electrical Equipment-Part 2-33:Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis YY 0319-2008 51.101		2022-11-09
		7	Protection against excessive low frequency field variations produced by the gradient system	Medical Electrical Equipment-Part 2-33:Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis YY 0319-2008 51.102		2022-11-09
		8	Protection against excessive radio frequency energy	Medical Electrical Equipment-Part 2-33:Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis YY 0319-2008 51.103		2022-11-09
		9	Protection against exposure to static magnetic fields	Medical Electrical Equipment-Part 2-33:Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis YY 0319-2008 51.104		2022-11-09
		10	Methods to demonstrate compliance with the requirements	Medical Electrical Equipment-Part 2-33:Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis YY 0319-2008 51.105		2022-11-09
		11	Abnormal operation and fault conditions	Medical Electrical Equipment-Part 2-33:Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis YY 0319-2008 52.1		2022-11-09
		12	Liquid cryogen and cryogen gases	Medical Electrical Equipment-Part 2-33:Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis YY 0319-2008 59.101		2022-11-09
		13	SNR	Determination of essential image quality parameters YY/T 0482-2010 6.8		2022-11-09



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		14	Uniformity	Determination of essential image quality parameters YY/T 0482-2010 4.3		2022-11-09
		15	Electromagnetic compatibility	Determination of essential image quality parameters YY/T 0482-20109-2008 4.4		2022-11-09
		16	Two dimensional geometric distortion	Determination of essential image quality parameters YY/T 0482-2010 4.5		2022-11-09
		17	Spatila resolution	Determination of essential image quality parameters YY/T 0482-2010 4.6		2022-11-09
		18	artifact	Determination of essential image quality parameters YY/T 0482-2010 4.7		2022-11-09
		19	Constancy test	Determination of essential image quality parameters YY/T 0482-2010 5		2022-11-09
		20	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		2022-11-09
		21	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		2022-11-09
		22	protection form mechenial	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 201.9		2022-11-09
		23	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		2022-11-09
		24	Emergency field shut-down unit	Medical Electrical Equipment-Part 2-33:Particular Requirements for the basic safety and essential performance		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				of Magnetic Resonance Equipment for Medical Diagnosis YY 9706.233-2021 201.15		
		25	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		2022-11-09
		26	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		2022-11-09
84	Traditional Chinese medicine device	1	Working Condition	Tongue features acquisition device YY/T 1488-2016 4.1		2022-11-09
		2	Optical requirements	Tongue features acquisition device YY/T 1488-2016 4.2		2022-11-09
		3	imaging quality	Tongue features acquisition device YY/T 1488-2016 4.3		2022-11-09
		4	Structural requirements	Tongue features acquisition device YY/T 1488-2016 4.4		2022-11-09
		5	function	Tongue features acquisition device YY/T 1488-2016 4.5		2022-11-09
		6	manual	Tongue features acquisition device YY/T 1488-2016 4.7		2022-11-09
		7	Working Condition	Pulse graph acquisiton device for traditional chinese medicine YY/T 1489-2016 4.1		2022-11-09
		8	Safety limits of mechanical force	Pulse graph acquisiton device for traditional chinese medicine YY/T 1489-2016 4.2		2022-11-09
		9	Accuracy of applied mechanical force	Pulse graph acquisiton device for traditional chinese medicine YY/T 1489-2016 4.3		2022-11-09
		10	Accuracy of pulse pressure	Pulse graph acquisiton device for traditional chinese medicine YY/T 1489-2016 4.4		2022-11-09



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		№	Item/ Parameter			
		11	Accuracy of pulse rate	Pulse graph acquisition device for traditional chinese medicine YY/T 1489-2016 4.5		2022-11-09
		12	Pressure relief function	Pulse graph acquisition device for traditional chinese medicine YY/T 1489-2016 4.6		2022-11-09
		13	Effective geometry of sensor	Pulse graph acquisition device for traditional chinese medicine YY/T 1489-2016 4.7		2022-11-09
		14	Time constant of dynamic amplifier	Pulse graph acquisition device for traditional chinese medicine YY/T 1489-2016 4.8		2022-11-09
		15	appearance	Pulse graph acquisition device for traditional chinese medicine YY/T 1489-2016 4.10		2022-11-09
		16	manual	Pulse graph acquisition device for traditional chinese medicine YY/T 1489-2016 4.11		2022-11-09
85	Ultrasound endoscope	1	acoustic working frequency	ultrasound endoscope YY/T 1676-2020 4.1		2022-11-09
		2	depth of penetration	ultrasound endoscope YY/T 1676-2020 4.2		2022-11-09
		3	lateral resolution	ultrasound endoscope YY/T 1676-2020 4.3		2022-11-09
		4	axial resolution	ultrasound endoscope YY/T 1676-2020 4.4		2022-11-09
		5	dead zone	ultrasound endoscope YY/T 1676-2020 4.5		2022-11-09
		6	slice thickness	ultrasound endoscope YY/T 1676-2020 4.6		2022-11-09
		7	Horizontal geometric position accuracy	ultrasound endoscope YY/T 1676-2020 4.7		2022-11-09
		8	Longitudinal geometric position accuracy	ultrasound endoscope YY/T 1676-2020 4.8		2022-11-09



