

Name: Sichuan Testing Center for Biomaterials and Medical Devices Co., Ltd.

Address: Sichuan University Biomaterials Building, No.29, Wangjiang Road, Chengdu, Sichuan, China

Registration No. CNAS L3940

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

Effective Date: 2022-03-09 Expiry Date: 2024-04-11

SCHEDULE 3 ACCREDITED TESTING SCOPE

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date				
		№	Item/ Parameter							
Passive medical device										
1. General items / parameters										
1	Medical Devices	1	Tests for in vitro cytotoxicity	Biological evaluation of medical devices-Part 5:Tests for in vitro cytotoxicity GB/T 16886.5-2017		2022-03-09				
				Biological evaluation of medical devices-Part 5:Tests for in vitro cytotoxicity ISO 10993-5: 2009		2022-03-09				
				Biological evaluation test methods for medical organic silicon materials GB/T 16175-2008		2022-03-09				
				Test methods for infusion, transfusion, injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005		2022-03-09				
				Biological evaluation of medical devices used in dentistry Part 2: Test method Cytotoxicity tests: Agar diffusion test and filter diffusion test YY/T 0127.9-2009		2022-03-09				
		2	Skin sensitization test	Biological evaluation of medical devices - Part 10:Tests for irritation and skin sensitization GB/T 16886.10-2017		2022-03-09				

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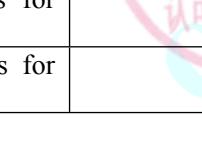
No	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		No	Item/ Parameter			
		3	Irritation test	Biological evaluation of medical devices - Part 10: Biological evaluation of medical devices- Part 10: Tests for skin sensitization ISO 10993-10:2021		2022-03-09
				Test for hypersensitivity of medical devices Part 2:Murine Local Lymph Node Assay (LLNA):BrdU-ELISA method YY/T 0879.2-2015		2022-03-09
				Organic silicon material for medical use- Biological evaluation test methods GB/T 16175-2008		2022-03-09
				Test methods for infusion, transfusion, injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005		2022-03-09
				Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization GB/T 16886.10-2017		2022-03-09
		4	Intracutaneous (intradermal) reactivity test	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization ISO 10993-10:2010		2022-03-09
				Biological evaluation of medical devices- Part 23: Tests for irritation ISO 10993-23:2021		2022-03-09
				Test methods for infusion, transfusion, injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005		2022-03-09
				Biological evaluation test methods for medical organic silicon materials GB/T 16175-2008		2022-03-09
				Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization GB/T 16886.10-2017		2022-03-09

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		№	Item/ Parameter			
		5 Oral irritation test		Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization GB/T 16886.10-2017		2022-03-09
				Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization ISO 10993-10:2010		2022-03-09
				Biological evaluation of medical devices used in dentistry-Part 13:Oral mucous irritation test YY/T 0127.13-2018		2022-03-09
				Biological evaluation of medical devices- Part 23: Tests for irritation ISO 10993-23:2021		2022-03-09
		6 Ocular irritation test		Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization GB/T 16886.10-2017		2022-03-09
				Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization ISO 10993-10:2010		2022-03-09
				Biological evaluation of medical devices- Part 23: Tests for irritation ISO 10993-23:2021		2022-03-09
				Biological evaluation test methods for medical organic silicon materials GB/T 16175-2008		2022-03-09
		7 Vaginal irritation test		Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization GB/T 16886.10-2017		2022-03-09
				Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization ISO 10993-10:2010		2022-03-09
				Biological evaluation of medical devices- Part 23: Tests for irritation ISO 10993-23:2021		2022-03-09
		8 Rectal irritation test		Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization GB/T 16886.10-2017		2022-03-09
				Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization ISO 10993-10:2010		2022-03-09
				Biological evaluation of medical devices- Part 23: Tests for irritation ISO 10993-23:2021		2022-03-09
		9 Penile irritation test		Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization GB/T 16886.10-2017		2022-03-09



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No	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		No	Item/ Parameter			
10	CHINA NATIONAL ACCREDITATION SERVICE FOR CONFORMITY ASSESSMENT SCHEDULED TESTS	Acute systemic toxicity test		Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization ISO 10993-10:2010		2022-03-09
				Biological evaluation of medical devices- Part 23: Tests for irritation ISO 10993-23:2021		2022-03-09
				Biological evaluation of medical devices - Part 11:Tests for systemic toxicity GB/T 16886.11-2021		2022-03-09
				Biological evaluation of medical devices - Part 11:Tests for systemic toxicity ISO 10993-11:2017		2022-03-09
				Biological evaluation test methods for medical organic silicon materials GB/T 16175-2008		2022-03-09
				Test methods for infusion, transfusion, injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005		2022-03-09
				Biological evaluation of medical devices used in dentistry-Part 2:Test method-Acute oral toxicity test YY/T 0127.14-2009		2022-03-09
		Pyrogenicity test		Biological evaluation of medical devices - Part 11: Tests for systemic toxicity GB/T 16886.11-2021		2022-03-09
				Biological evaluation of medical devices - Part 11: Tests for systemic toxicity ISO 10993-11:2017		2022-03-09
				Organic silicon material for medical use- Biological evaluation test methods GB/T 16175-2008		2022-03-09
				Test methods for infusion, transfusion, injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005		2022-03-09
				China pharmacopoeia 2020 version Vol IV General chapters 1142 Pyrogenicity test	合格评定 认可 批准 通过	2022-03-09
12	Bacterial endotoxin test			Test methods for infusion, transfusion, injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005	合格评定 认可 批准 通过	2022-03-09
				China pharmacopoeia 2020 version Vol IV General chapters 1143 Bacterial endotoxin test	认可 批准 通过	2022-03-09
		Sterility test		Test methods for infusion, transfusion, injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005		2022-03-09

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		№	Item/ Parameter			
		14	Tests for subacute systemic toxicity	China pharmacopoeia 2020 version Vol IV General chapters 1101 Sterility test		2022-03-09
				Biological evaluation of medical devices - Part 11:Tests for systemic toxicity GB/T 16886.11-2021		2022-03-09
				Biological evaluation of medical devices - Part 11: Tests for systemic toxicity ISO 10993-11:2017		2022-03-09
				Organic silicon material for medical use- Biological evaluation test methods GB/T 16175-2008		2022-03-09
				Biological evaluation of medical devices used in dentistry Part 15: Test method Subacute and subchronic systemic toxicity test: oral route YY/T 0127.15-2018		2022-03-09
				Test methods for infusion, transfusion, injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005		2022-03-09
		15	Tests for subchronic systemic toxicity	Biological evaluation of medical devices - Part 11:Tests for systemic toxicity GB/T 16886.11-2021		2022-03-09
				Biological evaluation of medical devices - Part 11: Tests for systemic toxicity ISO 10993-11:2017		2022-03-09
				Organic silicon material for medical use- Biological evaluation test methods GB/T 16175-2008		2022-03-09
				Biological evaluation of medical devices used in dentistry-Part 15: Test method- Subacute and subchronic systemic toxicity test: oral route YY/T 0127.15-2018		2022-03-09
		16	Tests for chronic systemic toxicity	Test methods for infusion, transfusion, injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005		2022-03-09
				Biological evaluation of medical devices - Part 11:Tests for systemic toxicity GB/T 16886.11-2021		2022-03-09
		17	Tests for systemic toxicity: inhalation	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity ISO 10993-11:2017		2022-03-09
				Biological evaluation of medical devices - Part 11:Tests for systemic toxicity GB/T 16886.11-2021		2022-03-09

