MDS – G020

دليل المواصفات القياسية المعترف بها للأجهزة والمستلزمات الطبية
(لدعم طلبات الإذن بتسويق الأجهزة والمستلزمات الطبية) (MDS – G020)

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مقدمة

تهدف قائمة المواصفات القياسية المعترف بها مساعدة مقدمي طلبات الإذن بتسويق الأجهزة و المستلزمات الطبية على إستيفاء المتطلبات اللازمة للحصول على أذن بتسويق الأجهزة والمستلزمات الطبية وذلك عن طريق إثبات إمتثال الجهاز أو المستلزم الطبي للمبادئ الأساسية للسلامة والأداء وذلك خلال دورة حياة الجهاز الطبي كاملة. وقد تم تصنيف قوائم المواصفات بناء على مجال عمل الأجهزة و المستلزمات الطبية وحصر المواصفات العامة والتي تنطبق على اغلب الأجهزة والمتسلزمات الطبية في مجال واحد.

تنويه هام: يجب على مقدمي الطلبات التأكد من مراجعة آخر إصدار للمواصفات القياسية عبر جهاز التقييس المصدر لها.

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16.	ISO 5092 Additive manufacturing for medical — General principles — Additive manufacturing of non-active implants
17.	ISO/ASTM TR 52916 Additive manufacturing for medical — Data — Optimized medical image data

Anesthetic, Respiratory, and Ventilators	
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21.	ISO 23328-1 Breathing system filters for anaesthetic and respiratory use - Part 1: Salt test method to assess filtration performance
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23.	ISO 26782 Anaesthetic and respiratory equipment - Spirometers intended for the measurement of time forced expired volumes in humans
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31.	IEC 60601-1-8 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
32.	IEC 60601-1-9 Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design
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35.	IEC 60601-1-12 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 environment
36.	ISO 10651-4 Lung ventilators — Part 4: Particular requirements for user-powered resuscitators
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44.	ISO 5367 Anaesthetic and respiratory equipment — Breathing sets and connectors
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46.	ISO 7376 Anaesthetic and respiratory equipment — Laryngoscopes for tracheal intubation
47.	ISO 8836 Suction catheters for use in the respiratory tract
48.	ISO 11712 Anaesthetic and respiratory equipment — Supralaryngeal airways and connectors
49.	ISO 14408 Tracheal tubes designed for laser surgery — Requirements for marking and accompanying information

50.	ISO 16628 Anaesthetic and respiratory equipment — Tracheobronchial tubes
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52.	ISO 23368 Anaesthetic and respiratory equipment — Low-flow nasal cannulae for oxygen therapy
53.	ISO 23371 Anaesthetic and respiratory equipment — Cuff pressure indication, control and regulation devices
54.	ISO 23372 Anaesthetic and respiratory equipment — Air entrainment devices
55.	ISO 8835-7 Inhalational anaesthesia systems — Part 7: Anaesthetic systems for use in areas with limited logistical supplies of electricity and anaesthetic gases
56.	ISO 11195 Gas mixers for medical use — Stand-alone gas mixers
57.	ISO 18835 Inhalational anaesthesia systems — Draw-over anaesthetic systems
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60.	ISO 80601-2-67

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62.	ISO 7396-1 Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum
63.	ISO 16571 Systems for evacuation of plume generated by medical devices
64.	ISO 18777-1 Transportable liquid oxygen systems for medical use — Part 1: Common requirements and particular requirements for base units
65.	ISO 18777-2 Transportable liquid oxygen systems for medical use — Part 2: Particular requirements for portable units
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67.	ISO 80369-1 Small-bore connectors for liquids and gases in healthcare applicationsPart 1: General requirements
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70.	ISO 80601-2-12 Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
71.	ISO 80601-2-70 Medical electrical equipment — Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment
72.	ISO 80601-2-72 Medical electrical equipment — Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients
73.	ISO 80601-2-74 Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment
74.	IEC 80601-2-77 Medical electrical equipment — Part 2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment
75.	IEC 80601-2-78 Medical electrical equipment — Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation
76.	ISO 80601-2-79 Medical electrical equipment — Part 2-79: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment
77.	ISO 80601-2-80 Medical electrical equipment — Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency
78.	ISO 80601-2-84 Medical electrical equipment — Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment

79.	ISO 18190 Anaesthetic and respiratory equipment — General requirements for airways and related equipment
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90.	ISO 10993-14 Identification and quantification of degradation products from ceramics
91.	ISO 10993-15 Identification and quantification of degradation products from metals and alloys
92.	ISO 10993-17 Toxicological risk assessment of medical device constituents
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94.	ISO 10993-20 Principles and methods for immunotoxicology testing of medical devices
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96.	ISO 18562-1 Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process
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4.	ISO 24166-1 Snap-on bottles for metering pumps — Part 1: Tubular glass
5.	ISO 24072 Aerosol bacterial retention test method for air-inlet filter on administration devices
6.	ISO/TS 23128 Medical devices — Transfusion set and blood bag compatibility test method
7.	ISO 22413 Transfer sets for pharmaceutical preparations — Requirements and test methods
8.	ISO 21882 Sterile packaged ready for filling glass vials
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10.	ISO 15759 Medical infusion equipment — Plastics caps with inserted elastomeric liner for containers manufactured by the blow-fill-seal (BFS) process
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12.	ISO 15378 Primary packaging materials for medicinal products — Particular requirements for the application of ISO 9001, with reference to good manufacturing practice (GMP)
13.	ISO 15375 Medical infusion bottles — Suspension devices for multiple use — Requirements and test methods
14.	ISO 15137 Self-adhesive hanging devices for infusion bottles and injection vials — Requirements and test methods
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16.	ISO 13926-3 Pen systems — Part 3: Seals for pen-injectors for medical use
17.	ISO 13926-2 Pen systems — Part 2: Plunger stoppers for pen-injectors for medical use
18.	ISO 13926-1 Pen systems — Part 1: Glass cylinders for pen-injectors for medical use
19.	ISO 11418-7 Containers and accessories for pharmaceutical preparations — Part 7: Screw-neck vials made of glass tubing for liquid dosage forms
20.	ISO 11418-5 Containers and accessories for pharmaceutical preparations — Part 5: Dropper assemblies
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22.	ISO 11418-3 Containers and accessories for pharmaceutical preparations — Part 3: Screw-neck glass bottles (veral) for solid and liquid dosage forms
23.	ISO 11418-2 Containers and accessories for pharmaceutical preparations — Part 2: Screw-neck glass bottles for syrups
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32.	ISO 11040-1 Prefilled syringes — Part 1: Glass cylinders for dental local anaesthetic cartridges
33.	ISO 9187-2 Injection equipment for medical use — Part 2: One-point-cut (OPC) ampoules
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35.	ISO 8872 Aluminium caps and aluminium/plastic caps for infusion bottles and injection vials — General requirements and test methods
36.	ISO 8871-5 Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 5: Functional requirements and testing
37.	ISO 8871-4 Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 4: Biological requirements and test methods
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63.	ISO 6710 Single-use containers for human venous blood specimen collection
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74.	ISO 720 Glass — Hydrolytic resistance of glass grains at 121 °C — Method of test and classification
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3.	ISO/TS 21726 Biological evaluation of medical devices — Application of the threshold of toxicological concern (TTC) for assessing biocompatibility of medical device constituents
4.	ISO/TS 37137-1 Biological evaluation of absorbable medical devices — Part 1: General requirements