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		№	Item/ Parameter			
		9	Measurement deviation of perimeter and area	ultrasound endoscope YY/T 1676-2020 4.9		2022-11-09
		10	M-mode performance index	ultrasound endoscope YY/T 1676-2020 4.10		2022-11-09
		11	three-dimensional ultrasonography	ultrasound endoscope YY/T 1676-2020 4.11		2022-11-09
		12	Geometric position accuracy of retraction direction	ultrasound endoscope YY/T 1676-2020 4.12		2022-11-09
		13	Image geometric distortion	ultrasound endoscope YY/T 1676-2020 4.13		2022-11-09
		14	ultrasonic colour flow imaging performance	ultrasound endoscope YY/T 1676-2020 4.14		2022-11-09
		15	angle of ultrasound visual field	ultrasound endoscope YY/T 1676-2020 4.15		2022-11-09
86	Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic,	1	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		2022-11-09
		2	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		2022-11-09
		3	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		2022-11-09



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monitoring and cosmetic/aesthetic use		4	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		2022-11-09
		5	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		2022-11-09
		6	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		2022-11-09
		7	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		2022-11-09
		8	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		2022-11-09
		9	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		2022-11-09
		10	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		2022-11-09



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		11	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		2022-11-09
		12	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		2022-11-09
87	Liquid chromatography	1	appearance	Clinical mass spectrometer-Part1: Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.2		2022-11-09
		2	mass range	Clinical mass spectrometer-Part1: Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.3		2022-11-09
		3	mass accuracy and mass resolution	Clinical mass spectrometer-Part1: Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.4		2022-11-09
		4	scanning speed	Clinical mass spectrometer-Part1: Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.5		2022-11-09
		5	Accuracy of flow rate of infusion pump	Clinical mass spectrometer-Part1: Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.6		2022-11-09
		6	Accuracy of autosampler and column incubator	Clinical mass spectrometer-Part1: Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.7		2022-11-09
		7	Linearity of autosampler	Clinical mass spectrometer-Part1: Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.8		2022-11-09
		8	sensitivity	Clinical mass spectrometer-Part1: Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.9		2022-11-09
		9	Precision	Clinical mass spectrometer-Part1: Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.10		2022-11-09



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		10	linear	Clinical mass spectrometer-Part1: Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.11		2022-11-09
		11	Carryover rate	Clinical mass spectrometer-Part1: Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.12		2022-11-09
		12	Software	Clinical mass spectrometer-Part1: Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.13		2022-11-09
		13	environmental test	Clinical mass spectrometer-Part1: Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.14		2022-11-09
		14	Electrical safety	Clinical mass spectrometer-Part1: Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.15		2022-11-09
		15	electromagnetic compatibility	Clinical mass spectrometer-Part1: Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.16		2022-11-09
88	Assisted surgical medical equipment and assisted surgical medical system employing robotictchnology	1	master-slave operationl RA equipment accuracy	Assisted surgical medical equipment and assisted surgical medical system employing robotictchnology YY/T 1712-2021 4.2		2022-11-09
		2	Positioning accuracy of navigation guided RA equipment	Assisted surgical medical equipment and assisted surgical medical system employing robotictchnology YY/T 1712-2021 4.3		2022-11-09
		3	maximumspace and effective workspace	Assisted surgical medical equipment and assisted surgical medical system employing robotictchnology YY/T 1712-2021 4.4		2022-11-09
		4	Load carrying capacity of manipulator	Assisted surgical medical equipment and assisted surgical medical system employing robotictchnology YY/T 1712-2021 4.5		2022-11-09
		5	master-slave operationl delay time	Assisted surgical medical equipment and assisted surgical medical system employing robotictchnology YY/T 1712-2021 4.6		2022-11-09
		6	environmental test	Assisted surgical medical equipment and assisted surgical		2022-11-09



