الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

MDS – G020

SFDA Recognized Standards

(Supporting Medical Device Premarket Submissions)

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Introduction

This list aims to Supporting Medical Device Premarket Submissions to fulfill medical device marketing authorization requirments through complying with the Essential Principles throughout the medical life cycle.

Purchasing standards

Saudi standards may be purchased through SFDA standards store " mwasfah" or by visiting ISO or IEC or other webstores

Standards Catagories

General	
1.	ISO 13485 :2016 Medical devices -- Quality management systems -- Requirements for regulatory purposes
2.	ISO 14971:2019 Medical devices — Application of risk management to medical devices
3.	ISO 13022:2012 Medical products containing viable human cells — Application of risk management and requirements for processing practices
4.	ISO 20417:2021 Medical devices — Information to be supplied by the manufacturer
5.	ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
6.	ISO 15223-2:2010 Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 2: Symbol development, selection and validation
7.	ISO/TR 20416:2020 Medical devices — Post-market surveillance for manufacturers
8.	ISO 13408-1:2008+Amd 1:2013 Aseptic processing of health care products - Part 1: General requirements
9.	ISO/TS 37137-1:2021 Biological evaluation of absorbable medical devices — Part 1: General requirements

10.	ISO 22442-1:2020 Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management
11.	ISO 22442-2:2020 Medical devices utilizing animal tissues and their derivatives — Part 2: Controls on sourcing, collection and handling
12.	ISO 22442-3:2007 Medical devices utilizing animal tissues and their derivatives — Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents
13.	ISO/TS 21726:2019 Biological evaluation of medical devices — Application of the threshold of toxicological concern (TTC) for assessing biocompatibility of medical device constituents
14.	ISO 14155:2020 Clinical investigation of medical devices for human subjects — Good clinical practice
15.	ISO 10993-1:2018 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
16.	IEC 62304:2006 Medical device software — Software life cycle processes
17.	IEC 62366-1:2015+Amd 1:2020 Medical devices — Part 1: Application of usability engineering to medical devices
18.	ISO 80369-1:2018 Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements

Anesthetic, Respiratory, and Ventilators	
1.	ISO 5362:2006 Anaesthetic reservoir bags
2.	ISO 4135:2022 Anaesthetic and respiratory equipment - Vocabulary
3.	ISO 26825:2020 Anaesthetic and respiratory equipment — User-applied labels for syringes containing drugs used during anaesthesia — Colours, design and performan
4.	ISO 19223:2019 Lung ventilators and related equipment — Vocabulary and semantics
5.	ISO 7396-2:2007 Medical gas pipeline systems - Part 2: Anaesthetic gas scavenging disposal systems
6.	ISO 80601-2-13:2022 Medical electrical equipment — Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation
7.	ISO 9170-1:2017 Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum
8.	ISO 9170-2:2008 Terminal units for medical gas pipeline systems - Part 2: Terminal units for anaesthetic gas scavenging systems
9.	ISO 9360-1:2000 Anaesthetic and respiratory equipment - Heat and moisture exchangers (HMEs) for humidifying respired gases in humans - Part 1: HMEs for use with minimum tidal volumes of 250 ml

10.	ISO 9360-2:2001 Anaesthetic and respiratory equipment - Heat and moisture exchangers (HMEs) for humidifying respired gases in humans - Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml
11.	ISO 10079-1:2022 Medical suction equipment — Part 1: Electrically powered suction equipment — Amendment 1: Changes to requirements for operating at extremes of temperature
12.	ISO 10079-2:2022 Medical suction equipment - Part 2: Manually powered suction equipment
13.	ISO 10079-3: 2022 Medical suction equipment - Part 3: Suction equipment powered from a vacuum or positive pressure gas source
14.	ISO 10079-4:2021 Medical suction equipment — Part 4: General requirements
15.	ISO 10524-1:2018 Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flow-metering devices
16.	ISO 10524-2:2018 Pressure regulators for use with medical gases - Part 2: Manifold and line pressure regulators
17.	ISO 10524-3:2019 Pressure regulators for use with medical gases - Part 3: Pressure regulators integrated with cylinder valves (VIPRs)
18.	ISO 10524-4:2008 Pressure regulators for use with medical gases - Part 4: Low-pressure regulators

19.	ISO 11197:2019 Medical supply units
20.	ISO 15001:2010 Anaesthetic and respiratory equipment - Compatibility with oxygen
21.	ISO 15002:2008 Flow-metering devices for connection to terminal units of medical gas pipeline systems
22.	ISO 18778:2022 Respiratory equipment — Particular requirements for basic safety and essential performance of infant cardiorespiratory monitors
23.	ISO 19054:2005 Rail systems for supporting medical equipment
24.	ISO 19054:2005 /AMD 1:2016 Rail systems for supporting medical equipment — Amendment 1
25.	ISO 23328-1:2003 Breathing system filters for anaesthetic and respiratory use - Part 1: Salt test method to assess filtration performance
26.	ISO 23328-2:2002 Breathing system filters for anaesthetic and respiratory use - Part 2: Non-filtration aspects
27.	ISO 26782:2009 Anaesthetic and respiratory equipment - Spirometers intended for the measurement of time forced expired volumes in humans
28.	ISO 81060-1:2007 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type

29.	ISO 80601-2-55:2018 Medical electrical equipment – Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
30.	ISO 5359:2014 Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases
31.	ISO 5359:2014/Amd 1:2017 Anaesthetic and respiratory equipment – Low-pressure hose assemblies for use with medical gases
32.	ISO 5360:2016 Anaesthetic vaporizers — Agent-specific filling systems
33.	ISO 27427:2023 Anaesthetic and respiratory equipment -- Nebulizing systems and components
34.	ISO 18250-1:2018 Medical devices — Connectors for reservoir delivery systems for healthcare applications — Part 1: General requirements and common test methods
35.	IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
36.	IEC 60601-1-8:2006+AMD1:2012+AMD2:2020 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
37.	IEC 60601-1-9:2007+AMD1:2013+AMD2:2020 Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design