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
18	CHINA NATIONAL ACCREDITATION SERVICE FOR CONFORMITY ASSESSMENT SCHEDULED TESTS	route	route	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity ISO 10993-11:2017		2022-03-09
				Biological evaluation of medical devices used in dentistry Part 5:Inhalation toxicity test YY/T 0127.5-2014		2022-03-09
				Biological evaluation of medical devices - Part 3: Test for genotoxicity, carcinogenicity and reproductive toxicity GB/T 16886.3-2019		2022-03-09
				In vitro mammalian chromosome aberration test OECD 473:2016		2022-03-09
				Biological evaluation of medical devices - Part 3: Test for genotoxicity, carcinogenicity and reproductive toxicity ISO 10993-3:2014		2022-03-09
				Test for genotoxicity of medical devices-Part 2:In vitro mammalian chromosome aberration test YY/T0870.2-2019		2022-03-09
				Test for genotoxicity of medical devices- Part 5:Mammalian bone marrow chromosome aberration test YY/T 0870.5-2014		2022-03-09
				Biological evaluation of medical devices used in dentistry-Part 2: Test method-In Vitro mammalian chromosome aberration test YY/T 0127.16-2009		2022-03-09
		Chromosome aberration test	Micronucleus test	Biological evaluation of medical devices - Part 3: Test for genotoxicity, carcinogenicity and reproductive toxicity GB/T 16886.3-2019		2022-03-09
				Biological evaluation of medical devices - Part 3: Test for genotoxicity, carcinogenicity and reproductive toxicity ISO 10993-3:2014		2022-03-09
				Test for genotoxicity of medical devices- Part 4: Mammalian bone marrow erythrocyte micronucleus test YY/T 0870.4-2014		2022-03-09
		20	TK gene mutation test using mouse lymphoma cells	Biological evaluation of medical devices - Part 3: Test for genotoxicity, carcinogenicity and reproductive toxicity GB/T 16886.3-2019		2022-03-09

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
20	CHINA NATIONAL ACCREDITATION SERVICE FOR MEDICAL DEVICE ASSESSMENT SCHEDULE OF ACCREDITATION CERTIFICATE			Biological evaluation of medical devices - Part 3: Test for genotoxicity, carcinogenicity and reproductive toxicity ISO 10993-3:2014		2022-03-09
				In Vitro Mammalian Cell Gene Mutation Test OECD 490:2016		2022-03-09
				Test for genotoxicity of medical devices Part 3: TK gene mutation test using mouse lymphoma cells YY/T0870.3-2019		2022-03-09
				Biological evaluation of medical devices used in dentistry Part 17: Mouse lymphoma cells (TK) gene mutation test YY/T 0127.17-2014		2022-03-09
		21	Salmonella typhimurium reverse mutation assay	Biological evaluation of medical devices - Part 3: Test for genotoxicity, carcinogenicity and reproductive toxicity GB/T 16886.3-2019		2022-03-09
				Biological evaluation of medical devices - Part 3: Test for genotoxicity, carcinogenicity and reproductive toxicity ISO 10993-3:2014		2022-03-09
				Bacterial Reverse Mutation Test OECD 471:1997		2022-03-09
				Test for genotoxicity of medical devices- Part 1:Bacterial reverse mutation test YY/T0870.1-2013		2022-03-09
		22	In Vitro Mammalian Cell Micronucleus Test	Biological evaluation of medical devices used in dentistry-Part 2:Test method-Salmonella typhimurium reverse mutation assay (Ames mutagenicity test) YY/T 0127.10-2009		2022-03-09
				Biological evaluation of medical devices - Part 3: Test for genotoxicity, carcinogenicity and reproductive toxicity GB/T 16886.3-2019	国合资格认定 认可	2022-03-09
				Biological evaluation of medical devices - Part 3: Test for genotoxicity, carcinogenicity and reproductive toxicity ISO 10993-3:2014	认可 劼腾	2022-03-09
				Test for genotoxicity of medical devices- Part 6: In vitro		2022-03-09

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		№	Item/ Parameter			
				mammalian cell YY/T 0870.6-2019		
		23	carcinogenicity test	Biological evaluation of medical devices - Part 3: Test for genotoxicity,carcinogenicity and reproductive toxicity GB/T 16886.3-2019	Accredited only for Cell Transformation Assays	2022-03-09
				Biological evaluation of medical devices - Part 3: Test for genotoxicity,carcinogenicity and reproductive toxicity ISO 10993-3:2014	Accredited only for Cell Transformation Assays	2022-03-09
		24	Local effects after implantation	Biological evaluation of medical devices - Part 6: Test for local effects after implantation GB/T 16886.6-2015		2022-03-09
				Biological evaluation of medical devices - Part 6: Test for local effects after implantation ISO 10993-6:2016		2022-03-09
				Test methods for infusion, transfusion, injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005		2022-03-09
				Organic silicon material for medical use- Biological evaluation test methods GB/T 16175-2008		2022-03-09
		25	Subcutaneous implant test	Biological evaluation of dental materials-Part 2:Biological evaluation test method of dental materials-Subcutaneous implant test YY/T 0127.8-2001		2022-03-09
		26	Bone implant test	Biological evaluation of dental materials-Part 2:Biological evaluation test method of dental materials-Bone implant test YY/T 0127.4-2009		2022-03-09
		27	In vivo thrombosis test	Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood GB/T 16886.4-2003		2022-03-09
				Biological evaluation of medical devices- Part 4: Selection of tests for interactions with blood ISO 10993-4:2017		2022-03-09

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		№	Item/ Parameter			
28	In vitro thrombosis test			Test methods for infusion, transfusion, injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005		2022-03-09
				Test method for thrombogenicity study -Part 1: Thrombogenicity study in dogs in vascular YY/T 1770.1-2021		2022-03-09
		28	In vitro thrombosis test	Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood GB/T 16886.4-2003		2022-03-09
				Biological evaluation of medical devices- Part 4: Selection of tests for interactions with blood ISO 10993-4:2017		2022-03-09
				Test methods for infusion, transfusion, injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005		2022-03-09
	Haemolysis test			Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood GB/T 16886.4-2003		2022-03-09
				Biological evaluation of medical devices- Part 4: Selection of tests for interactions with blood ISO 10993-4:2017		2022-03-09
		29	Haemolysis test	Test methods for infusion, transfusion, injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005		2022-03-09
				Organic silicon material for medical use- Biological evaluation test methods GB/T 16175-2008		2022-03-09
				Biological evaluation of dental materials-Unit 1: Haemolysis test YY/T 0127.1-1993		2022-03-09
30	Coagulation test			Test for hemolysis of medical devices-Part1:Material induced hemolysis assay YY/T 1651.1-2019		2022-03-09
				Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood GB/T 16886.4-2003	Accredited only for CT,PT,PTT,TT	2022-03-09
				Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood ISO 10993-4:2017		2022-03-09
				Test methods for infusion, transfusion, injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005		2022-03-09