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				medical system employing robotictchnology YY/T 1712-2021 4.7		
		7	safety requirements	Assisted surgical medical equipment and assisted surgical medical system employing robotictchnology YY/T 1712-2021 4.8		2022-11-09
89	Nerve and Muscle Stimulators	1	Application conditions	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.4		2022-11-09
		2	General requirements	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.5		2022-11-09
		3	classification	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.6		2022-11-09
		4	Identification, marking and documentation	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.7		2022-11-09
		5	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		2022-11-09
		6	Protection against mechanical hazards	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.9		2022-11-09
		7	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		2022-11-09
		8	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		2022-11-09



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		9	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		2022-11-09
		10		particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.13		2022-11-09
		11	PEMS	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.14		2022-11-09
		12	Structure of me equipment	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.15		2022-11-09
		13	ME system	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.16		2022-11-09
		14	electromagnetic compatibility	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.17		2022-11-09
90	Medical electrical equipment intended for use in the emergency medical services environment	1	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		2022-11-09
		2	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		2022-11-09



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		3	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		2022-11-09
		4	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		2022-11-09
		5	Additional requirements for IP classification marking	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 6.2		2022-11-09
		6	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		2022-11-09
		7	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		2022-11-09
		8	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		2022-11-09



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		9	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		2022-11-09
		10	Additional requirements for power supply/grid interruptions for 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 8.2		2022-11-09
		11	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		2022-11-09
		12	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		2022-11-09
		13	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		2022-11-09
		14	Requirements for installation of ME	Medical electrical equipment-Part 1-12:General requirements for basic safety and essential performance-Collateral		2022-11-09



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		№	Item/ Parameter			
			equipment	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		
		15	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		2022-11-09
91	Immunoassay equipment	1	All items	Fluorescence immunochromatography analyzer YY/T 1792-2021		2022-11-09
92	Damp heat disinfection and sterilization equipment	1	All items	Medical plasma virus inactivated device YY/T 1510-2017		2022-11-09
93	Inspection and other auxiliary equipment	1	All items	Medical biochemical incubator YY/T 1641-2018		2022-11-09
		2	All items	Medical freezer YY/T 1757-2021		2022-11-09
		3	All items	Automated feces analyzer YY/T 1745-2021		2022-11-09
		4	All items	Sperm quality analyzer YY/T 1795-2021		2022-11-09
94	Mass spectrometry analysis equipment	1	All items	Clinical mass spectrometer-Part 2: Matrix-assisted laser desorption ionization-time of flight mass spectrometer YY/T 1740.2-2021		2022-11-09
		2	All items	High performance liquid chromatography GB/T 26792-2019		2022-11-09
95	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		2022-11-09



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				9706.202-2021		
96	Physiological parameter analysis and measurement equipment	1	All items	Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs GB 9706.226-2021		2022-11-09
		2	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		2022-11-09
		3	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		2022-11-09
		4	Partial items	Clinical infrared thermometers— Part 1 :Ear GB/T 21417.1-2008	except for 4.4.4	2022-11-09
		5	All items	Electrophysiology catheter YY/T 1519-2017		2022-11-09
		6	All items	Multi-channels electrophysiology recording system YY/T 1635-2018		2022-11-09
97	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		2022-11-09
		2	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		2022-11-09
		3	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		2022-11-09
		4	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		2022-11-09

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				9706.245-2020		
		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		2022-11-09
98	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		2022-11-09
		2	All items	Medical electrical equipment--Part 2:Particular requirements for the safety of diagnostic and therapeutic laser equipment GB 9706.222-2022		2022-11-09
99	endoscopic equipment	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		2022-11-09
100	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		2022-11-09
101	electrocardiographs	1	All items	Medical electrical equipment-Part 2-25:Particular requirements for the basic safety and essential performance of electrocardiographs GB 9706.225-2021		2022-11-09
		2	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		2022-11-09
102	electrocardiographic monitoring equipment	1	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		2022-11-09
103	heating devices using blankets, pads or	1	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		2022-11-09