38.	IEC 60601-1-10:2007+AMD1:2013+AMD2:2020 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
39.	IEC 60601-1-11:2015+AMD1:2020 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
40.	IEC 60601-1-12:2014+AMD1:2020 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
41.	ISO 10651-4: 2023 Lung ventilators — Part 4: Particular requirements for user-powered resuscitators
42.	ISO 10651-5:2006 Lung ventilators for medical use — Particular requirements for basic safety and essential performance — Part 5: Gas-powered emergency resuscitators
43.	ISO 17510:2015 Medical devices — Sleep apnoea breathing therapy — Masks and application accessories
44.	ISO 18082:2014 Anaesthetic and respiratory equipment — Dimensions of non-interchangeable screwthreaded (NIST) low-pressure connectors for medical gases
45.	ISO 18082:2014/Amd 1:2017 Anaesthetic and respiratory equipment — Dimensions of non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases — Amendment 1
46.	ISO 5356-1:2015 Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets

47.	ISO 5356-2:2012 Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors
48.	ISO 5356-2:2012/Amd 1:2019 Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors — Amendment 1
49.	ISO 5361:2023 Anaesthetic and respiratory equipment — Tracheal tubes and connectors
50.	ISO 5366:2016 Anaesthetic and respiratory equipment — Tracheostomy tubes and connectors
51.	ISO 5367:2023 Anaesthetic and respiratory equipment — Breathing sets and connectors
52.	ISO 5364:2016 Anaesthetic and respiratory equipment — Oropharyngeal airways
53.	ISO 7376:2020 Anaesthetic and respiratory equipment — Laryngoscopes for tracheal intubation
54.	ISO 8836:2019 Suction catheters for use in the respiratory tract
55.	ISO 11712:2023 Anaesthetic and respiratory equipment — Supralaryngeal airways and connectors
56.	ISO 14408:2016 Tracheal tubes designed for laser surgery — Requirements for marking and accompanying information
57.	ISO 16628:2022 Anaesthetic and respiratory equipment — Tracheobronchial tubes

58.	ISO 21917:2021 Anaesthetic and respiratory equipment — Voice prostheses
59.	ISO 23368:2022 Anaesthetic and respiratory equipment — Low-flow nasal cannulae for oxygen therapy
60.	ISO 23371:2022 Anaesthetic and respiratory equipment — Cuff pressure indication, control and regulation devices
61.	ISO 23372:2022 Anaesthetic and respiratory equipment — Air entrainment devices
62.	ISO 8835-7:2011 Inhalational anaesthesia systems — Part 7: Anaesthetic systems for use in areas with limited logistical supplies of electricity and anaesthetic gases
63.	ISO 11195:2018 Gas mixers for medical use — Stand-alone gas mixers
64.	ISO 18835:2015 Inhalational anaesthesia systems — Draw-over anaesthetic systems
65.	ISO 20789:2018 Anaesthetic and respiratory equipment — Passive humidifiers
66.	ISO 23747:2015 Anaesthetic and respiratory equipment — Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans
67.	ISO 80601-2-67:2020 Medical electrical equipment — Part 2-67: Particular requirements for basic safety and essential performance of oxygen-conserving equipment
68.	ISO 80601-2-69:2020 Medical electrical equipment — Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment

69.	ISO 7396-1:2016 Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum
70.	ISO 7396-1:2016/Amd 1:2017 Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum — Amendment 1
71.	ISO 16571:2014 Systems for evacuation of plume generated by medical devices
72.	ISO 18777-1 Transportable liquid oxygen systems for medical use — Part 1: Common requirements and particular requirements for base units
73.	ISO 18777-2 Transportable liquid oxygen systems for medical use — Part 2: Particular requirements for portable units
74.	ISO 21969:2009 High-pressure flexible connections for use with medical gas systems
75.	ISO 80369-1:2018 Small-bore connectors for liquids and gases in healthcare applications Part 1: General requirements
76.	ISO 80369-6:2016 Small bore connectors for liquids and gases in healthcare applications Part 6: Connectors for neuraxial applications
77.	ISO 80369-20:2015 Small-bore connectors for liquids and gases in healthcare applications Part 20: Common test methods
78.	ISO 80601-2-12:2023

	Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
79.	ISO 80601-2-70:2020 Medical electrical equipment — Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment
80.	ISO 80601-2-72:2023 Medical electrical equipment — Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients
81.	ISO 80601-2-74:2021 Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment
82.	IEC 80601-2-77:2019 Medical electrical equipment — Part 2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment
83.	IEC 80601-2-78:2019 Medical electrical equipment — Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation
84.	ISO 80601-2-79:2018 Medical electrical equipment — Part 2-79: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment
85.	ISO 80601-2-80:2018 Medical electrical equipment — Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency
86.	ISO 80601-2-84:2020 Medical electrical equipment — Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment

87.	ISO 18190:2016 Anaesthetic and respiratory equipment — General requirements for airways and related equipment
88.	ISO 80601-2-87:2021 Medical electrical equipment — Part 2-87: Particular requirements for basic safety and essential performance of high-frequency ventilators
89.	ISO 18250-1:2020 Medical devices — Connectors for reservoir delivery systems for healthcare applications — Part 1: General requirements and common test methods
90.	SFDA.MD/ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
91.	SFDA.MD/ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process
92.	SFDA.MD/ISO 18562-2:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 2: Tests for emissions of particulate matter
93.	SFDA.MD/ISO 18562-3:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 3: Tests for emissions of volatile organic compounds (VOCs)
94.	SFDA.MD/ISO 18562-4:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 4: Tests for leachables in condensate
95.	SASO-IEC-60086-4:2007 Primary batteries - Part 4: Safety of lithium batteries”

96.	SASO-IEC-62281:2018 Safety of primary and secondary lithium cells and batteries during transport
97.	SASO-IEC-62133-1:2017 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 1: Nickel systems
98.	SASO-IEC-62133-2:2017 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
99.	SFDA.MD/IEC 62304+AMD 1:2017 Medical device software - Software life cycle processes”
100.	EN 1041:2008+A1:2013 Information supplied by the manufacturer of medical devices

Transfusion , infusion and injection , and blood processing equipment	
1.	ISO 28620:2020 Medical devices — Non-electrically driven portable infusion devices
2.	ISO 24166-3:2022 Snap-on bottles for metering pumps — Part 3: Plastic
3.	ISO 24166-2:2022 Snap-on bottles for metering pumps — Part 2: Moulded glass
4.	ISO 24166-1:2022 Snap-on bottles for metering pumps — Part 1: Tubular glass
5.	ISO 24072:2023 Aerosol bacterial retention test method for air-inlet filter on administration devices
6.	ISO/TS 23128:2019 Medical devices — Transfusion set and blood bag compatibility test method
7.	ISO 22413:2021 Transfer sets for pharmaceutical preparations — Requirements and test methods
8.	ISO 21882:2019 Sterile packaged ready for filling glass vials
9.	ISO 22413:2021 Transfer sets for pharmaceutical preparations — Requirements and test methods
10.	ISO 21882:2019 Sterile packaged ready for filling glass vials

