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Medical Device Industry Standard Information Sheet

serial number	Standard number	Standard name	Revisions	Alternative standards	Scope of application	Date of implementation
1	YY 0300—2025	Dentistry Prosthetic teeth	recension	YY 0300—2009	This document specifies the classification, requirements and test methods of polymer and ceramic teeth used for dental restoration. This document applies to synthetic resin teeth and ceramic teeth for dental restoration.	July 1, 2028
2	YY 0621—2025	Dentistry Metal-ceramic and ceramic-ceramic system compatibility testing	recension	YY 0621.1—2016、YY/T 0621.2—2020	This document specifies the requirements for evaluating the thermodynamic compatibility between veneer porcelain and metal or ceramic substrate materials used for dental restorations, describes the corresponding test methods. This document applies only to materials used in combination. It is not possible to claim compliance with the requirements for a single material. The requirements for ceramic materials are described in GB 30367. The requirements for metal materials are described in GB 17168.	July 1, 2028

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3	YY 0710—2025	Dentistry Polymer-based crowns and veneer materials	recension	YY 0710—2009	This document specifies the classification and requirements for polymer-based crowns and veneer materials, and describes the test methods used to determine compliance with these requirements. This document applies to polymer-based crowns and veneer materials for formal crowns or veneers made in a lab (dental fabrication room or dental craft room). It is also suitable for polymer-based crowns and veneers that the manufacturer claims do not require the use of macroscopic mechanical retention, such as beads or silk threads, to bond to the base structure.	July 1, 2028
4	YY 0780—2025	Traditional Chinese medicine equipment electroacupuncture treatment instrument	recension	YY 0780—2018	This document specifies the requirements for electroacupuncture and describes the corresponding test methods. This document applies to instruments for the treatment and adjuvant treatment of patients by electroacupuncture.	July 1, 2028

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5	YY 0948—2025	Cardiopulmonary Diversion System Single-use arteriovenous cannulation	recension	YY 0948—2015	This document specifies the requirements for single-use sterile arteriovenous cannulation for drainage or perfusion of blood during the implementation of cardiopulmonary bypass, extracorporeal pulmonary assist, left or right heart bypass, cardiopulmonary support, extracorporeal life support, extracorporeal carbon dioxide removal, and other cardiopulmonary bypass techniques, describing the corresponding test methods. This document is intended for single-use sterile arteriovenous cannulation for use when draining or perfusing blood. This standard is not applicable to: YY 0450.1-2020 introduced devices (e.g., guidewires); ex vivo organ perfusion cannulation; YY 0285.3—2017 The endovascular catheter.	July 1, 2028

serial number	Standard number	Standard name	Revisions	Alternative standards	Scope of application	Date of implementation
6	YY 0989.6—2025	Surgical Implants Active Implantable Medical Devices Part 6: Specific requirements for active implantable medical devices, including implantable defibrillators, for the treatment of tachyarrhythmias	recension	YY 0989.6—2016	This document specifies the requirements for active implantable medical devices, including implantable defibrillators, for the treatment of tachyarrhythmias. This document applies to implantable cardioverter-defibrillators, implantable cardiac resynchronization therapy/defibrillators, active implantable medical devices with tachyarrhythmia function, and certain non-implantable components and accessories of active implantable medical devices. This document does not apply to active implantable medical devices for the treatment of bradyarrhythmias or cardiac resynchronization. GB 16174.2-2024 stipulates such requirements.	July 1, 2028