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2.	ISO 9713 Neurosurgical implants — Self-closing intracranial aneurysm clips
3.	ISO 13179-1 Implants for surgery — Coatings on metallic surgical implants — Part 1: Plasma-sprayed coatings derived from titanium or titanium-6 aluminum-4 vanadium alloy powders
4.	ISO 14607 Non-active surgical implants — Mammary implants — Particular requirements
5.	ISO 14630 Non-active surgical implants — General requirements
6.	ISO 16054 Implants for surgery — Minimum data sets for surgical implants
7.	ISO 16061 Instruments for use in association with non-active surgical implants — General requirements
8.	ISO 17327-1 Non-active surgical implants — Implant coating — Part 1: General requirements
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10.	ISO 19227 Implants for surgery — Cleanliness of orthopedic implants — General requirements
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21.	ISO 5840-2 Cardiovascular implants — Cardiac valve prostheses — Part 2: Surgically implanted heart valve substitutes
22.	ISO 5840-3 Cardiovascular implants — Cardiac valve prostheses — Part 3: Heart valve substitutes implanted by transcatheter techniques
23.	ISO 7198 Cardiovascular implants and extracorporeal systems — Vascular prostheses — Tubular vascular grafts and vascular patches
24.	ISO 7199 Cardiovascular implants and artificial organs — Blood-gas exchangers (oxygenators)
25.	ISO 8637-1 Extracorporeal systems for blood purification — Part 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators
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29.	ISO 15675 Cardiovascular implants and artificial organs — Cardiopulmonary bypass systems — Arterial blood line filters

30.	ISO 15676 Cardiovascular implants and artificial organs — Requirements for single-use tubing packs for cardiopulmonary bypass and extracorporeal membrane oxygenation (ECMO)
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54.	ISO 5832-9 Implants for surgery — Metallic materials — Part 9: Wrought high nitrogen stainless steel
55.	ISO 5832-11 Implants for surgery — Metallic materials — Part 11: Wrought titanium 6-aluminium 7-niobium alloy
56.	ISO 5832-12 Implants for surgery — Metallic materials — Part 12: Wrought cobalt-chromium-molybdenum alloy
57.	ISO 5832-14 Implants for surgery — Metallic materials — Part 14: Wrought titanium 15-molybdenum 5-zirconium 3-aluminium alloy
58.	ISO 5833 Implants for surgery — Acrylic resin cements

59.	ISO 6474-1 Implants for surgery — Ceramic materials — Part 1: Ceramic materials based on high purity alumina
60.	ISO 6474-2 Implants for surgery — Ceramic materials — Part 2: Composite materials based on a high-purity alumina matrix with zirconia reinforcement
61.	ISO 13779-4 Implants for surgery — Hydroxyapatite — Part 4: Determination of coating adhesion strength
62.	ISO 13782 Implants for surgery — Metallic materials — Unalloyed tantalum for surgical implant applications
63.	ISO 16402 Implants for surgery — Acrylic resin cement — Flexural fatigue testing of acrylic resin cements used in orthopaedics
64.	ISO/TS 21560 General requirements of tissue-engineered medical products

Prosthetics and Orthotics	
1.	ISO 10328 Prosthetics - Structural testing of lower-limb prostheses - Requirements and test methods
2.	ISO 22523 External limb prostheses and external orthoses - Requirements and test methods
3.	ISO 22675 Prosthetics - Testing of ankle-foot devices and foot units - Requirements and test methods
4.	ISO/TS 4549 Orthotics -Method for testing the reliability of microprocessor-controlled ankle moment units of ankle-foot orthoses
5.	ISO 8548-1 Prosthetics and orthotics — Limb deficiencies — Part 1: Method of describing limb deficiencies present at birth
6.	ISO 8548-2 Prosthetics and orthotics — Limb deficiencies — Part 2: Method of describing lower limb amputation stumps
7.	ISO 8548-3 Prosthetics and orthotics — Limb deficiencies — Part 3: Method of describing upper limb amputation stumps
8.	ISO 8548-4 Prosthetics and orthotics — Limb deficiencies — Part 4: Description of causal conditions leading to amputation
9.	ISO 8548-5 Prosthetics and orthotics — Limb deficiencies — Part 5: Description of the clinical condition of the person who has had an amputation

10.	ISO 8551 Prosthetics and orthotics — Functional deficiencies — Description of the person to be treated with an orthosis, clinical objectives of treatment, and functional requirements of the orthosis
11.	ISO 13404 Prosthetics and orthotics — Categorization and description of external orthoses and orthotic components
12.	ISO 13405-1 Prosthetics and orthotics — Classification and description of prosthetic components — Part 1: Classification of prosthetic components
13.	ISO 13405-2 Prosthetics and orthotics — Classification and description of prosthetic components — Part 2: Description of lower limb prosthetic components
14.	ISO 13405-3 Prosthetics and orthotics — Classification and description of prosthetic components — Part 3: Description of upper limb prosthetic components
15.	ISO 15032 Prostheses — Structural testing of hip units
16.	ISO/TS 16955 Prosthetics — Quantification of physical parameters of ankle foot devices and foot units
17.	ISO 21063 Prosthetics and orthotics — Soft orthoses — Uses, functions, classification and description
18.	ISO 21064 Prosthetics and orthotics — Foot orthotics — Uses, functions classification and description
19.	ISO 21065

	Prosthetics and orthotics — Terms relating to the treatment and rehabilitation of persons having a lower limb amputation
20.	ISO 24562 Prosthetics — Geometrical aspects of lower limb prosthetic adapters
21.	ISO 29781 Prostheses and orthoses — Factors to be included when describing physical activity of a person who has had a lower limb amputation(s) or who has a deficiency of a lower limb segment(s) present at birth
22.	ISO 29782 Prostheses and orthoses — Factors to be considered when specifying a prosthesis for a person who has had a lower limb amputation

Surgical Instruments	
1.	ISO 7151 Surgical instruments — Non-cutting, articulated instruments — General requirements and test methods
2.	ISO 7153-1 Surgical instruments — Materials — Part 1: Metals
3.	ISO 7740 Instruments for surgery — Scalpels with detachable blades — Fitting dimensions
4.	ISO 7741 Instruments for surgery — Scissors and shears — General requirements and test methods
5.	ISO 13402 Surgical and dental hand instruments — Determination of resistance against autoclaving, corrosion and thermal exposure

Sterilization and Disinfectants	
1.	ISO 11140-1 Sterilization of health care products - Chemical indicators - Part 1: General requirements
2.	ISO 11140-3 Sterilization of health care products - Chemical indicators - Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test
3.	ISO 13408-2 Aseptic processing of health care products - Part 2: Filtration
4.	ISO 13408-3 Aseptic processing of health care products - Part 3: Lyophilization
5.	ISO 13408-4 Aseptic processing of health care products - Part 4: Clean-in-place technologies
6.	ISO 13408-5 Aseptic processing of health care products - Part 5: Sterilization in place
7.	ISO 13408-7 Aseptic processing of health care products - Part 7: Alternative processes for medical devices and combination products
8.	ISO 14937 Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
9.	ISO 15882 Sterilization of health care products — Chemical indicators — Guidance for selection, use and interpretation of results
10.	ISO 15883-1 Washer-disinfectors - Part 1: General requirements, terms and definitions and tests

11.	ISO 15883-2 Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.
12.	ISO 15883-3 Washer-disinfectors - Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers (ISO 15883-3:2006)
13.	ISO 15883-4 Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes
14.	ISO 15883-5 Washer-disinfectors — Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy
15.	ISO 15883-6 Washer-disinfectors — Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment
16.	ISO 15883-7 Washer-disinfectors — Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment
17.	ISO/TS 16775 Packaging for terminally sterilized medical devices — Guidance on the application of ISO 11607-1 and ISO 11607-2
18.	ISO 17664-1 Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices
19.	ISO 17664-2 Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices

20.	ISO 11137-2 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
21.	ISO 11137-3 Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects of development, validation and routine control
22.	ISO/TS 11137-4 Sterilization of health care products — Radiation — Part 4: Guidance on process control
23.	ISO 11138-8 Sterilization of health care products — Biological indicators — Part 8: Method for validation of a reduced incubation time for a biological indicator
24.	ISO 11140-4 Sterilization of health care products — Chemical indicators — Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam
25.	ISO 11140-5 Sterilization of health care products — Chemical indicators — Part 5: Class 2 indicators for Bowie and Dick-type air removal tests
26.	ISO 11140-6 Sterilization of health care products — Chemical indicators — Part 6: Type 2 indicators and process challenge devices for use in performance testing of small steam sterilizers
27.	ISO 11607-1 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
28.	ISO 11607-2 Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes
29.	ISO 11737-1