11.	ISO 21881:2019 Sterile packaged ready for filling glass cartridges
12.	ISO/TR 19727:2017 Medical devices — Pump tube spallation test — General procedure
13.	ISO 15759:2005 Medical infusion equipment — Plastics caps with inserted elastomeric liner for containers manufactured by the blow-fill-seal (BFS) process
14.	ISO 15747:2018 Plastic containers for intravenous injections
15.	ISO 15378:2017 Primary packaging materials for medicinal products — Particular requirements for the application of ISO 9001:2015, with reference to good manufacturing practice (GMP)
16.	ISO 15375:2010 Medical infusion bottles — Suspension devices for multiple use — Requirements and test methods
17.	ISO 15137:2005 Self-adhesive hanging devices for infusion bottles and injection vials — Requirements and test methods
18.	ISO 15010:1998 Disposable hanging devices for transfusion and infusion bottles — Requirements and test methods
19.	ISO 13926-3:2019 Pen systems — Part 3: Seals for pen-injectors for medical use
20.	ISO 13926-2:2017 Pen systems — Part 2: Plunger stoppers for pen-injectors for medical use

21.	ISO 13926-1:2018 Pen systems — Part 1: Glass cylinders for pen-injectors for medical use
22.	ISO 11418-7:2016 Containers and accessories for pharmaceutical preparations — Part 7: Screw-neck vials made of glass tubing for liquid dosage forms
23.	ISO 11418-5:2015 Containers and accessories for pharmaceutical preparations — Part 5: Dropper assemblies
24.	ISO 11418-4:2005 Containers and accessories for pharmaceutical preparations — Part 4: Tablet glass bottles
25.	ISO 11418-3:2016 Containers and accessories for pharmaceutical preparations — Part 3: Screw-neck glass bottles (veral) for solid and liquid dosage forms
26.	ISO 11418-2:2016 Containers and accessories for pharmaceutical preparations — Part 2: Screw-neck glass bottles for syrups
27.	ISO 11418-1:2016 Containers and accessories for pharmaceutical preparations — Part 1: Drop-dispensing glass bottles
28.	ISO 11040-8:2016 Prefilled syringes — Part 8: Requirements and test methods for finished prefilled syringes
29.	ISO 11040-7:2015 Prefilled syringes — Part 7: Packaging systems for sterilized subassembled syringes ready for filling
30.	ISO 11040-6:2019 Prefilled syringes — Part 6: Plastic barrels for injectables and sterilized subassembled syringes ready for filling

31.	ISO 11040-5:2012 Prefilled syringes — Part 5: Plunger stoppers for injectables
32.	ISO 11040-4:2015 Prefilled syringes — Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling
33.	ISO 11040-3:2012 Prefilled syringes — Part 3: Seals for dental local anaesthetic cartridges
34.	ISO 11040-2:2011 Prefilled syringes — Part 2: Plunger stoppers for dental local anaesthetic cartridges
35.	ISO 11040-1:2015 Prefilled syringes — Part 1: Glass cylinders for dental local anaesthetic cartridges
36.	ISO 9187-2:2010 Injection equipment for medical use — Part 2: One-point-cut (OPC) ampoules
37.	ISO 9187-1:2010 Injection equipment for medical use — Part 1: Ampoules for injectables
38.	ISO 8872:2022 Aluminium caps and aluminium/plastic caps for infusion bottles and injection vials — General requirements and test methods
39.	ISO 8871-5:2016 Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 5: Functional requirements and testing
40.	ISO 8871-4:2006 Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 4: Biological requirements and test methods

41.	ISO 8871-3:2003 Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 3: Determination of released-particle count
42.	ISO 8871-2:2020 Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 2: Identification and characterization
43.	ISO 8871-1:2003 Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 1: Extractables in aqueous autoclavates
44.	ISO 8536-15:2022 Infusion equipment for medical use — Part 15: Light-protective infusion sets for single use
45.	ISO 8536-14:2016 Infusion equipment for medical use — Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact
46.	ISO 8536-13:2016 Infusion equipment for medical use — Part 13: Graduated flow regulators for single use with fluid contact
47.	ISO 8536-12:2021 Infusion equipment for medical use — Part 12: Check valves for single use
48.	ISO 8536-11:2015 Infusion equipment for medical use — Part 11: Infusion filters for single use with pressure infusion equipment
49.	ISO 8536-10:2015 Infusion equipment for medical use — Part 10: Accessories for fluid lines for single use with pressure infusion equipment

50.	ISO 8536-9:2015 Infusion equipment for medical use — Part 9: Fluid lines for single use with pressure infusion equipment
51.	ISO 8536-8:2015 Infusion equipment for medical use — Part 8: Infusion sets for single use with pressure infusion apparatus
52.	ISO 8536-7:2009 Infusion equipment for medical use — Part 7: Caps made of aluminium-plastics combinations for infusion bottles
53.	ISO 8536-6:2016 Infusion equipment for medical use — Part 6: Freeze drying closures for infusion bottles
54.	ISO 8536-5:2004 Infusion equipment for medical use — Part 5: Burette infusion sets for single use, gravity feed
55.	ISO 8536-4:2019 Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed
56.	ISO 8536-3:2009 Infusion equipment for medical use — Part 3: Aluminium caps for infusion bottles
57.	ISO 8536-2:2023 Infusion equipment for medical use — Part 2: Closures for infusion bottles
58.	ISO 8536-1:2011 Infusion equipment for medical use — Part 1: Infusion glass bottles
59.	ISO 8362-7:2006 Injection containers and accessories — Part 7: Injection caps made of aluminium-plastics combinations without overlapping plastics part

60.	ISO 8362-6:2010 Injection containers and accessories — Part 6: Caps made of aluminium-plastics combinations for injection vials
61.	ISO 8362-5:2016 Injection containers and accessories — Part 5: Freeze drying closures for injection vials
62.	ISO 8362-4:2011 Injection containers and accessories — Part 4: Injection vials made of moulded glass
63.	ISO 8362-3:2001 Injection containers and accessories — Part 3: Aluminium caps for injection vials
64.	ISO 8362-2:2015 Injection containers and accessories — Part 2: Closures for injection vials
65.	ISO 8362-1:2018 Injection containers and accessories — Part 1: Injection vials made of glass tubing
66.	ISO 6710:2017 Single-use containers for human venous blood specimen collection
67.	ISO 4802-2:2016 Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 2: Determination by flame spectrometry and classification
68.	ISO 4802-1:2016 Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 1: Determination by titration method and classification
69.	ISO 3826-4:2015 Plastics collapsible containers for human blood and blood components — Part 4: Aphaeresis blood bag systems with integrated features