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	mattresses			medical use YY 9706.235-2021		
		2	All items	Medical electrical equipment--Part 2-52: Particular requirements for the basic safety and essential performance of medical beds YY 9706.252-2021		2022-11-09
104	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		2022-11-09
105	ventilators、anaesthetic、Emergency equipment 、auxiliary device	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		2022-11-09
		2	All items	Medical suction equipment Part 1-Electrically powered suction equipment YY/T 0636.1-2021		2022-11-09
		3	All items	Medical suction equipment Part 2-Manually powered powered suction equipment YY/T 0636.2-2021		2022-11-09
		4	All items	Medical suction equipment Part 3-suction equipment powered from a vacuum or positive pressure gas source YY/T 0636.3-2021		2022-11-09
		5	All items	Medical electrical equipment-Part 2-74:Particular requirements for basic safety and essential performance of respiratory humidifying equipment YY 9706.274-2022		2022-11-09
106	ventilators	1	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		2022-11-09
107	radiotherapy treatment planning systems	1	All items	Medical electrical equipment radiotherapy treatment planning systems YY 0637-2013		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
108	Active implant medical device	1	All items	Implants for surgery-Active implantable medical devices-Part 6: Particular requirements for active implantable medical devices intended to treat arrhythmia (including implantable defibrillators) YY 0989.6—2016		2022-11-09
109	Haemodialysis equipment	1	All items	Medical electrical equipment-Part 2-16: Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment GB 9706.216-2021		2022-11-09
		2	All items	Medical electrical equipment-Part 2-39 : Particular requirements for basic safety and essential performance of peritoneal dialysis equipment GB 9706.239-2021		2022-11-09
		3	All items	Haemodialysis equipment 2010- YY 0054-2010		2022-11-09
		4	All items	Continuous blood purification equipment YY 0645-2018		2022-11-09
110	Medical electrical equipment	1	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 controllers YY/T 9706.110-2021		2022-11-09
		2	All items	Medical electrical equipment-Part 2: Particular requirements for the safety of external cardiac pacemakers with internal power source YY 0945.2- 2015		2022-11-09
111	Surgical equipment	1	All items	Cutting tools for electric osseous tissue surgical equipment--Part 4: Milling cutter YY/T 1629.4-2020		2022-11-09
		2	All items	Cutting tools for electric osseous tissue surgical equipment--Part 5: Saw blade YY/T 1629.5-2020		2022-11-09
		3	All items	Cutting tools for electric osseous tissue surgical equipment--Part 6: Rasp YY/T 1629.6-2021		2022-11-09
		4	All items	Disposable abdominal trocars YY/T 1710-2020		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
112	Cardiopulmonary bypass systems	1	All items	Cardiopulmonary bypass systems--Centrifugal pump-head YY/T 1739-2020		2022-11-09
113	Traditional Chinese medicine device	1	All items	Meridian stimulator YY/T 1666-2019		2022-11-09
		2	All items	Electrical resistance detector at acupuncture points equipment YY/T 1661-2019		2022-11-09
114	Cybersecurity for Medical Electrical Equipment	1		Basic Requirements of Cybersecurity for Medical Electrical Equipment YY /T1843-2022 4.1,4.2,4.3		2022-11-09
115	Artificial Intelligence Medical Device		All Parameters	Artificial intelligence medical device—Quality requirements and evaluation—Part 2: General requirements for datasets YY/T 1833.2-2022 4,5		2022-11-09
		1	Recommendation for documentation 、 Recommendation for management responsibility 、 Recommendation for resource management、 Recommendation for data set lifecycle and Recommendation for quality control, privacy, and security .	IEEE Recommended Practice for the Quality Management of Datasets for Medical Artificial Intelligence IEEE 2801-2022 4,5,6,7,8		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
Clean area (room)						
1	laboratory animal - requirements of environment and housing facilities		all parameters	Laboratory animal -Requirements of environment and housing facilities GB 14925-2010		2022-11-09
2	clean room(zone) of the pharmaceutical industry		all parameters	clean room(zone) of the pharmaceutical industry		2022-11-09
3	clean room	1	temperature	Code for design of clean room GB50073-2013 6.1		2022-11-09
		2	relative humidity	Code for design of clean room GB50073-2013 6.1		2022-11-09
		3	static pressure	Code for design of clean room GB50073-2013 6.2		2022-11-09
		4	air flow pattern	Code for design of clean room GB50073-2013 6.3		2022-11-09
		5	airflow velocity	Code for design of clean room GB50073-2013 6.3		2022-11-09
		6	noise	Code for design of clean room GB50073-2013 4.4		2022-11-09
		7	illumination	Code for design of clean room GB50073-2013 9.2		2022-11-09
		8	air volume	Code for design of clean room GB50073-2013 A.3.1		2022-11-09
		9	air cleanliness	Code for design of clean room GB50073-2013 A.3.5		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		10	air supply volume	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.1		2022-11-09
		11	air volume of room or system	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.1		2022-11-09
		12	room exhaust	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.16		2022-11-09
		13	section wind speed	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.1		2022-11-09
		14	sectional wind speed nonuniformity	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.3		2022-11-09
		15	airflow speed of air supply or specific boundary	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.1		2022-11-09
		16	static pressure	Code for construction and acceptance of cleanroom GB50591-2010 16.2 附录,E.2		2022-11-09
		17	cleanliness of 0.6m after opening	Code for construction and acceptance of cleanroom GB50591-2010 16.2 附录,E.2		2022-11-09
		18	portal airflow velocity	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.2		2022-11-09
		19	concentration of ammonia in room	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.14		2022-11-09
		20	cleanliness level	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.4		2022-11-09
		21	temperature	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.5		2022-11-09
		22	relative humidity	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.5		2022-11-09
		23	temperature and humidity toggle	Code for construction and acceptance of cleanroom GB50591-		2022-11-09