	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
30.	ISO 11737-2 Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
31.	ISO 11737-3 Sterilization of health care products — Microbiological methods — Part 3: Bacterial endotoxin testing
32.	ISO 13004 Sterilization of health care products — Radiation — Substantiation of selected sterilization dose: Method VDmaxSD
33.	ISO 13408-6 Aseptic processing of health care products — Part 6: Isolator systems
34.	ISO 14160 Sterilization of health care products — Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives — Requirements for characterization, development, validation and routine control of a sterilization process for medical devices
35.	ISO 18362 Manufacture of cell-based health care products — Control of microbial risks during processing
36.	ISO 18472 Sterilization of health care products — Biological and chemical indicators — Test equipment
37.	ISO/TS 21387 Sterilization of medical devices — Guidance on the requirements for the validation and routine processing of ethylene oxide sterilization processes using parametric release
38.	ISO/TS 22421 Sterilization of health care products — Common requirements for sterilizers for terminal sterilization of medical devices in health care facilities

39.	ISO 22441 Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
40.	ISO/TS 22456 Sterilization of healthcare products — Microbiological methods— Guidance on conducting bioburden determinations and tests of sterility for biologics and tissue-based products
41.	ISO 17665-1 Sterilization of health care products -- moist heat -- part 1: requirements for the development, validation and routine control of a sterilization process for medical devices
42.	ISO/TS 17665-2 Sterilization of health care products -- moist heat -- part 2: guidance on the application of iso 17665-1
43.	ISO/TS 17665-3 Sterilization of health care products -- moist heat -- part 3: guidance on the designation of a medical device to a product family and processing category for steam sterilization
44.	ISO 25424 Sterilization of health care products -- low temperature steam and formaldehyde -- requirements for development, validation and routine control of a sterilization process for medical devices
45.	EN 13624 Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area — Test method and requirements (phase 2, step 1)
46.	EN 14561 Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants — Test methods and requirements (phase 2, step 1)
47.	EN 14348 Chemical disinfectants and antiseptics — Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area — Test method and requirements (phase 2, step 2)

48.	ISO/TS 5111 Guidance on quality of water for sterilizers, sterilization and washer-disinfectors for health care products

In vitro diagnostic	
1.	ISO 18113-1 In vitro diagnostic medical devices Information supplied by the manufacturer (labelling) Part 1: Terms, definitions, and general requirements
2.	ISO 18113-2 In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for professional use
3.	ISO 18113-3 In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 3: In vitro diagnostic instruments for professional use
4.	ISO 18113-4 In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 4: In vitro diagnostic reagents for self-testing
5.	ISO 18113-5 In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 5: In vitro diagnostic instruments for self-testing
6.	ISO 11137-1 Sterilization of health care products Radiation Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
7.	ISO 11137-2 Sterilization of health care products Radiation Part 2: Establishing the sterilization dose
8.	ISO 11737-1 Sterilization of health care products Microbiological methods Part 1: Determination of a population of microorganisms on products
9.	ISO 11737-2 Sterilization of health care products Microbiological methods Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

10.	ISO 11737-3 Sterilization of health care products Microbiological methods Part 3: Bacterial endotoxin testing
11.	ISO 11135 Sterilization of health-care products Ethylene oxide Requirements for the development, validation and routine control of a sterilization process for medical devices
12.	ISO 25424 Sterilization of health care products Low temperature steam and formaldehyde Requirements for development, validation and routine control of a sterilization process for medical devices
13.	ISO 17511 In vitro diagnostic medical devices Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples
14.	ISO 6717 In vitro diagnostic medical devices Single-use containers for the collection of specimens from humans other than blood
15.	ISO 15197 In vitro diagnostic test systems Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus
16.	ISO 17511 In vitro diagnostic medical devices Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples
17.	ISO 23640 In vitro diagnostic medical devices Evaluation of stability of in vitro diagnostic reagents
18.	ISO 17593 Clinical laboratory testing and in vitro medical devices Requirements for in vitro monitoring systems for self-testing of oral anticoagulant therapy

19.	ISO 20916 In vitro diagnostic medical devices Clinical performance studies using specimens from human subjects Good study practice
20.	IEC 61010-2-101 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
21.	IEC 61326-2-6 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
22.	IEC 62366-1 Medical devices Part 1: Application of usability engineering to medical devices
23.	ISO 13485 Medical devices -- Quality management systems -- Requirements for regulatory purposes
24.	ISO 14971 Medical devices — Application of risk management to medical devices
25.	ISO 20417 Medical devices — Information to be supplied by the manufacturer
26.	ISO 15223-1 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
27.	ISO 15223-2 Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 2: Symbol development, selection and validation
28.	EN 13532 General requirements for in vitro diagnostic medical devices for self-testing

29.	EN 13612 Performance evaluation of in vitro diagnostic medical devices
30.	EN 13641 Elimination or reduction of risk of infection related to in vitro diagnostic reagents

Electromedical	
1.	IEC 60118-13 Electroacoustics - Hearing aids - Part 13: Requirements and methods of measurement for electromagnetic immunity to mobile digital wireless devices
2.	IEC 60522-1 Medical electrical equipment - Diagnostics X-rays - Part 1: Determination of quality equivalent filtration and permanent filtration
3.	IEC 60580 Medical electrical equipment - Dose area product meters
4.	IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
5.	IEC 60601-2-1 Medical electrical equipment - Part 2-1: Particular requirements for the safety of electron accelerators in the range of 1 MeV to 50 MeV
6.	IEC 60601-2-2 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
7.	IEC 60601-2-3 Medical electrical equipment - Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment
8.	IEC 60601-2-5 Medical electrical equipment - Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment
9.	IEC 60601-2-8 Medical electrical equipment - Part 2-8: Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV

10.	IEC 60601-2-17 Medical electrical equipment - Part 2-17: Particular requirements for the safety of automatically-controlled brachytherapy after loading equipment
11.	IEC 60601-2-18 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment (IEC 60601-2-18:2009)
12.	IEC 60601-2-19 Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators
13.	IEC 60601-2-20 Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators
14.	IEC 60601-2-21 Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers
15.	IEC 60601-2-23 Medical electrical equipment - Part 2-23: Particular requirements for the safety, including essential performance, of transcutaneous partial pressure monitoring equipment
16.	IEC 60601-2-27 Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment.
17.	IEC 60601-2-28 Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
18.	IEC 60601-2-29 Medical electrical equipment - Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators

19.	IEC 60601-2-33 Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis
20.	IEC 60601-2-36 Medical electrical equipment - Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy
21.	IEC 60601-2-37 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
22.	IEC 60601-2-39 Medical electrical equipment - Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment
23.	IEC 60601-2-40 Medical electrical equipment - Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment
24.	IEC 60601-2-41 Medical electrical equipment - Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis
25.	IEC 60601-2-45 Medical electrical equipment - Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices
26.	IEC 60601-2-46 Medical electrical equipment -- Part 2-46: Particular requirements for the safety of operating tables
27.	IEC 60601-2-47 Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems

28.	IEC 60601-2-49 Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment
29.	IEC 60601-2-50 Medical electrical equipment - Part 2-50: Particular requirementsfor the basic safety and essential performance of infant phototherapy equipment
30.	IEC 60601-2-52 Medical electrical equipment Part 2-52: Particular requirements for the basic safety and essential performance of medical beds
31.	IEC 60601-2-52 Medical electrical equipment Part 2-52: Particular requirements for the basic safety and essential performance of medical beds Technical Corrigendum 1
32.	IEC 60645-1 Electroacoustic - Audiological equipment - Part 1: Pure-tone audiometers
33.	IEC 61676 Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology
34.	IEC 62220-1-1 Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-1: Determination of the detective quantum efficiency - Detectors used in radiographic imaging
35.	IEC 62220-1-2 Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-2: Determination of the detective quantum efficiency - Detectors used in mammography
36.	IEC 62220-1-3 Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-3: Determination of the detective quantum efficiency - Detectors used in dynamic imaging