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7	YY/T 0310—2025	General technical specifications for X-ray computed tomography equipment	recension	YY/T 0310—2015、YY/T 1417—2016	This document specifies the composition and requirements of X-ray computed tomography equipment (hereinafter referred to as CT scanning device) and describes the corresponding test methods. This document applies to CT scanning devices, including CT scanning devices that provide image data for radiotherapy planning.	July 1, 2026
8	YY/T 0528—2025	Dentistry Test Methods for Corrosion of Metallic Materials	recension	YY/T 0528—2018	This document describes the test methods for detecting the corrosion behavior of metal materials used in the oral cavity so that the test methods in this document are referenced by the standards for such metal materials. This document does not apply to devices.	July 1, 2026
9	YY/T 0679—2025	Steam formaldehyde sterilizer	recension	YY/T 0679—2016	This document specifies the type, marking, and requirements of steam formaldehyde sterilizers, and describes the corresponding test methods. This document applies to sterilizers that use a mixture of steam and formaldehyde to sterilize non-heat-resistant medical items.	January 1, 2027

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10	YY/T 0764—2025	Ophthalmic instruments Projection and electronic eye charts for visual acuity measurement	recension	YY/T 0764—2009	This document specifies the requirements, accompanying documents and markings for projection and electronic eye charts for visual acuity measurement, and describes the corresponding test methods. This document applies to projection and electronic eye charts for visual acuity measurement.	July 1, 2026
11	YY/T 1274—2025	Peritoneal dialysis equipment	recension	YY/T 1274—2016、YY/T 1493—2016	This document specifies the requirements for peritoneal dialysis equipment and describes the corresponding test methods. This document applies to peritoneal dialysis equipment (hereinafter referred to as the device). This document does not apply to: single-use consumables (e.g., dialysate, dialysate tubing) during peritoneal dialysis; continuous blood purification equipment; Hemodialysis equipment.	January 1, 2027

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12	YY/T 1488—2025	Traditional Chinese medicine equipment tongue image information collection equipment	recension	YY/T 1488—2016	This document specifies the requirements for tongue image information collection equipment and describes the corresponding test methods. This document applies to tongue image information collection devices.	July 1, 2026
13	YY/T 1567—2025	Female condom Technical requirements and test methods	recension	YY/T 1567—2017	This document specifies the minimum technical requirements for female condoms and describes the corresponding test methods. This document applies to female condoms provided to consumers for contraception and to help prevent sexually transmitted diseases.	July 1, 2026

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14	YY/T 1945—2025	Blood melting equipment	formulate	/	This document specifies the requirements for blood melting equipment (hereinafter referred to as melting equipment) and describes the corresponding test methods. This document is applicable to melting equipment using the principle of constant temperature water thawing. This document does not apply to plasma melting equipment for the preparation of cryoprecipitate and melting equipment using microwave oven method, radio frequency method, dry hot air method.	July 1, 2027

serial number	Standard number	Standard name	Revisions	Alternative standards	Scope of application	Date of implementation
15	YY/T 1958—2025	17α-Hydroxyprogesterone Assay Kit (Labeled Immunoassay)	formulate	/	This document specifies the technical requirements, labeling, labeling, and instructions for use, packaging, transportation, and storage of the 17α-hydroxyprogesterone assay kit (labeled immunoassay), and describes the corresponding test methods. This document is suitable for the in vitro quantitative determination of 17 α-hydroxyprogesterone content in human serum, plasma, and heel blood (filter paper dried blood tablets) by enzyme labeling, (electro)chemiluminescence labeling, (time-resolved) fluorescent labeling, and other methods. This document does not apply to: a) immunochromatographic kits; b) Calibrators and quality controls to be sold separately.	July 1, 2026

serial number	Standard number	Standard name	Revisions	Alternative standards	Scope of application	Date of implementation
16	YY/T 1959—2025	Technical conditions for intraoral digital X-ray imaging systems	formulate	/	This document defines the terms and definitions of intraoral digital X-ray imaging systems (hereinafter referred to as imaging systems), specifies the classification and composition, requirements, and describes the corresponding test methods. This document is intended for imaging systems using digital X-ray detectors with single-exposure imaging. This document does not apply to: intraoral imaging using film or light-excited phosphorescent image plates as X-ray receivers; Extraoral X-ray imaging system.	July 1, 2026