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			range	2010 16.2,附录 E.5.2		
		24	regional temperature difference and regional humidity difference	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.5.2		2022-11-09
		25	noise	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.6		2022-11-09
		26	illumination	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.7		2022-11-09
		27	tightness	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 G.2-G.4	only test pressure attenuation method	2022-11-09
		28	air flow pattern	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.12.1		2022-11-09
		29	directional flow	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.12.2		2022-11-09
		30	streamline parallelism	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.12.3		2022-11-09
		31	recovrey time of cleanliness	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.11		2022-11-09
		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	2022-11-09
		33	temperature	Specification for production management of aseptic medical instruments YY 0033-2000 附录 C		2022-11-09
		34	relative humidity	Specification for production management of aseptic medical instruments YY 0033-2000 附录 C		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		35	airflow velocity	Specification for production management of aseptic medical instruments YY 0033-2000 附录 C		2022-11-09
		36	ventilation	Specification for production management of aseptic medical instruments YY 0033-2000 附录 C		2022-11-09
		37	static pressure	Specification for production management of aseptic medical instruments YY 0033-2000 附录 C		2022-11-09
		38	airborne particles	Specification for production management of aseptic medical instruments YY 0033-2000 附录 A、附录 C		2022-11-09
		39	airborne microbe	Specification for production management of aseptic medical instruments YY 0033-2000 附录 A、附录 C		2022-11-09
		40	settling microbe	Specification for production management of aseptic medical instruments YY 0033-2000 附录 A、附录 C		2022-11-09
4	Class II biological safety cabinets	1	appearance	Class II biological safety cabinets YY0569-2011 5.1		2022-11-09
		2	structure	Class II biological safety cabinets YY0569-2011 5.2		2022-11-09
		3	HEPA completeness	Class II biological safety cabinets YY0569-2011 5.4.2		2022-11-09
		4	noise	Class II biological safety cabinets YY0569-2011 5.4.3		2022-11-09
		5	illumination	Class II biological safety cabinets YY0569-2011 5.4.4		2022-11-09
		6	vibration	Class II biological safety cabinets YY0569-2011 5.4.5		2022-11-09
		7	downflow air velocity	Class II biological safety cabinets YY0569-2011 5.4.7		2022-11-09
		8	inflow air velocity	Class II biological safety cabinets YY0569-2011 5.4.8		2022-11-09
		9	air flow pattern	Class II biological safety cabinets YY0569-2011 5.4.9		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		10	temperature rise	Class II biological safety cabinets YY0569-2011 5.4.12		2022-11-09
		11	UV lamp	Class II biological safety cabinets YY0569-2011 5.4.14		2022-11-09
5	clean bench		all parameters	clean bench JG/T 292-2010		2022-11-09
6	biosafety laboratories	1	minimum negative pressure relative to the atmosphere	Architectural and technical code for biosafety laboratories GB 50346-2011 3.3		2022-11-09
		2	minimum negative pressure difference of adjacent room	Architectural and technical code for biosafety laboratories GB 50346-2011 3.3		2022-11-09
		3	cleanliness level	Architectural and technical code for biosafety laboratories GB 50346-2011 3.3		2022-11-09
		4	minimum number of ventilation	Architectural and technical code for biosafety laboratories GB 50346-2011 3.3		2022-11-09
		5	temperature	Architectural and technical code for biosafety laboratories GB 50346-2011 3.3		2022-11-09
		6	relative humidity	Architectural and technical code for biosafety laboratories GB 50346-2011 3.3		2022-11-09
		7	noise	Architectural and technical code for biosafety laboratories GB 50346-2011 3.3		2022-11-09
		8	average illumination	Architectural and technical code for biosafety laboratories GB 50346-2011 3.3		2022-11-09
		9	tightness	Architectural and technical code for biosafety laboratories GB 50346-2011 3.3	only test pressure attenuation method	2022-11-09
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	2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		2	air cleanliness	Architectural and technical code for hospital clean operating department GB50333-2013 3.0.2,3.0.3		2022-11-09
		3	pressure	Architectural and technical code for hospital clean operating department GB50333-2013 4.0.1		2022-11-09
		4	minimum number of ventilation	Architectural and technical code for hospital clean operating department GB50333-2013 4.0.1		2022-11-09
		5	airflow velocity	Architectural and technical code for hospital clean operating department GB50333-2013 4.0.1		2022-11-09
		6	temperature	Architectural and technical code for hospital clean operating department GB50333-2013 4.0.1		2022-11-09
		7	relative humidity	Architectural and technical code for hospital clean operating department GB50333-2013 4.0.1		2022-11-09
		8	minimum fresh air volume	Architectural and technical code for hospital clean operating department GB50333-2013 4.0.1		2022-11-09
		9	noise	Architectural and technical code for hospital clean operating department GB50333-2013 4.0.1		2022-11-09
		10	minimum illumination	Architectural and technical code for hospital clean operating department GB50333-2013 4.0.1		2022-11-09
		11	minimum recovery time of cleanliness	Architectural and technical code for hospital clean operating department GB50333-2013 4.0.1		2022-11-09
		8	industrial cleanroom	1	temperature	ChP General rule 9205 Table 1
2	relative humidity			ChP General rule 9205 Table 1		2022-11-09
3	static pressure			ChP General rule 9205 Table 1		2022-11-09
4	number of ventilation			ChP General rule 9205 Table 1		2022-11-09
5	downflow air velocity			ChP General rule 9205 Table 1		2022-11-09