37.	IEC 80601-2-35 Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use
38.	IEC 80601-2-31 Medical electrical equipment - Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source
39.	IEC 80601-2-58 Medical electrical equipment - Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery
40.	IEC 80601-2-59 Medical electrical equipment - Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening
41.	IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
42.	IEC 60601-1-6Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
43.	IEC 80601-2-26 Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalograph
44.	IEC 60601-2-31 Medical electrical equipment - Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source
45.	IEC 60601-2-57 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

46.	ISO 81060-2 Non-invasive sphygmomanometers — Part 2: Clinical investigation of intermittent automated measurement type
47.	ISO 81060-3 Non-invasive sphygmomanometers — Part 3: Clinical investigation of continuous automated measurement type
48.	ISO/TS 81060-5 Non-invasive sphygmomanometers — Part 5: Requirements for the repeatability and reproducibility of NIBP simulators for testing of automated non-invasive sphygmomanometers
49.	ISO 80601-2-56 Medical electrical equipment — Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
50.	ISO 80601-2-80 Medical electrical equipment - Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency
51.	ISO 80601-2-90 Medical electrical equipment Part 2-90: Particular requirements for basic safety and essential performance of respiratory high-flow therapy equipment
52.	IEC-62281 Safety of primary and secondary lithium cells and batteries during transport
53.	ISO 80601-2-90 Medical electrical equipment — Part 2-90: Particular requirements for basic safety and essential performance of respiratory high-flow therapy equipment
54.	IEC-60601-1-10

	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
55.	IEC 80601-2-49 Medical electrical equipment — Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
56.	IEC 80601-2-52 Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds
57.	IEC 80601-2-71 Medical electrical equipment — Part 2-71: Particular requirements for the basic safety and essential performance of functional Near-Infrared Spectroscopy (NIRS) equipment
58.	ISO 80601-2-85 Medical electrical equipment — Part 2-85: Particular requirements for the basic safety and essential performance of cerebral tissue oximeter equipment
59.	IEC 80601-2-30 Medical electrical equipment — Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers
60.	ISO 80601-2-61 Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

Radiology	
1.	IEC 61217 Radiotherapy equipment - Coordinates, movements and scales
2.	IEC 62220-1 Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-1: Determination of the detective quantum efficiency - Detectors used in radiographic imaging
3.	IEC 60627 Diagnostic X-ray imaging equipment - Characteristics of general purpose and mammographic anti-scatter grids
4.	ISO 15382 Radiological protection — Procedures for monitoring the dose to the lens of the eye, the skin and the extremities
5.	ISO 5579 Non-destructive testing — Radiographic testing of metallic materials using film and X- or gamma rays — Basic rules
6.	ISO 5580 Non-destructive testing — Industrial radiographic illuminators — Minimum requirements
7.	ISO 11699-1 Non-destructive testing — Industrial radiographic film — Part 1: Classification of film systems for industrial radiography
8.	ISO 11699-2 Non-destructive testing — Industrial radiographic films — Part 2: Control of film processing by means of reference values
9.	ISO 12721 Non-destructive testing — Thermal neutron radiographic testing — Determination of beam L/D ratio

10.	ISO 14096-1 Non-destructive testing — Qualification of radiographic film digitisation systems — Part 1: Definitions, quantitative measurements of image quality parameters, standard reference film and qualitative control
11.	ISO 14096-2 Non-destructive testing — Qualification of radiographic film digitisation systems — Part 2: Minimum requirements
12.	ISO 15708-2 Non-destructive testing — Radiation methods for computed tomography — Part 2: Principles, equipment and samples
13.	ISO 15708-3 Non-destructive testing — Radiation methods for computed tomography — Part 3: Operation and interpretation
14.	ISO 15708-4 Non-destructive testing — Radiation methods for computed tomography — Part 4: Qualification
15.	ISO 16371-1 Non-destructive testing — Industrial computed radiography with storage phosphor imaging plates — Part 1: Classification of systems
16.	ISO 16371-2 Non-destructive testing — Industrial computed radiography with storage phosphor imaging plates — Part 2: General principles for testing of metallic materials using X-rays and gamma rays
17.	ISO 16526-1 Non-destructive testing — Measurement and evaluation of the X-ray tube voltage — Part 1: Voltage divider method
18.	ISO 16526-2 Non-destructive testing — Measurement and evaluation of the X-ray tube voltage — Part 2: Constancy check by the thick filter method

19.	ISO 16526-3 Non-destructive testing — Measurement and evaluation of the X-ray tube voltage — Part 3: Spectrometric method
20.	ISO 19232-1 Non-destructive testing — Image quality of radiographs — Part 1: Determination of the image quality value using wire-type image quality indicators
21.	ISO 19232-2 Non-destructive testing — Image quality of radiographs — Part 2: Determination of the image quality value using step/hole-type image quality indicators
22.	ISO 19232-3 Non-destructive testing — Image quality of radiographs — Part 3: Image quality classes
23.	ISO 19232-4 Non-destructive testing — Image quality of radiographs — Part 4: Experimental evaluation of image quality values and image quality tables
24.	ISO 19232-5 Non-destructive testing — Image quality of radiographs — Part 5: Determination of the image unsharpness and basic spatial resolution value using duplex wire-type image quality indicators
25.	ISO 20769-1 Non-destructive testing — Radiographic inspection of corrosion and deposits in pipes by X- and gamma rays — Part 1: Tangential radiographic inspection
26.	ISO 20769-2 Non-destructive testing — Radiographic inspection of corrosion and deposits in pipes by X- and gamma rays — Part 2: Double wall radiographic inspection
27.	ISO 21432 Non-destructive testing — Standard test method for determining residual stresses by neutron diffraction

28.	ISO 23159 Non-destructive testing — Gamma ray scanning method on process columns

Dentistry	
1.	ISO 3990 Dentistry — Evaluation of antibacterial activity of dental restorative materials, luting materials, fissure sealants and orthodontic bonding or luting materials
2.	ISO 7405 Dentistry — Evaluation of biocompatibility of medical devices used in dentistry
3.	ISO 3107 Dentistry — Zinc oxide-eugenol cements and non-eugenol zinc oxide cements
4.	ISO 4049 Dentistry — Polymer-based restorative materials
5.	ISO/TS 4640 Dentistry — Test methods for tensile bond strength to tooth structure
6.	ISO 6872 Dentistry — Ceramic materials
7.	ISO 6874 Dentistry — Polymer-based pit and fissure sealants
8.	ISO 6876 Dentistry — Root canal sealing materials
9.	ISO 6877 Dentistry — Endodontic obturating materials
10.	ISO/TS 4640 Dentistry — Test methods for tensile bond strength to tooth structure
11.	ISO 9917-1

	Dentistry — Water-based cements — Part 1: Powder/liquid acid-base cements
12.	ISO 9917-2 Dentistry — Water-based cements — Part 2: Resin-modified cements
13.	ISO 9693 Dentistry — Compatibility testing for metal-ceramic and ceramic-ceramic systems
14.	ISO 10271 Dentistry — Corrosion test methods for metallic materials
15.	ISO 14801 Dentistry — Implants — Dynamic loading test for endosseous dental implants
16.	ISO 22674 Dentistry — Metallic materials for fixed and removable restorations and appliances
17.	ISO 22794 Dentistry — Implantable materials for bone filling and augmentation in oral and maxillofacial surgery — Contents of a technical file
18.	ISO 22803 Dentistry — Membrane materials for guided tissue regeneration in oral and maxillofacial surgery — Contents of a technical file
19.	ISO 24234 Dentistry — Dental amalgam
20.	ISO/TS 11405 Dentistry — Testing of adhesion to tooth structure
21.	ISO 13116 Dentistry — Test method for determining radio-opacity of materials