serial number	Standard number	Standard name	Revisions	Alternative standards	Scope of application	Date of implementation
17	YY/T 1960—2025	Information provided by the manufacturer of the medical device	formulate	/	This document sets out the requirements for information provided by manufacturers of medical devices or accessories. This document includes generally applicable requirements for the identification and labeling of the medical device or accessory itself and on its packaging, the marking of the medical device or accessory, and the accompanying information. This document does not prescribe the manner in which the information is provided. The requirements of the medical device product standard or professional standard take precedence over the requirements of this document.	July 1, 2026
18	YY/T 1961—2025	Motor Neuron Survival Gene (SMN) Assay Kit	formulate	/	This document specifies the requirements, labeling, labeling, and instructions for use of the Motor Neuron Survival Gene (SMN) Test Kit, as well as packaging, transportation, storage, and describes the corresponding test methods. This document is applicable to the detection kits established by fluorescence quantitative PCR, PCR-fluorescent probe method, fluorescent PCR-capillary electrophoresis, and fluorescence PCR melting curve method.	July 1, 2026

serial number	Standard number	Standard name	Revisions	Alternative standards	Scope of application	Date of implementation
19	YY/T 1962—2025	Aldosterone Assay Kit (Chemiluminescence Immunoassay)	formulate	/	This document specifies the technical requirements, labeling, labeling, and instructions for use, packaging, transportation, and storage of the aldosterone assay kit (chemiluminescence immunoassay), and describes the corresponding test methods. This document is applicable to kits for the quantitative determination of aldosterone in human serum or plasma using chemiluminescence immunoassay as the principle.	July 1, 2026

serial number	Standard number	Standard name	Revisions	Alternative standards	Scope of application	Date of implementation
20	YY/T 1963—2025	Colorectal Cancer-related Gene Methylation Detection Kit (Fluorescent PCR Method)	formulate	/	This document specifies the requirements, labeling, and instructions for use of colorectal cancer-related gene methylation assays, as well as packaging, transportation, and storage, and describes the corresponding test methods. This document is suitable for qualitative detection of the methylation status of colorectal cancer-related genes such as genes such as Septin9, SDC2, BCAT1, SFRP2, TFPI2, NDRG4, and BMP3 in peripheral blood plasma and stool samples. This document is applicable to the kits of fluorescent PCR, PCR fluorescent probe method, etc., and is not suitable for the kits of high-throughput sequencing methods.	July 1, 2026

serial number	Standard number	Standard name	Revisions	Alternative standards	Scope of application	Date of implementation
21	YY/T 1964—2025	Tacrolimus assay kit	formulate	/	This document specifies the requirements, labeling, labeling, and instructions for use of the tacrolimus assay kit, as well as packaging, transportation, and storage, and describes the corresponding test methods. This document is applicable to kits for the quantitative determination of tacrolimus content in human whole blood by chemiluminescence immunoassay, homogeneous enzyme immunoassay, immunoturbidimetry, liquid chromatography-tandem mass spectrometry.	July 1, 2026
22	YY/T 1965—2025	Dentistry Surgical scalpel handle for the oral cavity	formulate	/	This document specifies the requirements and test methods for reusable oral surgical scalpel handles attached to a removable scalpel blade for oral surgery, such as cutting and/or removing soft tissues of the oral cavity. This document also specifies the marking and labelling requirements for such products. This document applies to reusable surgical scalpel handles in oral surgery.	July 1, 2026

serial number	Standard number	Standard name	Revisions	Alternative standards	Scope of application	Date of implementation
23	YY/T 1966—2025	Dentistry Reverse angle filler	formulate	/	This document specifies the requirements and test methods for the reverse angle filler, which restores teeth through the use of polymer-based restorative materials and cements. This document also specifies the requirements for design, dimensions and marking. This document applies to anti-angle fillers that restore teeth through the use of polymer-based restorative materials and cements.	July 1, 2026
24	YY/T 1967—2025	Flow cytometer	formulate	/	This document specifies the requirements, identification, labeling, and instructions for use, packaging, transportation, and storage of flow cytometers, and describes the corresponding test methods. This document applies to flow cytometers (hereinafter referred to as dot panels) used in medical laboratories. The dot matrix is based on flow cytometry fluorescence technology for the qualitative and/or quantitative detection of various analytes such as nucleic acids, proteins, peptides, and small molecules in human samples.	July 1, 2026