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		№	Item/ Parameter			
CHINA NATIONAL ACCREDITATION CENTER FOR CONFORMITY ASSESSMENT	31	Platelet function test		Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood GB/T 16886.4-2003		2022-03-09
				Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood ISO 10993-4:2017		2022-03-09
				Test methods for infusion, transfusion, injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005		2022-03-09
				Test methods of interaction of medical devices with platelet-Part 1: <i>In vitro</i> platelet count assay YY/T 1649.1-2019		2022-03-09
				Test method for interactions of medical devices with platelet-Part 2: <i>In vitro</i> platelet activation products (β -TG, PF4 and TxB2) assay YY/T 1649.-2019		2022-03-09
	32	Haematology test		Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood GB/T 16886.4-2003		2022-03-09
				Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood ISO 10993-4:2017		2022-03-09
				Test methods for infusion, transfusion, injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005		2022-03-09
	33	Complement system test		Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood GB/T 16886.4-2003		2022-03-09
				Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood ISO 10993-4:2017		2022-03-09
				Test for complement activation of medical devices-Part 1:Serum whole complement activation YY/T0878.1-2013		2022-03-09
				Test for complement activation of medical devices-Part 2:Serum alternative pathway complement activation YY/T 0878.2-2015		2022-03-09
				Test methods for infusion, transfusion, injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005		2022-03-09
				Test for complement activation of medical devices- Part 3: Test for complement activation of medical devices- Part 3: Assay for the product of complement activation (C3a and SC5b-9) YY/T		2022-03-09

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		№	Item/ Parameter			
				0878.3-2019		
		34	Bio-degrade test of polymeric medical devices	Biological evaluation of medical devices-Part 13: Identification and quantification of degradation products from polymeric medical devices GB/T 16886.13-2017	Except for degraded production identification	2022-03-09
		35	Bio-degrade test of ceramics	Biological evaluation of medical devices-Part 13: Identification and quantification of degradation products from polymeric medical devices ISO 10993-13:2010	Except for degraded production identification	2022-03-09
		35	Bio-degrade test of ceramics	Biological evaluation of medical devices- Part 14:Identification and quantification of degradation products from ceramics GB/T 16886.14-2003	Accredited only for the extractable components	2022-03-09
		36	Principles and methods for immunotoxicology testing	Biological evaluation of medical devices- Part 14:Identification and quantification of degradation products from ceramics ISO 10993-14:2001	Accredited only for the extractable components	2022-03-09
		36	Principles and methods for immunotoxicology testing	Biological evaluation of medical devices-Part 20: Principles and methods for immunotoxicology testing of medical devices ISO/TS 10993-20:2006 Biological evaluation of medical devices-Part 20: Principles and methods for immunotoxicology testing of medical devices GB/T 16886.20-2015 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	2022-03-09 2022-03-09 2022-03-09	2022-03-09

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37	Test in vivo degradation			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		2022-03-09
				Tissue engineered medical products-Part 20: Standard practice for evaluation of Immune responses of substrates and scaffold products: Cell Migration tests YY/T 0606.20-2014		2022-03-09
				Immunogenic evaluation method of medical devices —Part 6: Determination of animal spleen lymphocyte subsets by flow cytometry YY/T 1465.6-2019		2022-03-09
				Tissue engineering medical device products-Bioactive ceramics- Method to measure cell migration in porous materials YY/T 1744-2020		2022-03-09
				Immunogenic evaluation method of medical devices- Part 7: Liquid phase multiplex protein quantification technique by flow cytometry YY/T 1465.7-2021		2022-03-09
				Biological evaluation of medical devices-Part 9: Framework for identification and quantification of potential degradation products GB/T16886.9-2017	Accredited only for gravimetric analysis	2022-03-09
				Biological evaluation of medical devices-Part 9: Framework for identification and quantification of potential degradation products ISO 10993-9:2019	Accredited only for gravimetric analysis	2022-03-09
				Biological evaluation of medical devices - Part 6: Test for local effects after implantation GB/T 16886.6-2015		2022-03-09
				Biological evaluation of medical devices - Part 6: Test for local effects after implantation ISO 10993-6:2016		2022-03-09
				Biogical evaluation of medical devices-Part 13:Identification and quantification of degradation products from polymeric medical devices GB/T 16886.13-2017	Accredited only for gravimetric	2022-03-09

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CHINA NATIONAL ACCREDITATION SERVICE FOR CONFORMITY ASSESSMENT SCHEDULE OF ACCREDITATION CERTIFICATE	Biological evaluation of medical devices			analysis		
				Biological evaluation of medical devices-Part 14:Identification and quantificaton of degradation products from ceramics GB/T16886.14-2003	Accredited only for gravimetric analysis	2022-03-09
				Biological evaluation of medical devices-Part 15:Inentificatioin and quantificatioin of degradation products from metals and alloys GB/T16886.15-2003	Accredited only for gravimetric analysis	2022-03-09
		38	Identification and quantification of degradation products from metals and alloys	Biological evaluation of medical devices- Part 16: Toxicokinetic study design for degradation products and leachables GB/T 16886.16-2021		2022-03-09
				Biological evaluation of medical devices- Part 15: Identification and quantification of degradation products from metals and alloys GB/T 16886.15-2003		2022-03-09
		39	Toxicokinetic study design for degradation products and leachables	Biological evaluation of medical devices- Part 15: Identification and quantification of degradation products from metals and alloys ISO 10993-15:2019		2022-03-09
				Biological evaluation of medical devices- Part 16: Toxicokinetic study design for degradation products and leachables GB/T 16886.16-2021		2022-03-09
		40	Endodontic usage test	Biological evaluation of medical devices- Part 16: Toxicokinetic study design for degradation products and leachables ISO 10993-16:2017		2022-03-09
				Biological evaluation of medical devices used in dentistry Part 3: Endodontic usage test YY/T 0127.3-2014		2022-03-09
				Dentistry - evaluation of biocompatibility of medical devices used in dentistry ISO 7405:2018		2022-03-09
		41	Pulp and dentine	Biological evaluation of dental materials-Part 7:Biological		2022-03-09

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			usage test	evaluation test method of dental materials-Pulp and dentine usage test YY/T 0127.7-2017		
				Dentistry - evaluation of biocompatibility of medical devices used in dentistry ISO 7405:2018		2022-03-09
		42	Pulp capping test	Biological evaluation of medical devices used in dentistry Part 11:pulp capping test YY/T0127.11-2014		2022-03-09
				Dentistry - evaluation of biocompatibility of medical devices used in dentistry ISO 7405:2018		2022-03-09
		43	Residues DNA	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		2022-03-09
				Chinese pharmacopoeia 2020 version Vol IV general Chapters 3407 Detection of exogenous DNA residues by second fluorescence staining		2022-03-09
		44	Test for reproductive and developmental toxicity	Test for reproductive and developmental toxicity of medical devices Part 1: Screening test YY/T 1292.1-2015		2022-03-09
				Test for reproductive and developmental toxicity of medical devices Part 2: Prenatal developmental toxicity test YY/T 1292.2-2015		2022-03-09
		45	Nanomaterial: In vitro cytotoxicity test	Biological evaluation of medical devices-Nanomaterial: In vitro cytotoxicity tests (MTT assay and LDH assay) YY/T 0993-2015		2022-03-09
		46	Nanomaterial: Endotoxin test	Biological evaluation of medical devices-Nanomaterial: Endotoxin test YY/T1295-2015		2022-03-09
		47	T Lymphocyte transformation test in vitro	Immunogenic evaluation method of medical devices - Part 1: T Lymphocyte transformation test in vitro YY/T 1465.1-2016		2022-03-09
		48	Serum immunoglobulin and complement	Immunogenic evaluation method of medical devices - Part 2: Serum immunoglobulin and complement component detection Enzyme-linked immunoabsordent assay YY/T 1465.2-2016		2022-03-09