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		№	Item/ Parameter					
		6	air distribution	ChP General rule 9205 Table 1		2022-11-09		
		7	airborne particles	ChP General rule 9205 Table 1		2022-11-09		
		8	phytoplankton	ChP General rule 9205 Table 1		2022-11-09		
		9	Sedimentation bacteria	ChP General rule 9205 Table 1		2022-11-09		
		10	microorganisms on the surfaces	ChP General rule 9205 Table 1		2022-11-09		
		11	filter integrity	ChP General rule 9205 Table 1		2022-11-09		
		12	airborne particles	GMP Appendix 1 Article 48		2022-11-09		
		13	phytoplankton	GMP Appendix 1 Article 48		2022-11-09		
		14	Sedimentation bacteria	GMP Appendix 1 Article 48		2022-11-09		
		15	microorganisms on the surfaces	GMP Appendix 1 Article 48		2022-11-09		
		16	static pressure	GMP Article 48		2022-11-09		
		9	medical class II biological safety caninets	1	exterior	Guide for the check of medical class II biogological safety cabinets YY/T 1540-2017 5.1		2022-11-09
				2	upstream concentration	Guide for the check of medical class II biogological safety cabinets YY/T 1540-2017 5.2		2022-11-09
				3	Alarm and interlocking system sampeling port	Guide for the check of medical class II biogological safety cabinets YY/T 1540-2017 5.3		2022-11-09
				4	aispeed display	Guide for the check of medical class II biogological safety cabinets YY/T 1540-2017 5.4		2022-11-09