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25	YY/T 1968—2025	Preimplantation chromosomal aneuploidy analysis software	formulate	/	This document specifies the requirements for preimplantation chromosomal aneuploidy analysis software and describes the corresponding test methods. This document is suitable for the analysis of preimplantation low-depth high-throughput gene sequencing data generated by the sequencing of suitable detection kits and gene sequencers, so as to determine whether there are chromosomal aneuploidy, large deletions and duplication abnormalities in embryos.	July 1, 2026
26	YY/T 1969—2025	Microalbumin Assay Kit (Immunoturbidimetry)	formulate	/	This document specifies the requirements, labeling, labeling, and instructions for use, packaging, transportation, and storage of microalbumin assay kits (immunoturbidimetry) and describes the corresponding test methods. This document is intended for use as a kit for the quantitative detection of albumin in human urine samples by immunoturbidimetry.	July 1, 2026

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27	YY/T 1970—2025	Lipoprotein-associated phospholipase A2 assay kit (chemiluminescent immunoassay)	formulate	/	This document specifies the requirements, labeling, labeling, and instructions for use, packaging, transportation, and storage of the lipoprotein-associated phospholipase A2 assay kit (chemiluminescence immunoassay), and describes the corresponding test methods. This document is applicable to kits for the quantitative determination of human serum and plasma lipoprotein-associated phospholipase A2 based on the principle of chemiluminescence immunoassay, including chemiluminescence assay kits with microplates, tubes, magnetic particles, microbeads, and plastic beads as carriers.	July 1, 2026

serial number	Standard number	Standard name	Revisions	Alternative standards	Scope of application	Date of implementation
28	YY/T 1971.1—2025	Dentistry Portable dental equipment for use in non-permanent medical settings Part 1: General requirements	formulate	/	This document specifies the general requirements for portable dental equipment used in non-permanent medical settings and describes the corresponding test methods. This document applies to the design and manufacture of portable dental devices for use in non-permanent medical settings, including portable dental machines, portable dental patient chairs, portable physician chairs, portable dental lights, portable suction source devices, portable air compressors, and other portable dental equipment. This document does not apply to non-mobile dental equipment that is not intended to be used in a non-permanent medical setting or that is not designed to be disassembled, folded, or packaged for transportation between non-permanent medical settings, wearable dental devices (such as headlights and magnifying glasses), mobile dental equipment, or portable dental equipment. In addition, this document does not consider the requirements for non-mobile dental equipment that can be installed in dental mobile health facilities, such as vehicle-mounted or containerized mobile dental practices.	January 1, 2027

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29	YY/T 1972—2025	Dentistry Soft tissue circumcisor	formulate	/	This document specifies the performance requirements, marking, and labeling information for soft tissue circumcisors used with dental handpieces, and describes the corresponding test methods. This document is intended for use with a soft tissue circumcision knife for making a hole or circumcision in the gingival tissue and removing the gingival tissue in oral implant surgery.	July 1, 2026
30	YY/T 1973—2025	Medical lower limb exoskeleton robot	formulate	/	This document specifies the requirements for medical lower limb exoskeleton robots and describes the corresponding test methods. This document applies to medical lower limb exoskeleton robots.	July 1, 2026