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			component detection			
		49	Plaque forming cells assay Agar gel solid-phase method	Immunogenic evaluation method of medical devices Part 3: Plaque forming cells assay Agar gel solid-phase method YY/T 1465.3-2016		2022-03-09
		50	α -Gal antigen clearance	Immunogenic evaluation method of medical devices - Part 5: Determination of α -Gal antigen clearance in medical devices utilizing animal tissues and their derivatives with M86 antibody YY/T 1465.5-2016		2022-03-09
		51	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		2022-03-09
		52	Nanomaterials: Hemolysis test	Biological evaluation of medical devices-Nanomaterials-Hemolysis test YY/T 1532-2017		2022-03-09
		53	Phagocytosis of mouse peritoneal macrophages on chicken erythrocytes	Immunogenic evaluation method of medical devices —Part 4: Phagocytosis of mouse peritoneal macrophages on chicken erythrocytes—Ex-vivo method YY/T 1465.4-2017		2022-03-09
		54	In vitro mouse embryo assay	Medical devices for human in vitro assisted reproductive technology —In vitro mouse embryo assay YY/T 1434-2016		2022-03-09
				Medical devices for human assisted reproductive technology-A method used for staining blastocysts and cell number count YY/T 1688-2021		2022-03-09
		55	Determination of biocompatibility by ocular study with rabbit eyes	Ophthalmic optics-Contact lenses and contact lenses care products-Determination of biocompatibility by ocular study with rabbit eyes GB/T 28538-2012	认可 用章	2022-03-09
				Ophthalmic optics-Contact lenses and contact lenses care products-Determination of biocompatibility by ocular study with rabbit eyes ISO 9394:2012	认可 用章	2022-03-09

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		56	Microbial limit test	Chinese pharmacopoeia 2020 version Vol IV General chapters 1105 Microbial limit test for non-sterile products: microbial count Chinese pharmacopoeia 2020 version Vol IV General chapters 1106 Microbial limit test for non-sterile products: method of controlled bacteria test		2022-03-09
		57	a population of microorganisms	Hygienic standard for disposable sanitary products GB 15979-2002 Annex B		2022-03-09
		58	Coliform bacteria	Hygienic standard for disposable sanitary products GB 15979-2002 Annex B		2022-03-09
		59	Pseudomonas aeruginosa	Hygienic standard for disposable sanitary products GB 15979-2002 Annex B		2022-03-09
		60	Staphylococcus aureus	Hygienic standard for disposable sanitary products GB 15979-2002 Annex B		2022-03-09
		61	hemolytic streptococcus	Hygienic standard for disposable sanitary products GB 15979-2002 Annex B		2022-03-09
		62	Total number of fungal colonies	Hygienic standard for disposable sanitary products GB 15979-2002 Annex B		2022-03-09
		63	Qualitative of fungi	Hygienic standard for disposable sanitary products GB 15979-2002 Annex B		2022-03-09
		64	Sterilization testing	Hygienic standard for disposable sanitary products GB 15979-2002 Annex C		2022-03-09
		65	Antibacterial performance test	Hygienic standard for disposable sanitary products GB 15979-2002 Annex C		2022-03-09
		66	Antibiotic residue	China pharmacopoeia 2020 version Vol IV General chapters 3408 Antibiotic residue test (culture method)		2022-03-09
		67	E.COLI Host Cell Proteins residue	China pharmacopoeia 2020 version Vol IV General chapters 3412 Measurement of E.COLI Host Cell Proteins		2022-03-09
		68	Yeast Cell Proteins residue	China pharmacopoeia 2020 version Vol IV General chapters 3414 Measurement of yeast Cell Proteins		2022-03-09

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
2	Medical devices	1	melting temperature range	Determination of melting temperature range for precious metals and their alloys-Testing method of thermal analysis GB/T 1425-2021		2022-03-09
		2	solidus-Liquidus temperature range	Self-fluxing alloy powders-Determination of solidus-Liquidus temperature range YS/T 533-2006		2022-03-09
		3	Solidus temperature and liquidus temperature	Chinese pharmacopoeia 2020 version Vol IV general Chapters 0661 Thermal Analysis		2022-03-09
		4	IR	General rules for infrared analysis GB/T6040-2019		2022-03-09
		5	Relative Density	Chinese pharmacopoeia 2020 version Vol IV general Chapters 0601 Determination Method (Pycnometer Method)		2022-03-09
		6	Lidocaine hydrochloride	Chinese pharmacopoeia 2020 version Vol IV general Chapters 0512 High performance liquid chromatography		2022-03-09
		7	Protein content	Chinese pharmacopoeia 2020 version Vol IV general Chapters 0731 protein content determination method (The third method)		2022-03-09
		8	Sulfate	Chinese pharmacopoeia 2020 version Vol IV general Chapters 0802 Sulfate Inspection Method		2022-03-09
		9	Carbonization	Chinese pharmacopoeia 2020 version Vol IV general Chapters 08420842 carbonization inspection method		2022-03-09
		10	Moisture content	Chinese pharmacopoeia 2020 version Vol IV general Chapters 0832 Moisture Determination Method (The second method)	中国合格评定国家认可委员会 认可证书专用章	2022-03-09
		11	Particle size and particle size distribution	Chinese pharmacopoeia 2020 version Vol IV general Chapters 0982 Particle size and particle size distribution measurement method (the first method, the second method manual sieving method)	中国合格评定国家认可委员会 认可证书专用章	2022-03-09
		12	Ash content	Chinese pharmacopoeia 2020 version Vol IV general Chapters		2022-03-09

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				2302 Ash Determination Method		
		13	Residual carbodiimide	Chinese pharmacopoeia 2020 version Vol IV general Chapters 3206 carbodiimide residue determination method		2022-03-09
		14	Free formaldehyde	Chinese pharmacopoeia 2020 version Vol IV general Chapters 3207 Free Formaldehyde Determination Method (The second method)		2022-03-09
		15	Optical rotation	Chinese pharmacopoeia 2020 version Vol IV general Chapters 0621 Optical rotation measurement method		2022-03-09
		16	Fat content	National Food Safety Standard Determination of Fat in Food GB 5009.6-2016	Only use the first method and the second method	2022-03-09
		17	Density	Plastics-Methods for determining the density of non-cellular plastics-Part1: Immersion method, liquid pyknometer method and titration method GB/T1033.1-2008	Only use Immersion method	2022-03-09
		18	corrosion resistance	Medical instruments of stainless steel- Test methods of corrosion resistance YY/T 0149-2006 9		2022-03-09
		19	Radiopacity	Medical polymer products-Test methods of radiopacity YY/T 0586-2016		2022-03-09
		20	Hardness	Fine ceramics (advanced ceramics, advanced technical ceramics) -Test method for hardness of monolithic ceramics at room temperature GB/T 16534-2009	Except for knoop hardness	2022-03-09
		21	Radiopacity	Dentistry-Test method for determining radio-opacity of materials YY/T 1646-2019		2022-03-09
		22	Elastic moduli	Test methods for elastic moduli of fine ceramics (advanced ceramics, advanced technical ceramics) - Bending method GB/T 10700-2006		2022-03-09