70.	ISO 3826-3:2006 Plastics collapsible containers for human blood and blood components — Part 3: Blood bag systems with integrated features
71.	ISO 3826-2:2008 Plastics collapsible containers for human blood and blood components — Part 2: Graphical symbols for use on labels and instruction leaflets
72.	ISO 3826-1:2019 Plastics collapsible containers for human blood and blood components — Part 1: Conventional containers
73.	ISO 3749:2022 Glass syringes — Determination of extractable tungsten
74.	ISO 1135-5:2015 Transfusion equipment for medical use — Part 5: Transfusion sets for single use with pressure infusion apparatus
75.	ISO 1135-4:2015 Transfusion equipment for medical use — Part 4: Transfusion sets for single use, gravity feed
76.	ISO 1135-3:2016 Transfusion equipment for medical use — Part 3: Blood-taking sets for single use
77.	ISO 720:2020 Glass — Hydrolytic resistance of glass grains at 121 °C — Method of test and classification
78.	ISO 719:2020 Glass — Hydrolytic resistance of glass grains at 98 °C — Method of test and classification

Biological Evaluation	
1.	ISO/TR 10993-22:2017 Biological evaluation of medical devices — Part 22: Guidance on nanomaterials
2.	ISO 10993-23:2021 Biological evaluation of medical devices — Part 23: Tests for irritation
3.	ISO/TR 10993-33:2015 Biological evaluation of medical devices — Part 33: Guidance on tests to evaluate genotoxicity — Supplement to ISO 10993-3
4.	ISO/TR 10993-55:2023 Biological evaluation of medical devices — Part 55: Interlaboratory study on cytotoxicity
5.	ISO/TS 11796:2023 Biological evaluation of medical devices — Requirements for interlaboratory studies to demonstrate the applicability of validated in vitro methods to assess the skin sensitization of medical devices
6.	ISO/TR 21582:2021 Pyrogenicity — Principles and methods for pyrogen testing of medical devices
7.	ISO/TS 21726:2019 Biological evaluation of medical devices — Application of the threshold of toxicological concern (TTC) for assessing biocompatibility of medical device constituents
8.	ISO/TR 22442-4:2010 Medical devices utilizing animal tissues and their derivatives — Part 4: Principles for elimination and/or inactivation of transmissible spongiform encephalopathy (TSE) agents and validation assays for those processes

9.	ISO/TS 37137-1:2021 Biological evaluation of absorbable medical devices — Part 1: General requirements
10.	ISO/TR 37137:2014 Cardiovascular biological evaluation of medical devices — Guidance for absorbable implants

Implantable Devices	
1.	ISO 7197:2006 + Cor 1:2007 Neurosurgical implants — Sterile, single-use hydrocephalus shunts and components
2.	ISO 9713:2022 Neurosurgical implants — Self-closing intracranial aneurysm clips
3.	ISO 13179-1:2021 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/TR 14283:2018 Implants for surgery — Essential principles of safety and performance
5.	ISO 14607:2018 Non-active surgical implants — Mammary implants — Particular requirements
6.	ISO 14630:2012 Non-active surgical implants — General requirements
7.	ISO 16054:2019 Implants for surgery — Minimum data sets for surgical implants
8.	ISO 16061:2021 Instruments for use in association with non-active surgical implants — General requirements
9.	ISO 17327-1:2018 Non-active surgical implants — Implant coating — Part 1: General requirements
10.	ISO 19213:2017 Implants for surgery — Test methods of material for use as a cortical bone model

11.	ISO 19227:2018 Implants for surgery — Cleanliness of orthopedic implants — General requirements
12.	ISO 14708-1:2014 Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
13.	ISO 14708-2:2019 Implants for surgery — Active implantable medical devices — Part 2: Cardiac pacemakers
14.	ISO 14708-3:2017 Implants for surgery — Active implantable medical devices — Part 3: Implantable neurostimulators
15.	ISO 14708-4:2022 Implants for surgery — Active implantable medical devices — Part 4: Implantable infusion pump systems
16.	ISO 14708-5:2020 Implants for surgery — Active implantable medical devices — Part 5: Circulatory support devices
17.	ISO 14708-6:2019 Implants for surgery — Active implantable medical devices — Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators)
18.	ISO 14708-7:2019 Implants for surgery — Active implantable medical devices — Part 7: Particular requirements for cochlear and auditory brainstem implant systems
19.	ISO 27185:2012 Cardiac rhythm management devices — Symbols to be used with cardiac rhythm management device labels, and information to be supplied — General requirements
20.	IEC 60601-2-31:2020

	Medical electrical equipment — Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source
21.	ISO 5840-1:2021 Cardiovascular implants - Cardiovascular implants - Cardiac valve prostheses - Part 1: General requirements
22.	ISO 5840-2:2021 Cardiovascular implants — Cardiac valve prostheses — Part 2: Surgically implanted heart valve substitutes
23.	ISO 5840-3:2021 Cardiovascular implants — Cardiac valve prostheses — Part 3: Heart valve substitutes implanted by transcatheter techniques
24.	ISO 7198:2016 Cardiovascular implants and extracorporeal systems — Vascular prostheses — Tubular vascular grafts and vascular patches
25.	ISO 7199:2016 + Amd 1:2020 Cardiovascular implants and artificial organs — Blood-gas exchangers (oxygenators)
26.	ISO 8637-1:2017 Extracorporeal systems for blood purification — Part 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators
27.	ISO 8637-2:2018 Extracorporeal systems for blood purification — Part 2: Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters
28.	ISO 8637-3:2018 Extracorporeal systems for blood purification — Part 3: Plasmafilters