22.	ISO 29022 Dentistry — Adhesion — Notched-edge shear bond strength test
23.	ISO 6873 Dentistry — Gypsum products
24.	ISO 7491 Dental materials — Determination of colour stability
25.	ISO 9333 Dentistry — Brazing materials
26.	ISO 10139-1 Dentistry — Soft lining materials for removable dentures — Part 1: Materials for short-term use
27.	ISO 10139-2 Dentistry — Soft lining materials for removable dentures — Part 2: Materials for long-term use
28.	ISO 10477 Dentistry — Polymer-based crown and veneering materials
29.	ISO 13017 Dentistry — Magnetic attachments
30.	ISO 13078-2 Dentistry — Dental furnace — Part 2: Test method for evaluation of furnace programme via firing glaze
31.	ISO 13078-3 Dentistry — Dental furnace — Part 3: Test method for the evaluation of high temperature sintering furnace measurement with a separate thermocouple
32.	ISO 13078 Dentistry — Dental furnace — Test method for temperature measurement with separate thermocouple

33.	ISO 14233 Dentistry — Polymer-based die materials
34.	ISO 14356 Dentistry — Duplicating material
35.	ISO/TS 14569-2 Dental materials — Guidance on testing of wear — Part 2: Wear by two- and/or three body contact
36.	ISO 15854 Dentistry — Casting and baseplate waxes
37.	ISO/TS 19736 Dentistry — Bonding test between polymer teeth and denture base materials
38.	ISO 20795-1 Dentistry — Base polymers — Part 1: Denture base polymers
39.	ISO 20795-2 Dentistry — Base polymers — Part 2: Orthodontic base polymers
40.	ISO 21563 Dentistry — Hydrocolloid impression materials
41.	ISO 22112 Dentistry — Artificial teeth for dental prostheses
42.	ISO 22598 Dentistry — Colour tabs for intraoral tooth colour determination
43.	ISO 22674 Dentistry — Metallic materials for fixed and removable restorations and appliances

44.	ISO 23401-1 Dentistry — Chairside denture base relining materials — Part 1: Hard type materials
45.	ISO 28319 Dentistry — Laser welding and filler materials
46.	ISO 1797 Dentistry — Shanks for rotary and oscillating instruments
47.	ISO 3630-1 Dentistry — Endodontic instruments — Part 1: General requirements
48.	ISO 3630-2 Dentistry — Endodontic instruments — Part 2: Enlargers
49.	ISO 3630-3 Dentistry — Endodontic instruments — Part 3: Compactors
50.	ISO 3630-4 Dentistry — Endodontic instruments — Part 4: Auxiliary instruments
51.	ISO 3630-5 Dentistry — Endodontic instruments — Part 5: Shaping and cleaning instruments
52.	ISO 3823-1 Dental rotary instruments — Burs — Part 1: Steel and carbide burs
53.	ISO 3823-2 Dentistry — Rotary bur instruments — Part 2: Finishing burs
54.	ISO 3964 Dentistry — Coupling dimensions for handpiece connectors

55.	ISO 4865-1 Dentistry — General requirements of hand instruments — Part 1: Non-hinged hand instruments
56.	ISO 6360-1 Dentistry — Number coding system for rotary instruments — Part 1: General characteristics
57.	ISO 6360-2 Dentistry — Number coding system for rotary instruments — Part 2: Shapes
58.	ISO 6360-3 Dentistry — Number coding system for rotary instruments — Part 3: Specific characteristics of burs and cutters
59.	ISO 6360-4 Dentistry — Number coding system for rotary instruments — Part 4: Specific characteristics of diamond instruments
60.	ISO 6360-5 Dentistry — Number coding system for rotary instruments — Part 5: Specific characteristics of root-canal instruments
61.	ISO 6360-6 Dentistry — Number coding system for rotary instruments — Part 6: Specific characteristics of abrasive instruments
62.	ISO 6360-7 Dentistry — Number coding system for rotary instruments — Part 7: Specific characteristics of mandrels and special instruments
63.	ISO 7492 Dentistry — Dental explorer
64.	ISO 7711-1 Dentistry — Diamond rotary instruments — Part 1: General requirements

65.	ISO 7711-2 Dentistry — Rotary diamond instruments — Part 2: Discs
66.	ISO 7786 Dental rotary instruments — Laboratory abrasive instruments
67.	ISO 7787-1 Dentistry — Laboratory cutters — Part 1: Steel laboratory cutters
68.	ISO 7787-2 Dentistry — Laboratory cutters — Part 2: Carbide laboratory cutters
69.	ISO 7787-3 Dentistry — Laboratory cutters — Part 3: Carbide cutters for milling machines
70.	ISO 7787-4 Dental rotary instruments — Cutters — Part 4: Miniature carbide laboratory cutters
71.	ISO 7885 Dentistry — Sterile injection needles for single use
72.	ISO 8325 Dentistry — Test methods for rotary instruments
73.	ISO 9168 Dentistry — Hose connectors for air driven dental handpieces
74.	ISO 9173-1 Dentistry — Extraction forceps — Part 1: General requirements
75.	ISO 9173-2 Dentistry — Extraction forceps — Part 2: Designation

76.	ISO 9173-3 Dentistry — Extraction forceps — Part 3: Design
77.	ISO 9873 Dentistry — Intra-oral mirrors
78.	ISO 9997 Dentistry — Cartridge syringes
79.	ISO 10323 Dentistry — Bore diameters for rotary instruments such as discs and wheels
80.	ISO 11499 Dentistry — Single-use cartridges for local anaesthetics
81.	ISO 13295 Dentistry — Mandrels for rotary instruments
82.	ISO 13397-1 Periodontal curettes, dental scalers and excavators — Part 1: General requirements
83.	ISO 13397-2 Dentistry — Periodontal curettes, dental scalers and excavators — Part 2: Periodontal curettes of Gr-type
84.	ISO 13397-3 Periodontal curettes, dental scalers and excavators — Part 3: Dental scalers — H-type
85.	ISO 13397-5 Dentistry — Periodontal curettes, dental scalers and excavators — Part 5: Jacquette scalers
86.	ISO 13504 Dentistry — General requirements for instruments and related accessories used in dental implant placement and treatment

87.	ISO 14457 Dentistry — Handpieces and motors
88.	ISO 15087 Dental elevators — Part 1: General requirements
89.	ISO 15098 Dentistry — Dental tweezers
90.	ISO 16635-1 Dentistry — Dental rubber dam technique — Part 1: Hole punch
91.	ISO 16635-2 Dentistry — Dental rubber dam instruments — Part 2: Clamp forceps
92.	ISO 17509 Dentistry — Torque transmitter for handpieces
93.	ISO 17937 Dentistry — Osteotome
94.	ISO 18397 Dentistry — Powered scaler
95.	ISO 18556 Dentistry — Intraoral spatulas
96.	ISO 19490 Dentistry — Sinus membrane elevator
97.	ISO 19715 Dentistry — Filling instrument with contra angle

98.	ISO 20569 Dentistry — Trephine burs
99.	ISO 20570 Dentistry — Oral surgical scalpel handle
100.	ISO 20608 Dentistry — Powder jet handpieces and powders
101.	ISO 21531 Dentistry — Graphical symbols for dental instruments
102.	ISO 21533 Dentistry — Reprocessable cartridge syringes for intraligamentary injections
103.	ISO 21671 Dentistry — Rotary polishers
104.	ISO 21672-1 Dentistry — Periodontal probes — Part 1: General requirements
105.	ISO 21672-2 Dentistry — Periodontal probes — Part 2: Designation
106.	ISO 21850-1 Dentistry — Materials for dental instruments — Part 1: Stainless steel
107.	ISO 22569 Dentistry — Multifunction handpieces
108.	ISO 22570 Dentistry — Spoons and bone curettes