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		23	Transition temperature	Implants of Surgery-differential scanning calorimetry of poly ether ether ketone (PEEK) polymers and compounds for use in implantable medical devices YY/T 1707-2020		2022-03-09
		24	Compressive properties	Plastics - Determination of compressive properties GB/T 1041-2008		2022-03-09
		25	Specific optical rotation	Chemical reagent - General method for the determination of specific optical rotatory power (specific optical rotation) GB/T 613-2007		2022-03-09
		26	Density and apparent porosity	Test methods for density and apparent porosity of fine ceramics GB/T 25995-2010		2022-03-09
		27	Apparent porosity and bulk density	Test method for apparent porosity and bulk density of porous ceramic GB/T 1966-1996		2022-03-09
		28	Crystallite size and micro-strain	Determination of crystallite size and micro-strain of nano-materials - X-ray diffraction line broadening method GB/T 23413-2009		2022-03-09
		29	Static immersion test	Dentistry—Corrosion test methods for metallic materials YY/T 0528-2018 4.1		2022-03-09
		30	Sulfide tarnish test (cyclic immersion)	Dentistry—Corrosion test methods for metallic materials YY/T 0528-2018 4.3		2022-03-09
		31	Sulfide tarnish test (static immersion)	Dentistry—Corrosion test methods for metallic materials YY/T 0528-2018 4.4	国家认可 委员会 委员	2022-03-09
		32	Static immersion test with periodic analysis	Dentistry—Corrosion test methods for metallic materials YY/T 0528-2018 4.5	中国 认可 委员会 委员	2022-03-09
3	dental materials		Test method of soluble fluoride of dental materials	Test method of soluble fluoride of dental materials YY 0623-2008	认可 专用章	2022-03-09
4	Dental bleach		Test method of	Dental bleach materials-Test method of peroxide component		2022-03-09

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	materials		peroxide component	YY/T 0632-2008		
5	Test method for primary wound dressing-Part1: Aspects of absorbency		All Parameters	Test method for primary wound dressing-Part1: Aspects of absorbency YY/T 0471.1-2004		2022-03-09
6	Test method for primary wound dressing- Part2:Moisture vapour transmission rate of permeable film dressings		All Parameters	Test method for primary wound dressing-Part2:Moisture vapour transmission rate of permeable film dressings YY/T 0471.2-2004		2022-03-09
7	Test method for primary wound dressing- Part3:Waterproofness		All Parameters	Test method for primary wound dressing-Part3:Waterproofness YY/T 0471.3-2004		2022-03-09
8	primary wound dressing		Test method of part4:Conformability	Test method for primary wound dressing-Part4:Conformability YY/T 0471.4-2004	中国合格评定国家认可委员会	2022-03-09
9	primary wound dressing	1	Bacterial barrier properties(Low moisture condition)	Test method for primary wound dressing-Part5:Bacterial barrier properties YY/T 0471.5-2017 5	认可专用章	2022-03-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		2	Bacterial barrier properties(semi wet condition)(External dry)	Test method for primary wound dressing-Part5:Bacterial barrier properties YY/T 0471.5-2017 6		2022-03-09
		3	Bacterial barrier properties(semi wet condition) (External wet)	Test method for primary wound dressing-Part5:Bacterial barrier properties YY/T 0471.5-2017 7		2022-03-09
		4	Bacterial barrier properties(Wet condition)	Test method for primary wound dressing-Part5:Bacterial barrier properties YY/T 0471.5-2017 8		2022-03-09
10	Medical instruments of stainless steel-Test methods of corrosion resistance		Part Parameters	Medical instruments of stainless steel-Test methods of corrosion resistance YY/T 0149-2006	Except for Pressure Steam Method	2022-03-09
11	Test methods for boning properties of tissue adhesives-Part2: Strength in T-peel by tension loading	1	Test methods for boning properties part1: Strength in lap-shear by tension loading	Test methods for boning properties of tissue adhesives-Part1: Strength in lap-shear by tension loading YY/T 0729.1-2009		2022-03-09
		2	Test methods for boning properties part2: Strength in T-peel by tension loading	Test methods for boning properties of tissue adhesives-Part2: Strength in T-peel by tension loading YY/T 0729.2-2009		2022-03-09
		3	Test methods for boning properties of tissue adhesives-	Test methods for boning properties of tissue adhesives-Part3:Tension strength YY/T 0729.3-2009		2022-03-09

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			Part3:Tension strength			
		4	Test methods for boning properties part4: Wound closure strength	Test methods for boning properties of tissue adhesives-Part4: Wound closure strength YY/T 0729.4-2009		2022-03-09
12	Poly (lactide)	1	Determination of lactide monomer	Determination of lactide monomer residual in poly (lactide) for surgical implants YY/T 1776-2021		2022-03-09
13	3D printing titanium alloy implant	1	metal ion precipitation evaluation method	additive manufacturing medical product-3D printing titanium alloy implant metal ion precipitation evaluation method YY/T 1802-2021		2022-03-09
2. Passive Medical device						
1	Hip joint prostheses		Part of parameters	Hip joint prostheses YY 0118-2016	Except for fatigue property, total artificial hip abrasion, EO residual, X-ray detection, C, H, O, N, S, C ₁	2022-03-09
2	Implant for surgery-forgings and castings for		Part of parameters	Implant for surgery-forgings and castings for bone joint prosthesis-forgings with titanium 6-aluminium 4-vanadium alloy YY0117.1-2005	Except for C, H, O, N, S	2022-03-09



№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	bone joint prosthesis-forgings with titanium 6-aluminium 4-vanadium alloy					
3	Implants for osteosynthesis-Metallic bone plates		Part Parameters	Implants for osteosynthesis-Metallic bone plates YY 0017-2016	Except for C,H,O,N,S , corrosion resistance, fatigue properties	2022-03-09
4	Implant for surgery-forgings and castings for bone joint prosthesis-castings cobalt-chromium-molybdenum alloy		Part of parameters	Implant for surgery-forgings and castings for bone joint prosthesis-castings cobalt-chromium-molybdenum alloy YY0117.3-2005	Except for C,H,O,N,S , internal quality	2022-03-09
5	Implants for Osteosynthesis-Metallic bone screws		Part Parameters	Implants for Osteosynthesis-Metallic bone screws YY 0018-2016	Except for C,H,O,N,S	2022-03-09
6	Implants for ostesynthesis part 2-Metallic intramedullary nailing		Part Parameters	Implants for ostesynthesis part 2-Metallic intramedullary nailing YY/T0019.2-2011	Except for C,H,O,N,S	2022-03-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	nailing					
7	Implant for surgery-forgings and castings for bone joint prosthesis-castings with titanium 6-aluminium 4-vanadium alloy		Part of parameters	Implant for surgery-forgings and castings for bone joint prosthesis-castings with titanium 6-aluminium 4-vanadium alloy YY 0117.2-2005	Except for C,H,O,N,S , internal quality	2022-03-09
8	Implants for surgery-Hydroxyapatite -Part 2:Coating of hydroxyapatite		All Parameters	Implants for surgery-Hydroxyapatite-Part 2:Coating of hydroxyapatite GB23101.2-2008		2022-03-09
9	Ceramics hydroxyapatite		All Parameters	Implants for surgery-Hydroxyapatite-Part 1:Ceramics hydroxyapatite GB23101.1-2008/ISO13779-1:2008		2022-03-09
10	Hydroxyapatite Powder		All Parameters	Hydroxyapatite Powder YY 0303-1998		2022-03-09
11	Standard Specification for Composition of Anorganic Bone for Surgical Implants		All Parameters	Standard Specification for Composition of Anorganic Bone for Surgical Implants ASTM F1581-2008		2022-03-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
12	Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation		All Parameters	Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation ASTM F1088-18/YY/T 0683-2008		2022-03-09
13	silicone elastomer		All Parameters	General specification for surgical implants made of silicone elastomer YY0334-2002		2022-03-09
14	orthopaedics clamp(scissor)		All Parameters	General technique requirements for orthopaedics clamp(scissor) YY/T1122-2017		2022-03-09
15	orthopaedics saw		All Parameters	General technique requirements for orthopaedics saw YY/T1137-2017		2022-03-09
16	Medical forceps		All Parameters	Medical forceps YY/T0686-2017		2022-03-09
17	Standard Specification for Glass and Glass Ceramic Biomaterials for Implantation		All Parameters	Standard Specification for Glass and Glass Ceramic Biomaterials for Implantation ASTM F1538-2003		2022-03-09
18	InFUSEBone Graft/LT-CAGELumbar Tapered Fusion Devices		All Parameters	U.S. Food and Drug Administration (FDA) [Web site]. InFUSEBone Graft/LT-CAGELumbar Tapered Fusion Devices FDA P000058	中国合格评定国家认可委员会 认可专用章	2022-03-09
19	Peritoneal dialysis tube		Part of Parameters	Peritoneal dialysis tube YY 0030-2004	Except for radiation detectability	2022-03-09