29.	ISO 12417-1:2015 Cardiovascular implants and extracorporeal systems — Vascular device-drug combination products — Part 1: General requirements
30.	ISO 15675:2016 Cardiovascular implants and artificial organs — Cardiopulmonary bypass systems — Arterial blood line filters
31.	ISO 15676:2016 Cardiovascular implants and artificial organs — Requirements for single-use tubing packs for cardiopulmonary bypass and extracorporeal membrane oxygenation (ECMO)
32.	ISO/TS 17137:2021 Cardiovascular implants and extracorporeal systems — Cardiovascular absorbable implants
33.	ISO 18193:2021 Cardiovascular implants and artificial organs — Cannulae for extracorporeal circulation
34.	ISO 23500-1:2019 Preparation and quality management of fluids for haemodialysis and related therapies — Part 1: General requirements
35.	ISO 23500-2:2019 Preparation and quality management of fluids for haemodialysis and related therapies — Part 2: Water treatment equipment for haemodialysis applications and related therapies
36.	ISO 23500-3:2019 Preparation and quality management of fluids for haemodialysis and related therapies — Part 3: Water for haemodialysis and related therapies
37.	ISO 23500-4:2019 Preparation and quality management of fluids for haemodialysis and related therapies — Part 4: Concentrates for haemodialysis and related therapies

38.	ISO 23500-5:2019 Preparation and quality management of fluids for haemodialysis and related therapies — Part 5: Quality of dialysis fluid for haemodialysis and related therapies
39.	ISO 7206-1:2008 Implants for surgery — Partial and total hip joint prostheses — Part 1: Classification and designation of dimensions
40.	ISO 7206-2:2011+ Amd 1:2016 Implants for surgery — Partial and total hip joint prostheses — Part 2: Articulating surfaces made of metallic, ceramic and plastics materials
41.	ISO 7206-6:2013 Implants for surgery — Partial and total hip joint prostheses — Part 6: Endurance properties testing and performance requirements of neck region of stemmed femoral components
42.	ISO 7206-10:2018+ Amd 1:2021 Implants for surgery — Partial and total hip-joint prostheses — Part 10: Determination of resistance to static load of modular femoral heads
43.	ISO 7206-12:2016 Implants for surgery — Partial and total hip joint prostheses — Part 12: Deformation test method for acetabular shells
44.	ISO 7206-13:2016+ Amd 1:2022Implants for surgery — Partial and total hip joint prostheses — Part 13: Determination of resistance to torque of head fixation of stemmed femoral components
45.	ISO 21534:2007 Non-active surgical implants — Joint replacement implants — Particular requirements
46.	ISO/TS 20721:2020 Implants for surgery — General guidelines and requirements for assessment of absorbable metallic implants

47.	ISO 22926:2023 Implants for surgery — Specification and verification of synthetic anatomical bone models for testing
48.	ISO 5832-1:2016 Implants for surgery — Metallic materials — Part 1: Wrought stainless steel
49.	ISO 5832-2:2018 Implants for surgery — Metallic materials — Part 2: Unalloyed titanium
50.	ISO 5832-3:2021 Implants for surgery — Metallic materials — Part 3: Wrought titanium 6-aluminium 4-vanadium alloy
51.	ISO 5832-4:2014 Implants for surgery — Metallic materials — Part 4: Cobalt-chromium-molybdenum casting alloy
52.	ISO 5832-5:2022 Implants for surgery — Metallic materials — Part 5: Wrought cobalt-chromium-tungsten-nickel
53.	ISO 5832-6:2022 Implants for surgery — Metallic materials — Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy
54.	ISO 5832-7:2016 Implants for surgery — Metallic materials — Part 7: Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy
55.	ISO 5832-9:2019 Implants for surgery — Metallic materials — Part 9: Wrought high nitrogen stainless steel
56.	ISO 5832-11:2014 Implants for surgery — Metallic materials — Part 11: Wrought titanium 6-aluminium 7-niobium alloy

57.	ISO 5832-12:2019 Implants for surgery — Metallic materials — Part 12: Wrought cobalt-chromium-molybdenum alloy
58.	ISO 5832-14:2019 Implants for surgery — Metallic materials — Part 14: Wrought titanium 15-molybdenum 5-zirconium 3-aluminium alloy
59.	ISO 5833:2002 Implants for surgery — Acrylic resin cements
60.	ISO 6474-1:2019 Implants for surgery — Ceramic materials — Part 1: Ceramic materials based on high purity alumina
61.	ISO 6474-2:2019 Implants for surgery — Ceramic materials — Part 2: Composite materials based on a high-purity alumina matrix with zirconia reinforcement
62.	ISO 13779-4:2018 Implants for surgery — Hydroxyapatite — Part 4: Determination of coating adhesion strength
63.	ISO 13782:2019 Implants for surgery — Metallic materials — Unalloyed tantalum for surgical implant applications
64.	ISO 15374:1998 Implants for surgery — Requirements for production of forgings
65.	ISO 16402:2008 Implants for surgery — Acrylic resin cement — Flexural fatigue testing of acrylic resin cements used in orthopaedics
66.	ISO/TS 21560:2020 General requirements of tissue-engineered medical products

Prosthetics and Orthotics	
1.	ISO 10328:2016 Prosthetics - Structural testing of lower-limb prostheses - Requirements and test methods
2.	ISO 22523:2006 External limb prostheses and external orthoses - Requirements and test methods
3.	ISO 22675:2016 Prosthetics - Testing of ankle-foot devices and foot units - Requirements and test methods
4.	ISO/TS 4549:2023 Orthotics -Method for testing the reliability of microprocessor-controlled ankle moment units of ankle-foot orthoses
5.	ISO 8548-1:1989 Prosthetics and orthotics — Limb deficiencies — Part 1: Method of describing limb deficiencies present at birth
6.	ISO 8548-2:2020 Prosthetics and orthotics — Limb deficiencies — Part 2: Method of describing lower limb amputation stumps
7.	ISO 8548-3:1993 Prosthetics and orthotics — Limb deficiencies — Part 3: Method of describing upper limb amputation stumps
8.	ISO 8548-4:1998 Prosthetics and orthotics — Limb deficiencies — Part 4: Description of causal conditions leading to amputation

9.	ISO 8548-5:2003 Prosthetics and orthotics — Limb deficiencies — Part 5: Description of the clinical condition of the person who has had an amputation
10.	ISO 8549-1:2020 Prosthetics and orthotics — Vocabulary — Part 1: General terms for external limb prostheses and external orthoses
11.	ISO 8549-2:2023 Prosthetics and orthotics — Vocabulary — Part 2: Terms relating to external limb prostheses
12.	ISO 8549-3:2020 Prosthetics and orthotics — Vocabulary — Part 3: Terms relating to orthoses
13.	ISO 8549-4:2020 Prosthetics and orthotics — Vocabulary — Part 4: Terms relating to limb amputation
14.	ISO 8551:2020 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
15.	ISO 13404:2007 Prosthetics and orthotics — Categorization and description of external orthoses and orthotic components
16.	ISO 13405-1:2015 Prosthetics and orthotics — Classification and description of prosthetic components — Part 1: Classification of prosthetic components
17.	ISO 13405-2:2015 Prosthetics and orthotics — Classification and description of prosthetic components — Part 2: Description of lower limb prosthetic components