109.	ISO 23445 Dentistry — Tissue punches
110.	ISO 23450 Dentistry — Intraoral camera
111.	ISO 23940 Dentistry — Excavators
112.	ISO 5467-1 Dentistry — Mobile dental units and dental patient chairs — Part 1: General requirements
113.	ISO 7488 Dentistry — Mixing machines for dental amalgam
114.	ISO 7493 Dentistry — Operator's stool
115.	ISO 7494-1 Dentistry — Stationary dental units and dental patient chairs — Part 1: General requirements
116.	ISO 7494-2 Dentistry — Stationary dental units and dental patient chairs — Part 2: Air, water, suction and wastewater systems
117.	ISO 9680 Dentistry — Operating lights
118.	ISO 9687 Dentistry — Graphical symbols for dental equipment
119.	ISO 10637 Dentistry — Central suction source equipment

120.	ISO 10650 Dentistry — Powered polymerization activators
121.	ISO 11143 Dentistry — Amalgam separators
122.	ISO 13897 Dentistry — Dental amalgam reusable mixing-capsules
123.	ISO 16954 Dentistry — Test methods for dental unit waterline biofilm treatment
124.	ISO 21530 Dentistry — Materials used for dental equipment surfaces — Determination of resistance to chemical disinfectants
125.	ISO 22052 Dentistry — Central compressed air source equipment
126.	ISO 23402-1 Dentistry — Portable dental equipment for use in non-permanent healthcare environment — Part 1: General requirements
127.	IEC 80601-2-60 Medical electrical equipment — Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment
128.	ISO 10451 Dentistry — Contents of technical file for dental implant systems
129.	ISO 11953 Dentistry — Implants — Clinical performance of hand torque instruments
130.	ISO/TS 13498

	Dentistry — Torsion test of implant body/connecting part joints of endosseous dental implant systems
131.	ISO 14801 Dentistry — Implants — Dynamic loading test for endosseous dental implants
132.	ISO 16498 Dentistry — Minimal dental implant data set for clinical use
133.	ISO 19429 Dentistry — Designation system for dental implants
134.	ISO 22683 Dentistry — Rotational adaptability test between implant body and implant abutment in dental implant system
135.	ISO 22794 Dentistry — Implantable materials for bone filling and augmentation in oral and maxillofacial surgery — Contents of a technical file
136.	ISO 22803 Dentistry — Membrane materials for guided tissue regeneration in oral and maxillofacial surgery — Contents of a technical file
137.	ISO 5139 Dentistry — Polymer-based composite machinable blanks
138.	ISO 12836 Dentistry — Digitizing devices for CAD/CAM systems for indirect dental restorations — Test methods for assessing accuracy
139.	ISO 18618 Dentistry — Interoperability of CAD/CAM systems

140.	ISO 18675 Dentistry — Machinable ceramic blanks
141.	ISO 20896-1 Dentistry — Digital impression devices — Part 1: Methods for assessing accuracy
142.	ISO 23298 Dentistry — Test methods for machining accuracy of computer-aided milling machines

Optical and Ophthalmic	
1.	ISO 8429 Optics and optical instruments — Ophthalmology — Graduated dial scale
2.	ISO 8596 Ophthalmic optics — Visual acuity testing — Standard and clinical optotypes and their presentation
3.	ISO 8598-1 Optics and optical instruments — Focimeters — Part 1: General purpose instruments
4.	ISO 8612 Ophthalmic instruments — Tonometers
5.	ISO 8980-1 Ophthalmic optics — Uncut finished spectacle lenses — Part 1: Specifications for single-vision and multifocal lenses
6.	ISO 8980-2 Ophthalmic optics — Uncut finished spectacle lenses — Part 2: Specifications for power-variation lenses
7.	ISO 8980-3 Ophthalmic optics — Uncut finished spectacle lenses — Part 3: Transmittance specifications and test methods
8.	ISO 8980-4 Ophthalmic optics — Uncut finished spectacle lenses — Part 4: Specifications and test methods for the properties of anti-reflective coatings and hydrophobic coatings
9.	ISO 8980-5 Ophthalmic optics — Uncut finished spectacle lenses — Part 5: Minimum requirements for spectacle lens surfaces claimed to be abrasion-resistant

10.	ISO 9342-1 Optics and optical instruments — Test lenses for calibration of focimeters — Part 1: Reference lenses for focimeters used for measuring spectacle lenses
11.	ISO 9342-2 Optics and optical instruments — Test lenses for calibration of focimeters — Part 2: Test lenses for focimeters used for measuring contact lenses
12.	ISO 9394 Ophthalmic optics — Contact lenses and contact lens care products — Determination of biocompatibility by ocular study with rabbit eyes
13.	ISO 9801 Ophthalmic instruments — Trial case lenses
14.	ISO 10322 Ophthalmic optics — Semi-finished blanks
15.	ISO 10341 Ophthalmic instruments — Refractor heads
16.	ISO 10342 Ophthalmic instruments — Eye refractometers
17.	ISO 10343 Ophthalmic instruments — Ophthalmometers
18.	ISO 10939 Ophthalmic instruments — Slit-lamp microscopes
19.	ISO 10940 Ophthalmic instruments — Fundus cameras

20.	ISO 10942 Ophthalmic instruments — Direct ophthalmoscopes
21.	ISO 10943 Ophthalmic instruments — Indirect ophthalmoscopes
22.	ISO 10944 Ophthalmic instruments — Synoptophores
23.	ISO 11978 Ophthalmic optics — Contact lenses and contact lens care products — Labelling
24.	ISO 11979-2 Ophthalmic implants — Intraocular lenses — Part 2: Optical properties and test methods
25.	ISO 11979-3 Ophthalmic implants — Intraocular lenses — Part 3: Mechanical properties and test methods
26.	ISO 11979-4 Ophthalmic implants — Intraocular lenses — Part 4: Labelling and information
27.	ISO 11979-5 Ophthalmic implants — Intraocular lenses — Part 5: Biocompatibility
28.	ISO 11979-6 Ophthalmic implants — Intraocular lenses — Part 6: Shelf-life and transport stability testing
29.	ISO 11979-7 Ophthalmic implants — Intraocular lenses — Part 7: Clinical investigations of intraocular lenses for the correction of aphakia

30.	ISO 11979-8 Ophthalmic implants — Intraocular lenses — Part 8: Fundamental requirements
31.	ISO 11981 Ophthalmic optics — Contact lenses and contact lens care products — Determination of physical compatibility of contact lens care products with contact lenses
32.	ISO 11987 Ophthalmic optics — Contact lenses — Determination of shelf-life
33.	ISO 12865 Ophthalmic instruments — Retinoscopes
34.	ISO 12867 Ophthalmic instruments — Trial frames
35.	ISO 14534 Ophthalmic optics — Contact lenses and contact lens care products — Fundamental requirements
36.	ISO 14729 Ophthalmic optics — Contact lens care products — Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses
37.	ISO 14730 Ophthalmic optics — Contact lens care products — Antimicrobial preservative efficacy testing and guidance on determining discard date
38.	ISO 14889 Ophthalmic optics — Spectacle lenses — Fundamental requirements for uncut finished lenses
39.	ISO 15253 Ophthalmic optics and instruments — Optical and electro-optical devices for enhancing low vision

40.	ISO 15798 Ophthalmic implants — Ophthalmic viscosurgical devices
41.	ISO 16034 Ophthalmic optics — Specifications for single-vision ready-to-wear near- vision spectacles
42.	ISO 16672 Ophthalmic implants — Ocular endotamponades
43.	ISO 16971-1 Ophthalmic instruments — Optical coherence tomographs Part 1: Optical coherence tomographs for the posterior segment of the human eye
44.	ISO 18189 Ophthalmic optics — Contact lenses and contact lens care products — Cytotoxicity testing of contact lenses in combination with lens care solution to evaluate lens/solution interactions
45.	ISO 18259 Ophthalmic optics — Contact lens care products — Method to assess contact lens care products with contact lenses in a lens case, challenged with bacterial and fungal organisms
46.	ISO 18369-3 Ophthalmic optics — Contact lenses — Part 3: Measurement methods
47.	ISO 18369-4 Ophthalmic optics — Contact lenses — Part 4: Physicochemical properties of contact lens materials
48.	ISO 19045 Ophthalmic optics — Contact lens care products — Method for evaluating Acanthamoeba encystment by contact lens care products
49.	ISO 19980 Ophthalmic instruments — Corneal topographers