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31	YY/T 1974—2025	Dentistry Multi-function spray gun	formulate	/	This document specifies the classification, requirements, sampling, instructions for use, technical description, marking, labeling, and packaging of multi-function spray guns intended for use in the patient's mouth, describing the corresponding test methods. This document is for multi-purpose spray guns used in the patient's mouth. This document does not apply to dental handpieces and motors, oral digital viewers, dental light-curing machines, active scalers, sandblasting handpieces, polishing handpieces, suction cannulas, and saliva-suction devices.	July 1, 2027

serial number	Standard number	Standard name	Revisions	Alternative standards	Scope of application	Date of implementation
32	YY/T 1975—2025	Far infrared magnetic therapy patch (bag)	formulate	/	This document specifies the classification and requirements of far-infrared magnetic therapy patches (bags) and describes the corresponding test methods. This document applies to adhesive products containing far-infrared materials and magnetic materials. This document is not applicable to: patch products containing chemical ingredients, Chinese herbal medicines (or natural plants) and their extracts, etc., and the ingredients contained in them exert pharmacological, immunological or metabolic effects; Patch products that contain chemical ingredients, Chinese herbal medicines (or natural plants) and their extracts, etc., and cannot be proven to have no pharmacological, immunological or metabolic effects.	July 1, 2026
33	YY/T 1976—2025	Traditional Chinese medicine equipment glass cupping device	formulate	/	This document specifies the specifications, requirements and corresponding test methods of glass cupping devices. This document is for glass cuppers. This document does not apply to manual or electric negative pressure cupping devices.	July 1, 2026

serial number	Standard number	Standard name	Revisions	Alternative standards	Scope of application	Date of implementation
34	YY/T 1978—2025	Dentistry Ring drill	formulate	/	This document specifies the requirements for dental trephines used in implant dental procedures such as bone tissue removal or implant removal, gives classifications, describes the corresponding test methods, and specifies requirements for marking, labelling and instruction instructions. This document applies to dental trephines for implant surgery.	July 1, 2026
35	YY/T 1979—2025	Traditional Chinese medicine equipment Gua sha equipment	formulate	/	This document specifies the requirements for gua sha appliances and describes the corresponding test methods. This document is for gua sha appliances. This document does not apply to electronic gua sha appliances.	July 1, 2026

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36	YY/T 1980—2025	Single-use sterile incision protector	formulate	/	This document specifies the classification and marking, materials, requirements, labeling and instructions, packaging, transportation and storage of disposable sterile incision protective sleeves (hereinafter referred to as inward protective sleeves), and describes the corresponding test methods. This document is applicable to the incision protector that fixes, stretches, dilates and isolates contamination of the endoscopic incision or surgical incision during endoscopic surgery or open surgery. This document does not apply to single-use endoscope covers.	July 1, 2026
37	YY/T 1981—2025	Radiation Therapy Planning Software Electron Beam Dose Calculation Accuracy Requirements and Test Methods	formulate	/	This document specifies the requirements for the accuracy of the Radiation Therapy Planning Software (RTPS) electron beam dose calculation and describes the corresponding test methods. This document is applicable to radiotherapy planning software with remote beam dose calculation function for use with medical electron accelerators. This document does not apply to special applications of electron beam radiation therapy planning software.	January 1, 2027

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38	YY/T 1982—2025	Surgical implants Porous structure topography characteristics test method	formulate	/	This document describes the test method for the topography of the porous structure of surgical implants, including porosity, pore size, filament diameter, internal connectivity, pore gradient, porous thickness, and internal structural defects. This document applies to porous structures in surgical implants. The materials to which this document applies may include: metals, such as titanium, tantalum, magnesium, etc., and their alloys; ceramics, such as hydroxyapatite, β-tricalcium phosphate, etc.; Polymer materials (degradable, non-degradable), such as polyethylene, polyetheretherketone, polylactic acid or polycaprolactone, etc.; Composites. Its manufacturing technologies may include but are not limited to: additive manufacturing, adding foaming agent method, template method, gas porosity method, vapor deposition method, etc. This document does not apply to all kinds of porous coatings attached to non-porous substrates as specified in YY/T 0988.14, such as plasma spraying pure titanium coatings, plasma spraying hydroxyapatite coatings, sintered coatings formed by thermal polymerization of individual solids (powder particles, wires, nets, beads, etc.).	July 1, 2026