18.	ISO 13405-3:2015 Prosthetics and orthotics — Classification and description of prosthetic components — Part 3: Description of upper limb prosthetic components
19.	ISO 15032:2000 Prostheses — Structural testing of hip units
20.	ISO/TS 16955:2016 Prosthetics — Quantification of physical parameters of ankle foot devices and foot units
21.	ISO 21063:2017 Prosthetics and orthotics — Soft orthoses — Uses, functions, classification and description
22.	ISO 21064:2017 Prosthetics and orthotics — Foot orthotics — Uses, functions classification and description
23.	ISO 21065:2017 Prosthetics and orthotics — Terms relating to the treatment and rehabilitation of persons having a lower limb amputation
24.	ISO/TR 22676:2006 Prosthetics — Testing of ankle-foot devices and foot units — Guidance on the application of the test loading conditions of ISO 22675 and on the design of appropriate test equipment
25.	ISO 24562:2022 Prosthetics — Geometrical aspects of lower limb prosthetic adapters
26.	ISO 29781:2008 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

27.	ISO 29782:2022 Prostheses and orthoses — Factors to be considered when specifying a prosthesis for a person who has had a lower limb amputation
28.	ISO 29783-1:2008 Prosthetics and orthotics — Vocabulary — Part 1: Normal gait
29.	ISO 29783-2:2015 Prosthetics and orthotics — Vocabulary — Part 2: Prosthetic gait
30.	ISO 29783-3:2016 Prosthetics and orthotics — Vocabulary — Part 3: Pathological gait (excluding prosthetic gait)

Surgical Instruments	
1.	ISO 7151:1988 Surgical instruments — Non-cutting, articulated instruments — General requirements and test methods
2.	ISO 7153-1:2016 Surgical instruments — Materials — Part 1: Metals
3.	ISO 7740:1985 Instruments for surgery — Scalpels with detachable blades — Fitting dimensions
4.	ISO 7741:1986 Instruments for surgery — Scissors and shears — General requirements and test methods
5.	ISO 13402:1995 Surgical and dental hand instruments — Determination of resistance against autoclaving, corrosion and thermal exposure

Sterilization and Disinfectants	
1.	ISO 11135:2014/AMD 1:2018 Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices — Amendment 1: Revision of Annex E, Single batch release
2.	ISO 11140-1:2014 Sterilization of health care products - Chemical indicators - Part 1: General requirements
3.	ISO 11140-3:2007, including Cor 1:2007 Sterilization of health care products - Chemical indicators - Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test
4.	ISO 13408-2:2018 Aseptic processing of health care products - Part 2: Filtration
5.	ISO 13408-3:2006 Aseptic processing of health care products - Part 3: Lyophilization
6.	ISO 13408-4:2005 Aseptic processing of health care products - Part 4: Clean-in-place technologies
7.	ISO 13408-5:2006 Aseptic processing of health care products - Part 5: Sterilization in place
8.	ISO 13408-7:2012 Aseptic processing of health care products - Part 7: Alternative processes for medical devices and combination products

9.	ISO 14937:2009 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
10.	ISO 15882:2008 Sterilization of health care products — Chemical indicators — Guidance for selection, use and interpretation of results
11.	ISO 15883-1:2006/Amd 1:2014 Washer-disinfectors - Part 1: General requirements, terms and definitions and tests
12.	ISO 15883-2:2006 Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.
13.	ISO 15883-3:2006 Washer-disinfectors - Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers (ISO 15883-3:2006)
14.	ISO 15883-4:2018 Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes
15.	ISO 15883-5:2021 Washer-disinfectors — Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy
16.	ISO 15883-6:2011 Washer-disinfectors — Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment
17.	ISO 15883-7:2016 Washer-disinfectors — Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment

18.	ISO/TS 16775:2021 Packaging for terminally sterilized medical devices — Guidance on the application of ISO 11607-1 and ISO 11607-2
19.	ISO 17664-1:2021 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
20.	ISO 17664-2:2021 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
21.	ISO 11137-2:2013+Amd 1:2022 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
22.	ISO 11137-3:2017 Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects of development, validation and routine control
23.	ISO/TS 11137-4:2020 Sterilization of health care products — Radiation — Part 4: Guidance on process control
24.	ISO 11138-8:2021 Sterilization of health care products — Biological indicators — Part 8: Method for validation of a reduced incubation time for a biological indicator
25.	ISO 11139:2018 Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards
26.	ISO 11140-4:2007 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

27.	ISO 11140-5:2007 Sterilization of health care products — Chemical indicators — Part 5: Class 2 indicators for Bowie and Dick-type air removal tests
28.	ISO 11140-6:2022 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
29.	ISO 11607-1:2019+Amd 1:2023 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
30.	ISO 11607-2:2019, including Amd 1:2023 Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes
31.	ISO 11737-1:2018 Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
32.	ISO 11737-2:2019 Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
33.	ISO 11737-3:2023 Sterilization of health care products — Microbiological methods — Part 3: Bacterial endotoxin testing
34.	ISO 13004:2022 Sterilization of health care products — Radiation — Substantiation of selected sterilization dose: Method VDmaxSD
35.	ISO 13408-6:2021 Aseptic processing of health care products — Part 6: Isolator systems

36.	ISO 14160:2020 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
37.	ISO 18362:2016+Amd 1:2022 Manufacture of cell-based health care products — Control of microbial risks during processing
38.	ISO 18472:2018 Sterilization of health care products — Biological and chemical indicators — Test equipment
39.	ISO/TS 21387:2020 Sterilization of medical devices — Guidance on the requirements for the validation and routine processing of ethylene oxide sterilization processes using parametric release
40.	ISO/TS 22421:2021 Sterilization of health care products — Common requirements for sterilizers for terminal sterilization of medical devices in health care facilities
41.	ISO 22441:2022 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
42.	ISO/TS 22456:2021 Sterilization of healthcare products — Microbiological methods— Guidance on conducting bioburden determinations and tests of sterility for biologics and tissue-based products
43.	ISO 17665-1:2006 Sterilization of health care products -- moist heat -- part 1: requirements for the development, validation and routine control of a sterilization process for medical devices
44.	ISO/TS 17665-2:2009 Sterilization of health care products -- moist heat -- part 2: guidance on the application of iso 17665-1