50.	ISO 21987 Ophthalmic optics — Mounted spectacle lenses
51.	ISO 22665 Ophthalmic optics and instruments - Instruments to measure axial distances in the eye
52.	ISO 11980 Ophthalmic optics — Contact lenses and contact lens care products — Requirements and guidance for clinical investigations

Health Informatics	
1.	IEC/TS 81001-2-2 Health software and health IT systems safety, effectiveness and security Part 2-2: Guidance for the implementation, disclosure and communication of security needs, risks and controls
2.	IEC 82304-1 Health software — Part 1: General requirements for product safety
3.	IEC 62304 Medical device software — Software life cycle processes
4.	IEC 81001-5-1 Health software and health IT systems safety, effectiveness and security
5.	ANSI/AAMI SW96 Standard for medical device security - Security risk management for device manufacturers
6.	ISO/TS 24971-2 Medical devices - Guidance on the application of ISO 14971 - Part 2: Machine learning in artificial intelligence
7.	ISO/IEC 5259-2 Artificial intelligence - Data quality for analytics and machine learning (ML) - Part 2: Data quality measures

Assistive Products	
1.	ISO 19894 Walking trolleys — Requirements and test methods
2.	ISO 7176-1 Wheelchairs — Part 1: Determination of static stability
3.	ISO 7176-5 Wheelchairs — Part 5: Determination of dimensions, mass and manoeuvring space
4.	ISO 7176-8 Wheelchairs -- part 8: requirements and test methods for static, impact and fatigue strengths
5.	ISO 7176-11 Wheelchairs — Part 11: Test dummies
6.	ISO 7176-13 Wheelchairs — Part 13: Determination of coefficient of friction of test surfaces
7.	ISO 7176-15 Wheelchairs — Part 15: Requirements for information disclosure, documentation and labelling
8.	ISO 7176-16 Wheelchairs -- part 16: resistance to ignition of postural support devices
9.	ISO 7176-19 Wheelchairs Part 19: Wheelchairs for use as seats in motor vehicles
10.	ISO 7176-21 Wheelchairs -- part 21: requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers

11.	ISO 7176-25 Wheelchairs Part 25: Lead-acid batteries and chargers for powered wheelchairs. Requirements and test methods
12.	ISO 21856 Assistive products — General requirements and test methods
13.	ISO 20342-1 Assistive products for tissue integrity when lying down — Part 1: General requirements
14.	ISO 21801-1 Cognitive accessibility — Part 1: General guidelines
15.	ISO 21801-2 Cognitive accessibility — Part 2: Reporting
16.	ISO 21802 Assistive products — Guidelines on cognitive accessibility — Daily time management
17.	ISO 23600 Assistive products for persons with vision impairments and persons with vision and hearing impairments — Acoustic and tactile signals for pedestrian traffic lights
18.	ISO 24415-2 Tips for assistive products for walking — Requirements and test methods — Part 2: Durability of tips for crutches
19.	ISO 7176-2 Wheelchairs — Part 2: Determination of dynamic stability of electrically powered wheelchairs
20.	ISO 7176-4 Wheelchairs — Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range

21.	ISO 7176-6 Wheelchairs — Part 6: Determination of maximum speed of electrically powered wheelchairs
22.	ISO 7176-10 Wheelchairs — Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs
23.	ISO 7176-22 Wheelchairs — Part 22: Set-up procedures
24.	ISO 7176-28 Wheelchairs — Part 28: Requirements and test methods for stair-climbing devices
25.	ISO 7176-30 Wheelchairs — Part 30: Wheelchairs for changing occupant posture — Test methods and requirements
26.	ISO 7176-31 Wheelchairs — Part 31: Lithium-ion battery systems and chargers for powered wheelchairs — Requirements and test methods
27.	ISO 7176-32 Wheelchairs — Part 32: Test method for wheelchair castor assembly durability
28.	ISO 10542-1 Technical systems and aids for disabled or handicapped persons — Wheelchair tiedown and occupant-restraint systems — Part 1: Requirements and test methods for all systems
29.	ISO 10542-1 Technical systems and aids for disabled or handicapped persons — Wheelchair tiedown and occupant-restraint systems — Part 1: Requirements and test methods for all systems — Technical Corrigendum 1

30.	ISO 10865-1 Wheelchair containment and occupant retention systems for accessible transport vehicles designed for use by both sitting and standing passengers — Part 1: Systems for rearward-facing wheelchair-seated passengers
31.	ISO 10865-2 Wheelchair containment and occupant retention systems for accessible transport vehicles designed for use by both sitting and standing passengers — Part 2: Systems for forward-facing wheelchair-seated passengers
32.	ISO 16840-2 Wheelchair seating — Part 2: Determination of physical and mechanical characteristics of seat cushions intended to manage tissue integrity
33.	ISO 16840-3 Wheelchair seating — Part 3: Determination of static, impact, and repetitive load strengths for postural support devices
34.	ISO 16840-4 Wheelchair seating — Part 4: Seating systems for use in motor vehicles
35.	ISO 16840-6 Wheelchair seating Part 6: Determination of changes in properties of seat cushions following simulated use
36.	ISO 16840-10 Wheelchair seating — Part 10: Resistance to ignition of postural support devices — Requirements and test method
37.	ISO 16840-11 Wheelchair seating — Part 11: Determination of dissipation characteristics of sensible perspiration into seat cushions
38.	ISO 16840-12 Wheelchair seating — Part 12: Envelopment and immersion characterization of seat cushions using a dual semispherical indenter

39.	ISO 16840-13 Wheelchair seating — Part 13: Determination of the lateral stability property of a seat cushion
40.	ISO/TS 16840-14 Wheelchair seating — Part 14: Concepts related to managing external forces to maintain tissue integrity
41.	ISO 8670-2 Ostomy collection bags — Part 2: Requirements and test methods
42.	ISO 11948-1 Urine-absorbing aids — Part 1: Whole-product testing
43.	ISO 12505-1 Skin barrier for ostomy aids — Test methods — Part 1: Size, surface pH and water-absorbency
44.	ISO 12505-2 Skin barrier for ostomy aids — Test methods — Part 2: Wet integrity and adhesive strength
45.	ISO 15621 Absorbent incontinence products for urine, faeces, or both — General guidelines on evaluation
46.	ISO 16021 Absorbent incontinence products for urine and/or faeces — Basic principles for evaluation of single-use adult products from the perspective of users and caregivers
47.	ISO 17190-1 Urine-absorbing aids for incontinence — Polyacrylate superabsorbent powders — Part 1: Test method for determination of pH
48.	ISO 17190-2 Urine-absorbing aids for incontinence — Polyacrylate superabsorbent powders — Part 2: Test method for determination of the amount of residual acrylate monomers

49.	ISO 17190-3 Urine-absorbing aids for incontinence — Polyacrylate superabsorbent powders — Part 3: Test method for determination of the particle size distribution by sieve fractionation
50.	ISO 17190-4 Urine-absorbing aids for incontinence — Polyacrylate superabsorbent powders — Part 4: Test method for estimation of the moisture content as weight loss upon heating
51.	ISO 17190-5 Urine-absorbing aids for incontinence — Polyacrylate superabsorbent powders — Part 5: Test method for determination of the free swell capacity in saline by gravimetric measurement
52.	ISO 17190-6 Urine-absorbing aids for incontinence — Polyacrylate superabsorbent powders — Part 6: Test method for determination of the fluid retention capacity in saline solution by gravimetric measurement following centrifugation
53.	ISO 17190-7 Urine-absorbing aids for incontinence — Polyacrylate superabsorbent powders — Part 7: Test method for gravimetric determination of absorption against pressure
54.	ISO 17190-8 Urine-absorbing aids for incontinence — Polyacrylate superabsorbent powders — Part 8: Test method for determination of the permeability dependent absorption under pressure of saline solution by gravimetric measurement
55.	ISO 17190-9 Urine-absorbing aids for incontinence — Polyacrylate superabsorbent powders — Part 9: Test method for gravimetric determination of flow rate and bulk density
56.	ISO 17190-10 Urine-absorbing aids for incontinence — Polyacrylate superabsorbent powders — Part 10: Test method for determination of extractable polymer content by potentiometric titration
57.	ISO 17190-11