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	filter integrity	Guide for the check of medical class II biological safety cabinets YY/T 1540-2017 5.5		2022-11-09
		6	noise	Guide for the check of medical class II biological safety cabinets YY/T 1540-2017 5.6		2022-11-09
		7	illumination	Guide for the check of medical class II biological safety cabinets YY/T 1540-2017 5.7		2022-11-09
		8	downflow air velocity	Guide for the check of medical class II biological safety cabinets YY/T 1540-2017 5.8		2022-11-09
		9	inflow air velocity	Guide for the check of medical class II biological safety cabinets YY/T 1540-2017 5.9		2022-11-09
		10	air flow pattern	Guide for the check of medical class II biological safety cabinets YY/T 1540-2017 5.10		2022-11-09
		11	ultraviolet lamp	Guide for the check of medical class II biological safety cabinets YY/T 1540-2017 5.11		2022-11-09
Food						
1	Food	1	Acute oral toxicity test	National food safety standard, Acute oral toxicity test GB 15193.3-2014		2022-11-09
		2	Bacterial reverse mutation test	National food safety standard, Bacterial reverse mutation test GB 15193.4-2014		2022-11-09
		3	Mammalian erythrocyte micronucleus test	National food safety standard, Mammalian erythrocyte micronucleus test GB 15193.5-2014		2022-11-09
		4	Mammalian bone marrow cell chromosome aberration test	National food safety standard, Mammalian bone marrow cell chromosome aberration test GB 15193.6-2014		2022-11-09
		5	Mice spermatogonial cells	National food safety standard, Mice spermatogonial cells or spermatocyte chromosome aberration test GB 15193.8-2014		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			or spermatocyte chromosome aberration test			
		6	Rodent dominant lethal test	National food safety standard, Rodent dominant lethal test GB 15193.9-2014		2022-11-09
		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		2022-11-09
		8	Twenty eight days oral toxicity test	National food safety standard, Twenty-eight days oral toxicity test GB15193.22—2014		2022-11-09
		9	Ninety days oral toxicity test	National food safety standard, Ninety days oral toxicity test GB15193.13—2015		2022-11-09
		10	Teratogenicity study	National food safety standard, Teratogenicity study GB15193.14-2015		2022-11-09
		11	Reproductive toxicity test	National food safety standard, Reproductive toxicity test GB 15193.15-2015		2022-11-09
		12	Toxicokinetic test	National food safety standard, Toxicokinetic test GB 15193.16-2014		2022-11-09
		13	Chronic toxicity and carcinogenicity combined study	National food safety standard, Chronic toxicity and carcinogenicity combined study GB15193.17-2015		2022-11-09
		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		2022-11-09
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		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
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		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		2022-11-09
		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		2022-11-09
		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		2022-11-09
		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		2022-11-09
		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		2022-11-09
		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		2022-11-09
		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		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		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		2022-11-09
		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		2022-11-09
		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		2022-11-09
		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		2022-11-09
		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		2022-11-09
		14	Enhance immune function	Technical standards for testing & assessment of health food,Method for the Assessment of Enhancing Immune Function (2003)Page 22		2022-11-09
		15	Assisting memory improvement function	Technical standards for testing & assessment of health food,Method for the assessment of Assisting memory improvement function (2003)Page 58		2022-11-09
		16	Aassisting blood pressure reduction function	Technical standards for testing & assessment of health food,Method for the assessment of Aassisting blood pressure reduction function (2003)Page 78		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		17	Sleep improvement function	Technical standards for testing & assessment of health food,Method for the assessment of Sleep improvement function (2003)Page 81		2022-11-09
		18	Alleviating physical fatigue function	Technical standards for testing & assessment of health food,Method for the assessment of Alleviating physical fatigue function (2003)Page 87		2022-11-09
		19	Enhancing anoxia endurance function	Technical standards for testing & assessment of health food,Method for the assessment of Enhancing anoxia endurance function (2003)Page 94		2022-11-09
		20	Assisting irradiation	Technical standards for testing & assessment of health food,Method for the assessment of Assisting irradiation (2003)Page 97		2022-11-09
		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		2022-11-09
		22	Increasing bone density function	Technical standards for testing & assessment of health food,Method for the assessment of increasing bone density function (2003)Page 111		2022-11-09
		23	Protection against chemical injury of liver function	Technical standards for testing & assessment of health food,Method for the assessment of Protection against chemical injury of liver function (2003)Page 133		2022-11-09
		24	Assessment of Regulating Gastrointestinal Tract Flora Function	Technical standards for testing & assessment of health food,Method for the assessment of Assessment of Regulating Gastrointestinal Tract Flora Function (2003)Page 148		2022-11-09
		25	Facilitate feces excretion function	Technical standards for testing & assessment of health food,Method for the assessment of Facilitate feces excretion function (2003)Page 159		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		26	Antioxidative function	Method for the assessment of Antioxidative function SFDA [2012]107 ,Annex 1		2022-11-09
		27	Assisting the protection of gastric mucosa function	Method for the assessment of Assisting the protection of gastric mucosa function SFDA [2012]107,Annex2		2022-11-09
		28	Assisting blood sugar reduction function	Method for the assessment of Assisting blood sugar reduction function SFDA [2012]107 ,Annex 3		2022-11-09
		29	Improve nutritional anemia function	Method for the assessment of Improve nutritional anemia function SFDA[2012]107, Annex5		2022-11-09
		30	Assisting blood lipids reduction function	Method for the assessment of Assisting blood lipids reduction function SFDA [2012]107 ,Annex 6		2022-11-09
		31	Alleviating lead excretion function	Method for the assessment of Alleviating lead excretion function SFDA [2012]107, Annex 7		2022-11-09
		32	Weight control function	Method for the assessment of Weight control function SFDA [2012]107, Annex8		2022-11-09
		33	Clear the throat function	Method for the assessment of Clear the throat function SFDA [2012]107,Annex9		2022-11-09
		34	Facilitate digestion function	Technical standards for testing & assessment of health food,Method for the assessment of Facilitate digestion function (2003)Page 154		2022-11-09
Cosmetics						
1	Cosmetic	1	Acute Oral Toxicity Test	Safety and Technical Standards for Cosmetics,Acute Oral Toxicity Test (2015) Chapter 6,No.2		2022-11-09
		2	Acute Dermal Toxicity Test	Safety and Technical Standards for Cosmetics, Acute Dermal Toxicity Test (2015) Chapter 6,No.3		2022-11-09
		3	Dermal Irritation/Corrosion	Safety and Technical Standards for Cosmetics,Dermal Irritation/Corrosion Test (2015) Chapter 6,No.4		2022-11-09