45.	ISO/TS 17665-3:2013 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
46.	ISO 25424:2018+Amd 1:2022 Sterilization of health care products -- low temperature steam and formaldehyde -- requirements for development, validation and routine control of a sterilization process for medical devices
47.	EN 13624:2021 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)
48.	EN 14561:2005 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)
49.	EN 14348:2006 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)
50.	ISO/TS 5111:2022 Guidance on quality of water for sterilizers, sterilization and washer-disinfectors for health care products

In vitro diagnostic	
1.	ISO 18113-1:2022 In vitro diagnostic medical devices Information supplied by the manufacturer (labelling) Part 1: Terms, definitions, and general requirements
2.	ISO 18113-2:2022 In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for professional use
3.	ISO 18113-3:2022 In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 3: In vitro diagnostic instruments for professional use
4.	ISO 18113-4:2022 In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 4: In vitro diagnostic reagents for self-testing
5.	ISO 18113-5:2022 In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 5: In vitro diagnostic instruments for self-testing
6.	ISO 11137-1:2006 Sterilization of health care products Radiation Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
7.	ISO 11137-2:2013 Sterilization of health care products Radiation Part 2: Establishing the sterilization dose
8.	ISO 11737-1:2018 Sterilization of health care products Microbiological methods Part 1: Determination of a population of microorganisms on products

9.	ISO 11737-2:2019 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 11737-3:2023 Sterilization of health care products Microbiological methods Part 3: Bacterial endotoxin testing
11.	ISO 11135:2014 Sterilization of health-care products Ethylene oxide Requirements for the development, validation and routine control of a sterilization process for medical devices
12.	ISO 25424:2018 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 17511:2020 In vitro diagnostic medical devices Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples
14.	ISO 6717:2021 In vitro diagnostic medical devices Single-use containers for the collection of specimens from humans other than blood
15.	ISO 15197:2013 In vitro diagnostic test systems Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus
16.	ISO 17511:2020 In vitro diagnostic medical devices Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples
17.	ISO 23640:2011 In vitro diagnostic medical devices Evaluation of stability of in vitro diagnostic reagents

18.	ISO 17593:2022 Clinical laboratory testing and in vitro medical devices Requirements for in vitro monitoring systems for self-testing of oral anticoagulant therapy
19.	ISO 20916:2019 In vitro diagnostic medical devices Clinical performance studies using specimens from human subjects Good study practice
20.	IEC 61010-2-101:2018 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 61326-2-6:2020 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
22.	IEC 62366-1:2015/Amd 1:2020 Medical devices Part 1: Application of usability engineering to medical devices
23.	IEC 62304:2006 Medical device software — Software life cycle processes
24.	ISO 13485 :2016 Medical devices -- Quality management systems -- Requirements for regulatory purposes
25.	ISO 14971:2019 Medical devices — Application of risk management to medical devices
26.	ISO 20417:2021 Medical devices — Information to be supplied by the manufacturer

27.	ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
28.	ISO 15223-2:2010 Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 2: Symbol development, selection and validation
29.	ISO/TR 20416:2020 Medical devices — Post-market surveillance for manufacturers
30.	EN 13532:2002 General requirements for in vitro diagnostic medical devices for self-testing
31.	EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
32.	EN 13641:2002 Elimination or reduction of risk of infection related to in vitro diagnostic reagents

Electromedical	
1.	IEC 60118-13:2019 Electroacoustics - Hearing aids - Part 13: Requirements and methods of measurement for electromagnetic immunity to mobile digital wireless devices
2.	IEC 60522-1:2020 Medical electrical equipment - Diagnostics X-rays - Part 1: Determination of quality equivalent filtration and permanent filtration
3.	IEC TR 60522-2:2020 Medical electrical equipment - Diagnostics X-rays - Part 2: Guidance and rationale on quality equivalent filtration and permanent filtration
4.	IEC 60580:2019 Medical electrical equipment - Dose area product meters
5.	IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
6.	IEC 60601-2-1:2009 Medical electrical equipment - Part 2-1: Particular requirements for the safety of electron accelerators in the range of 1 MeV to 50 MeV
7.	IEC 60601-2-2:2017 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
8.	IEC 60601-2-3:2012+AMD1:2016 CSV Consolidated version Medical electrical equipment - Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment

9.	IEC 60601-2-5:2009 Medical electrical equipment - Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment
10.	IEC 60601-2-8:2010+AMD1:2015 CSV Consolidated version 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
11.	IEC 60601-2-17:2013 Medical electrical equipment - Part 2-17: Particular requirements for the safety of automatically-controlled brachytherapy after loading equipment
12.	IEC 60601-2-18:2015 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment (IEC 60601-2-18:2009)
13.	IEC 60601-2-19:2009+AMD1:2016 Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators
14.	IEC 60601-2-20:2009+AMD1:2016 CSV Consolidated version Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators
15.	IEC 60601-2-21:2009+AMD1:2016 CSV Consolidated version Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers
16.	IEC 60601-2-23:2011 Medical electrical equipment - Part 2-23: Particular requirements for the safety, including essential performance, of transcutaneous partial pressure monitoring equipment
17.	IEC 60601-2-27:2011 Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment.

18.	IEC 60601-2-28:2017 Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
19.	IEC 60601-2-29:2008 Medical electrical equipment - Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators
20.	IEC 60601-2-33:2010+AMD1: 2013+AMD2:2015 CSV Consolidated version Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis
21.	IEC 60601-2-36:2014 Medical electrical equipment - Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy
22.	IEC 60601-2-37:2007+AMD1:2015 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
23.	IEC 60601-2-39:2018 Medical electrical equipment - Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment
24.	IEC 60601-2-40:2016 Medical electrical equipment - Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment
25.	IEC 60601-2-41:2009+AMD1:2013 CSV Consolidated version Medical electrical equipment - Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis
26.	IEC 60601-2-45:2011+AMD1:2015 CSV Consolidated version Medical electrical equipment - Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices