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		№	Item/ Parameter			
					y	
20	orthopedic chisel		All Parameters	General technique requirements for orthopedic chisel YY/T 1141-2017		2022-03-09
21	chitosan		All Parameters	Tissue engineered medical products part 7: chitosan YY/T 0606.7-2008		2022-03-09
22	Silicone tubes and elastomeric parts for infusion and transfusion		All Parameters	Silicone tubes and elastomeric parts for infusion and transfusion YY/T 0031-2008		2022-03-09
23	alginate		Part of parameters	Tissue engineered medical products part 8: alginate YY/T 0606.8-2008	Except for NMR, average molecular weight,molecular weight distribution	2022-03-09
24	Wrought titanium and titanium dental implant		All Parameters	Wrought titanium and titanium dental implant YY 0315-2016		2022-03-09
25	sodium hyaluronate		All Parameters	Tissue engineered medical products part 9: sodium hyaluronate YY/T 0606.9—2007		2022-03-09
26	Plasma sprayed hydroxyapatite coated titanium dental implant		All Parameters	Plasma sprayed hydroxyapatite coated titanium dental implant YY0304-2009		2022-03-09



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		№	Item/ Parameter			
27	polymer-based crown and bridge materials		All Parameters	Dentistry-polymer-based crown and bridge materials YY 0710-2009		2022-03-09
28	Artificial teeth for dental prostheses		part of Parameters	Dentistry-Artificial teeth for dental prostheses YY 0300-2009	Except for radioactivity	2022-03-09
29	Denture base polymers		All parameters	Dentistry-Base polymers-Part 1:Denture base polymers YY 0270.1-2011		2022-03-09
30	Orthodontic base polymers		All parameters	Dentistry-Base polymers-Part 2:Orthodontic base polymers YY 0270.2-2011		2022-03-09
31	Elastomeric impression materials		All Parameters	Elastomeric impression materials YY0493-2011		2022-03-09
32	Dental-Ceramic		Part of Parameters	Dental-Ceramic YY 0716-2009	Except for radioactivity	2022-03-09
33	Dental root canal sealing materials		Part of Parameters	Dental root canal sealing materials YY 0717-2009	Except for Microbial hazard	2022-03-09
34	Casting gold alloys		Part of Parameters	Dentistry-Casting gold alloys YY 0620-2008	Except for Melting range, electrochemical properties	2022-03-09
35	Powder/liquid acid-base cements		Part of parameters	Dentistry-Water-based cements-Part 1:Powder/liquid acid-base cements YY0271.1-2016	Except for optical properties	2022-03-09



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		№	Item/ Parameter			
36	Dental prefabricated root post		All Parameters	Dental prefabricated root post YY/T 0517-2009		2022-03-09
37	Orthodontic bracket adhesive materials		All Parameters	Dental-Orthodontic bracket adhesive materials YY/T 0269-2009		2022-03-09
38	Resin-modified cements		All Parameters	Dental water-based cements-Part 2:Resin-modified cements YY0271.2-2016		2022-03-09
39	Polymer-based restorative materials		All Parameters	Dentistry-Polymer-based restorative materials YY 1042-2011		2022-03-09
40	Zinc oxide/eugenol and zinc oxide/non-eugenol cements		All Parameters	Dentistry-Zinc oxide/eugenol and zinc oxide/non-eugenol cements YY 0272-2009		2022-03-09
41	Dental root-canal obturating points		All Parameters	Dental root-canal obturating points YY 0495-2009		2022-03-09
42	Dental gypsum		All Parameters	Dental- gypsum products YY 0462-2003		2022-03-09
43	Casting investments and refractory die materials		All Parameters	Dentistry - Casting investments and refractory die materials YY/T 0463-2011		2022-03-09
44	Titanium and titanium alloy		All parameters	Titanium and titanium alloy dental implant attachments YY/T 0520-2009		2022-03-09

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		№	Item/ Parameter			
	dental implant attachments					
45	Dental pluggers		All Parameters	Dental pluggers YY/T 0275-2011		2022-03-09
46	Dental resin-based pit and fissure sealants		All Parameters	Dental resin-based pit and fissure sealants YY 0622-2008		2022-03-09
47	Root-canal lubricating &cleaning agent with EDTA		All Parameters	Root-canal lubricating &cleaning agent with EDTA YY/T 0516-2009		2022-03-09
48	Medical sodium hyaluronate gel		Part Parameters	Medical sodium hyaluronate gel YY/T 0308-2015	Except for Refractive Index	2022-03-09
49	Phosphoric etching gel		All Parameters	Phosphoric etching gel YY 0769-2009		2022-03-09
50	Dental casting alloys with noble metal content of at least 25% but less than 75%		Part of Parameters	Dental casting alloys with noble metal content of at least 25% but less than 75% YY 0626-2008	Except for Melting range	2022-03-09
51	Dentistry-Orthodontic products-Orthodontic elastomeric auxiliaries		All Parameters	Dentistry-Orthodontic products-Orthodontic elastomeric auxiliaries YY/T 0624-2016	2022-03-09	



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		№	Item/ Parameter			
52	Dentistry-Orthodontic products: Wires		All Parameters	Dentistry-Orthodontic products: Wires YY/T 0625-2016		2022-03-09
53	Cross-linked sodium hyaluronate gel for plastic Surgery		All Parameters	Cross-linked sodium hyaluronate gel for plastic Surgery YY/T 0962-2021		2022-03-09
54	Dentistry-Polymer-based die materials		All Parameters	Dentistry-Polymer-based die materials YY/T0911-2014		2022-03-09
55	Medical devices Symbols to be used with medical device labels, labelling and information to be supplied-Part 1:General requirements		All Parameters	Medical devices Symbols to be used with medical device labels, labelling and information to be supplied-Part 1:General requirements YY/T 0466.1-2016		2022-03-09
56	Dental polymer based adhesives for restoratives		All Parameters	Dental polymer based adhesives for restoratives YY/T 0518-2009	中国合格评定国家认可委员会 认可专用章	2022-03-09
57	Dental temporary polymer-based		All Parameters	Dental temporary polymer-based crown and bridge materials YY/T 0826-2011		2022-03-09



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		№	Item/ Parameter			
	crown and bridge materials					
58	Dentistry-Metallic materials for fixed and removable restorations and appliances		All Parameters	Dentistry-Metallic materials for fixed and removable restorations and appliances GB 17168-2013		2022-03-09
59	Implants for Surgery - Acrylic resin cements		All Parameters	Implants for Surgery -Acrylic resin cements YY 0459-2003		2022-03-09
60	Implants for Surgery Bioglass and glass ceramic biomaterials		All Parameters	Implants for Surgery Bioglass and glass ceramic biomaterials YY/T 0964-2014		2022-03-09
61	Dentistry-Soft lining materials for removable dentures-Part2:Materials for long-term use		All Parameters	Dentistry-Soft lining materials for removable dentures-Part2:Materials for long-term use YY 0714.2-2016	国家认可 委员会 专用章	2022-03-09
62	Medical carboxymethyl chitosan		Part of parameters	Medical carboxymethylchitosan YY/T 0953-2020	Except for weight average molecular	2022-03-09