	Urine-absorbing aids for incontinence — Test methods for characterizing polymer-based absorbent materials — Part 11: Determination of content of respirable particles
58.	ISO 17191 Urine-absorbing products for incontinence — Measurement of airborne respirable polyacrylate superabsorbent materials — Determination of dust in collection cassettes by sodium atomic absorption spectrometry
59.	ISO 22748 Absorbent incontinence products for urine and/or faeces — Product type names and illustrations2466
60.	ISO 24669 Water-absorbent polyacrylate in urine absorbing products — Requirements
61.	ISO 17049 Accessible design — Application of braille on signage, equipment and appliances
62.	ISO 17069 Accessible design — Consideration and assistive products for accessible meeting
63.	ISO 19029 Accessible design — Auditory guiding signals in public facilities

Medical Face Masks	
1.	EN 14683 Medical face masks Requirements and test methods
2.	ASTM F2100 Standard specification for performance of materials used in medical face masks
3.	ASTM F2101 Standard test method for evaluating the Bacterial Filtration Efficiency (BFE) of medical face mask materials, using a biological aerosol of staphylococcus aureus
4.	ASTM F2299 Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
5.	EN 149 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing and marking
6.	ASTM F1862 Standard test method for resistance of medical face masks to penetration by synthetic blood (horizontal projection of fixed volume at a known velocity)
7.	EN 143 RESPIRATORY PROTECTIVE DEVICES - PARTICLE FILTERS - REQUIREMENTS, TESTING, MARKING
8.	ASTM F2100 – 19 Standard Specification For Performance Of Materials Used In Medical Face Masks
9.	16 CFR Part 1610 STANDARD FOR THE FLAMMABILITY OF CLOTHING TEXTILES

Personal Protective Equipment for Medical Purpose	
1.	OSHA 1910.133 Eye and face protection

Complementary and Alternative Medicine	
1.	ISO 5227 Traditional Chinese medicine — Safety controls for cupping devices
2.	ISO 19611 Traditional Chinese medicine — Air extraction cupping device
3.	ISO 22213 Traditional Chinese medicine — Glass cupping device
4.	ISO 17218 Sterile acupuncture needles for single use
5.	ISO 18746 Traditional Chinese medicine — Sterile intradermal acupuncture needles for single use
6.	ISO 22236 Traditional Chinese medicine —Thread-embedding acupuncture needle for single use
7.	ISO 20308 Traditional Chinese medicine — Gua Sha instruments

Contraception	
1.	ISO 19671 Additional lubricants for male natural rubber latex condoms — Effect on condom strength
2.	ISO 25841 Female condoms — Requirements and test methods
3.	ISO 29942 Prophylactic dams — Requirements and test methods

Other	
1.	ISO 14644-1 Cleanrooms and associated controlled environments Part 1: Classification of air cleanliness by particle concentration
2.	ISO 14644-2 Cleanrooms and associated controlled environments — Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
3.	ISO 14644-3 Cleanrooms and associated controlled environments — Part 3: Test methods
4.	ISO 14644-4 Cleanrooms and associated controlled environments -- part 4: design, construction and start-up
5.	ISO 14644-5 Cleanrooms and associated controlled environments -- part 5: operations
6.	ISO 14644-7 Cleanrooms and associated controlled environments -- part 7: separative devices (clean air hoods, gloveboxes, isolators and mini-environments)
7.	ISO 14644-8 Cleanrooms and associated controlled environments -- part 8: classification of air cleanliness by chemical concentration (ACC)
8.	ISO 14644-9 Cleanrooms and associated controlled environments -- part 9: classification of surface cleanliness by particle concentration
9.	ISO 14644-10 Cleanrooms and associated controlled environments -- part 10: classification of surface cleanliness by chemical concentration

10.	IEC 60529 Degrees of protection provided by enclosures (IP Code)
11.	IEC 60825-1 Safety of laser products - Part 1: Equipment classification and requirements
12.	IEC 61000-3-2 Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤16 A per phase)
13.	IEC 61000-3-3 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
14.	IEC 61000-4-2 Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test
15.	IEC 61000-4-3 Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test
16.	IEC 61000-4-4 Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test
17.	IEC 61000-4-5 Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test
18.	IEC 61000-4-6 Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields

19.	IEC 61000-4-8 Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test
20.	IEC 61000-4-11 Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests for equipment with input current up to 16 A per phase
21.	CISPR 11 Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement
22.	ISO 22609 Clothing for protection against infectious agents -- medical face masks -- test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)
23.	ASTM F2100 Standard specification for performance of materials used in medical face masks
24.	ISO 11117 Gas cylinders.Valve protection caps and guards. Design, construction and tests
25.	ISO 22882 Castors and wheels — Requirements for castors for hospital beds
26.	ISO 22610 Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment — Test method to determine the resistance to wet bacterial penetration
27.	ASTM F1671/F1671M-22 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System
28.	ASTM F1980-21

	Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices
29.	ISO 10282 Single-use sterile rubber surgical gloves Specification
30.	ISO 11193-1 Single-use medical examination gloves Part 1: Specification for gloves made from rubber latex or rubber solution
31.	ISO 11193-2 Single-use medical examination gloves Part 2: Specification for gloves made from poly(vinyl hloride)
32.	EN 455-1 Medical gloves for single use - Part 1: Requirements and testing for freedom from holes
33.	EN 455-2 Medical gloves for single use - Part 2: Requirements and testing for physical properties
34.	EN 455-3 Medical gloves for single use - Part 3: Requirements and testing for biological evaluation
35.	EN 455-4 Medical gloves for single use - Part 4: Requirements and testing for shelf life determination
36.	ISO 7886-1 Sterile hypodermic syringes for single use Part 1: Syringes for manual use
37.	ISO 7886-2 Sterile hypodermic syringes for single use Part 2: Syringes for use with power-driven syringe pumps
38.	ISO 7886-3 Sterile hypodermic syringes for single use Part 3: Auto-disabled syringes for fixed-dose immunization

39.	ISO 7886-4 Sterile hypodermic syringes for single use Part 4: Syringes with re-use prevention feature

Annexe

Annex (1): Changing to Previous Documents

Number & Date of the Previous Version	Changes Description
MDS-G44 1.0 2019/12/16	• Update the following documents: ○ SFDA Recognized Standards (Supporting Medical Device Premarket Submissions)
MDS-G46 3.0 2020/06/17	• Update the following documents: ○ Guidance on Requirements for Medical Masks - Recognized Standards
MDS – G47 V1.0 2020/04/20	• Update the following documents: ○ Guidance on Requirements for Ventilators, Ventilator Tubing Connectors, and Ventilator Accessories – Recognized Standards.
MDS – G004 1.1 2022/12/14	• Update the following documents: ○ Guidance for Requirements of Surgical and Medical Examination Gloves - Recognized Standards
MDS – G005 1.1 2022/12/14	• Update the following documents: ○ Guidance for Requirements of sterile single-use hypodermic syringes - Recognized Standards
MDS – G006 1.1 2022/12/14	• Update the following documents: ○ Guidance for Requirements of blood glucose metering devices and strips for home use - Recognized Standards
MDS – G020 4.0 2026/09/17	• Update the following documents: ○ All dates and amendments are removed ○ All withdrawn standards are removed