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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		2022-11-09
5			Skin Sensitisation Test	Safety and Technical Standards for Cosmetics, Skin Sensitisation Test (2015) Chapter 6, No.6		2022-11-09
6			Skin Phototoxicity Test	Safety and Technical Standards for Cosmetics, Skin Phototoxicity Test (2015) Chapter 6, No.7		2022-11-09
7			Bacterial Reverse Mutation Assay	The announcement for Safety and Technical Standards for Cosmetics (2019, No.12) Annex 9		2022-11-09
8			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		2022-11-09
9			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		2022-11-09
10			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		2022-11-09
11			Mammalian Erythrocyte Micronucleus Test	Safety and Technical Standards for Cosmetics, Mammalian Erythrocyte Micronucleus Test (2015) Chapter 6, No.12		2022-11-09
12			Testicle Cells Chromosome Aberration Test	Safety and Technical Standards for Cosmetics, Testicle Cells Chromosome Aberration Test (2015) Chapter 6, No.13		2022-11-09
13			Subchronic Oral Toxicity Test	Safety and Technical Standards for Cosmetics, Subchronic Oral Toxicity Test (2015) Chapter 6, No.14		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		14	Subchronic Dermal Toxicity Test	Safety and Technical Standards for Cosmetics, Subchronic Dermal Toxicity Test (2015) Chapter 6, No.15		2022-11-09
		15	Combined Chronic Toxicity/Carcinogenicity Test	Safety and Technical Standards for Cosmetics, Combined Chronic Toxicity/Carcinogenicity Test (2015) Chapter 6, No.17		2022-11-09
		16	Skin absorption: in vivo method	skin absorption--in vivo method OECD 427(2004)		2022-11-09
		17	Guidelines for the testing of chemicals: 3T3 NRU phototoxicity test	The announcement for Safety and Technical Standards for Cosmetics (2016, No.147)		2022-11-09
		18	Skin Photoallergy Test	The announcement for Safety and Technical Standards for Cosmetics (2017, No.136) Annex 2		2022-11-09
		19	In Vitro Skin Irritation: Reconstructed Human Epidermis Test Method	In Vitro Skin Irritation: Reconstructed Human Epidermis Test Method OECD TG439 (2021)		2022-11-09
		20	In Vitro Skin Corrosion: Reconstructed Human Epidermis (RhE) Test Method	In Vitro Skin Corrosion: Reconstructed Human Epidermis (RhE) Test Method OECD TG431 (2021)		2022-11-09
		21	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		2022-11-09
		22	In Vitro Mammalian Cells Micronucleus Test	The announcement for Safety and Technical Standards for Cosmetics (2021, No.17) Annex 6		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		23	In Chemico Skin Sensitisation: Direct Peptide Reactivity Assay (DPRA)	The announcement for Safety and Technical Standards for Cosmetics (2019, No.12) Annex 6		2022-11-09
		24	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		2022-11-09
		25	In Vitro Skin Corrosion: Transcutaneous Electrical Resistance Test (TER)	The announcement for Safety and Technical Standards for Cosmetics (2017, No.136) Annex 1		2022-11-09
		26	Fluorescein Leakage Test Method for Identifying Ocular Corrosives and Severe Irritants	Fluorescein Leakage Test Method for Identifying Ocular Corrosives OECD TG460(2017)		2022-11-09
		27	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		2022-11-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		28	Teratogenicity Test	The announcement for Safety and Technical Standards for Cosmetics (2019, No.12) Annex 10		2022-11-09

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