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		№	Item/ Parameter			
					weight and molecular weight distribution	
63	Dentistry-Soft lining materials for removable dentures-Part1:Materials for short-term use		All Parameters	Dentistry-Soft lining materials for removable dentures-Part1:Materials for short-term use YY 0714.1-2009		2022-03-09
64	Dentistry-Ceramic materials		Part of parameters	Dentistry-Ceramic materials GB 30367-2013	Except for radioactivity	2022-03-09
65	Nonactive surgical implas-Type I collagen implants-Specific requirements		Part of parameters	Nonactive surgical implas-Type I collagen implants-Specific requirements YY 0954-2015	Except for acid hydrolyzate , collagen content(amine acid analyzer method)	2022-03-09
66	Poly(L-lactide) resins and fabricated forms for surgical implants-In vitro degradation testing		All Parameters	Poly(L-lactide) resins and fabricated forms for surgical implants-In vitro degradation testing YY/T 0474-2004	国家认可 委员会 认可证书专用章	2022-03-09

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
67	Dental materials-of colour stability		All Parameters	Dental materials-Determination of colour stability YY/T 0631-2008		2022-03-09
68	Standard specification for polyetherether ketone(PEEK) polymers for surgical implant applications		Part of parameters	Standard specification for polyetheretherketone(PEEK) polymers for surgical implant applications YY/T 0660-2008	Except for notched impact strength	2022-03-09
69	Polylactide resin		Part of parameters	standard specification for semi-crystalline poly (lactide) polymer and copolymer resin for surgical implants YY/T 0661-2017	Except for water residue, H-NMR, C-NMR, Molar Mass (GPC)	2022-03-09
70	Dental materials Testing of adhesion to tooth structure		All Parameters	Dental materials Testing of adhesion to tooth structure YY/T 0519-2009		2022-03-09
71	Dental calcium hydroxide pulp capping and lining materials		All Parameters	Dental calcium hydroxide pulp capping and lining materials YY/T 0824-2011		2022-03-09
72	Dentistry-Denture		Part of parameters	Dentistry-Denture adhesives YY/T 1280-2015	Except for microbiolo	2022-03-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	adhesives				gical items	
73	Dentistry-Brackets and tubes for use in orthodontics	All Parameters		Dentistry-Brackets and tubes for use in orthodontics YY/T 0915-2015		2022-03-09
74	Type I collagen		Part of parameters	YY/T 1453-2016	Exept for peptide map,acid hydrolyzate,fat content,Hydroxyproline content (amino acid analyzer method)	2022-03-09
75	Medical transfusion, infusion and injection apparatus part1: chemical analysis methods		Part Parameters	Test methods for infusion, transfusion, injection equipments for medical use-Part 1: Chemical analysis methods GB/T 14233.1-2008	Except for EO residue	2022-03-09
76	Customised activity denture		All Parameters	Customised activity denture STCBM/FB-005-2017		2022-03-09
77	Corneal cell carrier		All Parameters	Corneal cell carrier membrane STCBM/FB-001-2017		2022-03-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	membrane					
78	Custom fixed denture		All Parameters	Custom fixed denture STCBM/FB-004-2017		2022-03-09
79	skeletal pins and wires		All Parameters	Implant for surgery-Skeletal pins and wires-Part1: Material and mechanical requirements YY/T 0345.1-2020		2022-03-09
80	Soft tissue repair patch		All Parameters	Soft tissue repair patch STCBM/FB-002-2017		2022-03-09
81	Metal-ceramic systems		All Parameters	Dentistry-Compatibility testing-Part1: Metal-ceramic systems YY 0621.1-2016		2022-03-09
82	Collagen sponge		All parameters	Collagen sponge YY/T 1511-2017		2022-03-09
83	Dentistry—Additive manufacturing—Selective laser melting metallic materials for fixed and removable restorations and appliances		All parameters	Dentistry— Additive manufacturing—Selective laser melting metallic materials for fixed and removable restorations and appliances STCBM/FB-007-2019		2022-03-09
84	Dentistry-Casting and Baseplate waxes		All parameters	Dentistry-Casting and Baseplate waxes YY/T 0496-2016	中国合格评定国家认可委员会 认可证书专用章	2022-03-09
85	Custom orthodontic appliances /		All parameters	Custom orthodontic appliances / retainers STCBM/ FB-003-2017		2022-03-09



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	retainers					
86	Zirconia ceramics		All parameters	Zirconia ceramics STCBM/FB-006-2017		2022-03-09
87	Hydrocolloid dressing		All parameters	Contacting wound dressing-Part 4: Hydrocolloid dressing YY/T 1293.4-2016		2022-03-09
88	Polyurethane foam dressing		Part of parameters	Contacting wound dressing-Part 2: Polyurethane foam dressing YY/T 1293.2-2016	Except for EO residue	2022-03-09
89	Hydroxyapatite andbeta-tricalciumphosphatebone substitutes		Part of parameters	Implants for surgery—Calciumphosphates—Part 3 : Hydroxyapatite and beta-tricalcium phosphate bone substitute YY/T 1558.3-2017	Except for Interconnections, CT for Macropores size	2022-03-09
90	medical adhesive bandages		All parameters	medical adhesive bandages-General requirements YY/T 0148-2006		2022-03-09
91	Alginate dressing		All parameters	Contacting wound dressing-Part 5: Alginate dressing YY 1293.5-2017		2022-03-09
92	Hydrocolloid impression materials		Part of parameters	Dentistry-Hydrocolloidimpression materials YY 1027-2018	Except for Tensile bond strength	2022-03-09
93	Sodium hyaluronate		Part of parameters	Tissue engineering medical device products - Sodium hyaluronate YY/T 1571-2017	Except for weight average molecular weight and molecular	2022-03-09

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					weight distribution coefficient	
94	Steel and carbide dental drills	All parameters		dental rotary instruments specification for steel and carbide bur YY 91064-1999		2022-03-09
95	Selective laser melting metallic materials for fixed and removable restorations and appliances	All Parameters		Dentistry Additive manufacturing — Selective laser melting metallic materials for fixed and removable restorations and appliances YY/T 1702-2020		2022-03-09
96	Chitosan	Part of parameters		Tissue engineering medical device products-Chitosan YY/T 1699-2020	Except for Weight average molecular weight and relative molecular mass distribution	2022-03-09
97	Dental drill	Part of parameters		Dentistry-Test methods for rotary instruments YY/T 0874-2013	Except for Dimensions of the shank and the mandrel, Angle of the taper of	2022-03-09

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					the working part	
98	Ceramic-ceramic systems	All Parameters	Dentistry-Compatibility testing-Part2: Ceramic-ceramic systems YY/T 0621.2-2020/ISO 9693-2:2016			2022-03-09
99	Deep-frozen bone grafts and freeze bone grafts	All Parameters	Allogeneic grafts-Part2: Deep-frozen bone grafts and freeze bone grafts YY/T 0513.2-2020			2022-03-09
100	Demineralized bone grafts	All Parameters	Allogeneic grafts-Part3: Demineralized bone grafts YY/T 0513.3-2020			2022-03-09
101	sterile and single-use catheters	All Parameters	Intravascular catheters-Sterile and single-use catheters-Part1: General requirements YY 0285.1-2017			2022-03-09
102	Balloon dilatation catheters	All Parameters	Intravascular catheters-Sterile and single-use catheters-Part4: Balloon dilatation catheters YY 0285.4-2017			2022-03-09
103	Central venous catheters	All Parameters	Intravascular catheters-Sterile and single-use catheters-Part3: central venous catheters YY 0285.3-2017			2022-03-09
104	Fluoride compounds used for dental carious prevention	All Parameters	Fluoride compounds used for dental carious prevention YY/T0823-2020			2022-03-09
105	Mussel adhesive protein dressing	1	All Parameters	Contacting wound dressing Part 6 : Mussel adhesive protein dressing YY/T 1293.6-2020		2022-03-09
		2	Appearance	Contacting wound dressing Part 6 : Mussel adhesive protein dressing YY/T 1293.6-2020 6.1		2022-03-09
		3	Identify	Contacting wound dressing Part 6 : Mussel adhesive protein dressing YY/T 1293.6-2020 6.2		2022-03-09

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No	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		No	Item/ Parameter			
		4	Contents	Contacting wound dressing Part 6 : Mussel adhesive protein dressing YY/T 1293.6-2020 6.3		2022-03-09
		5	Protein content	Contacting wound dressing Part 6 : Mussel adhesive protein dressing YY/T 1293.6-2020 6.4		2022-03-09
		6	Dopa content	Contacting wound dressing Part 6 : Mussel adhesive protein dressing YY/T 1293.6-2020 6.5		2022-03-09
		7	pH value	Contacting wound dressing Part 6 : Mussel adhesive protein dressing YY/T 1293.6-2020 6.6		2022-03-09
		8	Heavy metal content	Contacting wound dressing Part 6 : Mussel adhesive protein dressing YY/T 1293.6-2020 6.7		2022-03-09
		9	Bacterial endotoxin	Contacting wound dressing Part 6 : Mussel adhesive protein dressing YY/T 1293.6-2020 6.8		2022-03-09
106		1	Parts of Parameters	General technical requirements for dental collagen membrane YY/T 1794-2021	Except for Structure, Residual ethylene oxide	2022-03-09
		2	Appearance	General technical requirements for dental collagen membrane YY/T 1794-2021 6.1.1		2022-03-09
		3	Size	General technical requirements for dental collagen membrane YY/T 1794-2021 6.1.2		2022-03-09
		4	Thermal denaturation	General technical requirements for dental collagen membrane YY/T 1794-2021 6.1.4		2022-03-09
		5	Water absorption	General technical requirements for dental collagen membrane YY/T 1794-2021 6.1.5		2022-03-09
		6	Tensile Strength	General technical requirements for dental collagen membrane YY/T 1794-2021 6.1.6		2022-03-09
		7	Elongation at break	General technical requirements for dental collagen membrane YY/T 1794-2021 6.1.7		2022-03-09



№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	Tearing force	General technical requirements for dental collagen membrane YY/T 1794-2021 6.1.8		2022-03-09
		9	pH value	General technical requirements for dental collagen membrane YY/T 1794-2021 6.2.1		2022-03-09
		10	Heavy metal content (calculated as Pb)	General technical requirements for dental collagen membrane YY/T 1794-2021 6.2.2		2022-03-09
		11	Trace elements (Cd, Cr, Cu, Pb, Mo, Fe, Ni, As, Hg)	General technical requirements for dental collagen membrane YY/T 1794-2021 6.2.3		2022-03-09
		12	Total protein content	General technical requirements for dental collagen membrane YY/T 1794-2021 6.2.5.1		2022-03-09
		13	Hydroxyproline content	General technical requirements for dental collagen membrane YY/T 1794-2021 6.2.5.2		2022-03-09
		14	Collagen identification	General technical requirements for dental collagen membrane YY/T 1794-2021 6.2.5.3		2022-03-09
		15	Miscellaneous protein	General technical requirements for dental collagen membrane YY/T 1794-2021 6.2.5.4		2022-03-09
		16	Fat content	General technical requirements for dental collagen membrane YY/T 1794-2021 6.2.5.5		2022-03-09
		17	DNA residue	General technical requirements for dental collagen membrane YY/T 1794-2021 6.2.5.6		2022-03-09
		18	Residual amount of host cells	General technical requirements for dental collagen membrane YY/T 1794-2021 6.2.5.7	见附录 国标 合 格	2022-03-09
		19	Residue on ignition	General technical requirements for dental collagen membrane YY/T 1794-2021 6.2.5.8	见附录 国标 合 格	2022-03-09
		20	Content of additives (chloroform)	General technical requirements for dental collagen membrane YY/T 1794-2021 6.2.5.9	见附录 国标 合 格	2022-03-09
		21	Additive residue (methanol)	General technical requirements for dental collagen membrane YY/T 1794-2021 6.2.6	见附录 国标 合 格	2022-03-09

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		22	Sterile	General technical requirements for dental collagen membrane YY/T 1794-2021 6.3.1		2022-03-09
		23	Bacterial endotoxin	General technical requirements for dental collagen membrane YY/T 1794-2021 6.3.2		2022-03-09
107	Implants for surgery—Ceramic materials based on yttria-stabilized tetragonal zirconia(Y-TZP)	SCHEDULE OF ACCREDITATION CERTIFICATE		Implants for surgery—Ceramic materials based on yttria-stabilized tetragonal zirconia(Y-TZP) YY/T 1715-2020	Only test bulk density, chemical composition, microstructure, Young's modulus, hardness	2022-03-09
		1	Parts of Parameters			
		2	Bulk density	Implants for surgery—Ceramic materials based on yttria-stabilized tetragonal zirconia(Y-TZP) YY/T 1715-2020 4.2		2022-03-09
		3	Chemical composition	Implants for surgery—Ceramic materials based on yttria-stabilized tetragonal zirconia(Y-TZP) YY/T 1715-2020 4.3		2022-03-09
		4	Microstructure	Implants for surgery—Ceramic materials based on yttria-stabilized tetragonal zirconia(Y-TZP) YY/T 1715-2020 4.4		2022-03-09
		5	Young's modulus	Implants for surgery—Ceramic materials based on yttria-stabilized tetragonal zirconia(Y-TZP) YY/T 1715-2020 4.8		2022-03-09
		6	Hardness	Implants for surgery—Ceramic materials based on yttria-stabilized tetragonal zirconia(Y-TZP) YY/T 1715-2020 4.9		2022-03-09
108	MedicalgradeTi-6Al-4V/Ti-6Al-4VELIpowder used for	1	Parts of Parameters	MedicalgradeTi-6Al-4V/Ti-6Al-4VELIpowder used for additive manufacturing YY/T 1701-2020	Except for chemical composition	2022-03-09

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
additivemanufacturing	additivemanufacturing	2	Appearance	MedicalgradeTi-6Al-4V/Ti-6Al-4VELIpowderusedfor additivemanufacturing YY/T 1701-2020 4.2.1		2022-03-09
		3	Size and distribution	MedicalgradeTi-6Al-4V/Ti-6Al-4VELIpowderusedfor additivemanufacturing YY/T 1701-2020 4.2.2.1		2022-03-09
		4	circularity/degreeofsphericity	MedicalgradeTi-6Al-4V/Ti-6Al-4VELIpowderusedfor additivemanufacturing YY/T 1701-2020 4.2.2.2		2022-03-09
		5	Apparent density	MedicalgradeTi-6Al-4V/Ti-6Al-4VELIpowderusedfor additivemanufacturing YY/T 1701-2020 4.2.3		2022-03-09
		6	Tap density	MedicalgradeTi-6Al-4V/Ti-6Al-4VELIpowderusedfor additivemanufacturing YY/T 1701-2020 4.2.4		2022-03-09
		7	Flow time	MedicalgradeTi-6Al-4V/Ti-6Al-4VELIpowderusedfor additivemanufacturing YY/T 1701-2020 4.2.5		2022-03-09



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