27.	IEC 60601-2-46:2016 Medical electrical equipment -- Part 2-46: Particular requirements for the safety of operating tables
28.	IEC 60601-2-47:2012 Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
29.	IEC 60601-2-49:2018 Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment
30.	IEC 60601-2-50:2009+AMD1:2016 Medical electrical equipment - Part 2-50: Particular requirementsfor the basic safety and essential performance of infant phototherapy equipment
31.	IEC 60601-2-52:2009 Medical electrical equipment Part 2-52: Particular requirements for the basic safety and essential performance of medical beds
32.	IEC 60601-2-52:2009/Cor 1:2010 Medical electrical equipment Part 2-52: Particular requirements for the basic safety and essential performance of medical beds Technical Corrigendum 1
33.	IEC 60601-2-52:2009/Amd 1:2015 Medical electrical equipment Part 2-52: Particular requirements for the basic safety and essential performance of medical beds Amendment 1
34.	IEC 60645-1:2017 Electroacoustic - Audiological equipment - Part 1: Pure-tone audiometers

35.	IEC 61676:2002+AMD1:2008 Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology
36.	IEC 62220-1-1:2015 Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-1: Determination of the detective quantum efficiency - Detectors used in radiographic imaging
37.	IEC 62220-1-2:2007 Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-2: Determination of the detective quantum efficiency - Detectors used in mammography
38.	IEC 62220-1-3:2008 Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-3: Determination of the detective quantum efficiency - Detectors used in dynamic imaging
39.	IEC 80601-2-35:2009+AMD1:2016 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
40.	IEC 80601-2-31:2020 Medical electrical equipment - Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source
41.	IEC 80601-2-58:2014+AMD1:2016 CSV Consolidated version 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
42.	IEC 80601-2-59:2017 Medical electrical equipment - Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening
43.	IEC 80601-2-59:2017/Amd 1:2023

	Medical electrical equipment — Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening — Amendment 1
44.	IEC 60601-1:2005+AMD1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
45.	IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
46.	IEC 80601-2-26:2019 Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalograph
47.	IEC 60601-2-31:2020 Medical electrical equipment - Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source
48.	IEC 60601-2-57:2011 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
49.	ISO 81060-2:2018 Non-invasive sphygmomanometers — Part 2: Clinical investigation of intermittent automated measurement type
50.	ISO 81060-2:2018/Amd 1:2020 Non-invasive sphygmomanometers — Part 2: Clinical investigation of intermittent automated measurement type — Amendment 1
51.	IEC 60601-2-4/AMD 2 Amendment 2 - Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators

52.	ISO 81060-3:2022 Non-invasive sphygmomanometers — Part 3: Clinical investigation of continuous automated measurement type
53.	ISO/TS 81060-5:2020 Non-invasive sphygmomanometers — Part 5: Requirements for the repeatability and reproducibility of NIBP simulators for testing of automated non-invasive sphygmomanometers
54.	ISO 80601-2-56:2017 Medical electrical equipment — Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
55.	ISO 80601-2-56:2017/Amd 1:2018 Medical electrical equipment — Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement — Amendment 1
56.	ISO 80601-2-80:2018 Medical electrical equipment - Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency
57.	ISO 80601-2-90:2021 Medical electrical equipment Part 2-90: Particular requirements for basic safety and essential performance of respiratory high-flow therapy equipment
58.	IEC-62281:2016 Safety of primary and secondary lithium cells and batteries during transport
59.	ISO 80601-2-90:2021 Medical electrical equipment — Part 2-90: Particular requirements for basic safety and essential performance of respiratory high-flow therapy equipment
60.	IEC-60601-1-10:2015

	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
61.	IEC 80601-2-49:2018 Medical electrical equipment — Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
62.	IEC 80601-2-52 Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds
63.	IEC 80601-2-71:2015 Medical electrical equipment — Part 2-71: Particular requirements for the basic safety and essential performance of functional Near-Infrared Spectroscopy (NIRS) equipment
64.	ISO 80601-2-85:2021 Medical electrical equipment — Part 2-85: Particular requirements for the basic safety and essential performance of cerebral tissue oximeter equipment
65.	IEC 80601-2-30:2018 Medical electrical equipment — Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers
66.	ISO 80601-2-61:2017 Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

Radiology	
1.	IEC 61217:2011 Radiotherapy equipment - Coordinates, movements and scales
2.	IEC 62220-1:2015 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 60627:2013 Diagnostic X-ray imaging equipment - Characteristics of general purpose and mammographic anti-scatter grids
4.	ISO 15382:2015 Radiological protection — Procedures for monitoring the dose to the lens of the eye, the skin and the extremities
5.	ISO 5576:1997 Non-destructive testing — Industrial X-ray and gamma-ray radiology — Vocabulary
6.	ISO 5579:2013 Non-destructive testing — Radiographic testing of metallic materials using film and X- or gamma rays — Basic rules
7.	ISO 5580:1985 Non-destructive testing — Industrial radiographic illuminators — Minimum requirements
8.	ISO 11699-1:2008 Non-destructive testing — Industrial radiographic film — Part 1: Classification of film systems for industrial radiography
9.	ISO 11699-2:2018 Non-destructive testing — Industrial radiographic films — Part 2: Control of film processing by means of reference values

10.	ISO 12721:2000 Non-destructive testing — Thermal neutron radiographic testing — Determination of beam L/D ratio
11.	ISO 14096-1:2005 Non-destructive testing — Qualification of radiographic film digitisation systems — Part 1: Definitions, quantitative measurements of image quality parameters, standard reference film and qualitative control
12.	ISO 14096-2:2005 Non-destructive testing — Qualification of radiographic film digitisation systems — Part 2: Minimum requirements
13.	ISO 15708-1:2017 Non-destructive testing — Radiation methods for computed tomography — Part 1: Terminology
14.	ISO 15708-2:2017 Non-destructive testing — Radiation methods for computed tomography — Part 2: Principles, equipment and samples
15.	ISO 15708-3:2017 Non-destructive testing — Radiation methods for computed tomography — Part 3: Operation and interpretation
16.	ISO 15708-4:2017 Non-destructive testing — Radiation methods for computed tomography — Part 4: Qualification
17.	ISO 16371-1:2011 Non-destructive testing — Industrial computed radiography with storage phosphor imaging plates — Part 1: Classification of systems
18.	ISO 16371-2:2017 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

19.	ISO 16526-1:2011 Non-destructive testing — Measurement and evaluation of the X-ray tube voltage — Part 1: Voltage divider method
20.	ISO 16526-2:2011 Non-destructive testing — Measurement and evaluation of the X-ray tube voltage — Part 2: Constancy check by the thick filter method
21.	ISO 16526-3:2011 Non-destructive testing — Measurement and evaluation of the X-ray tube voltage — Part 3: Spectrometric method
22.	ISO 19232-1:2013 Non-destructive testing — Image quality of radiographs — Part 1: Determination of the image quality value using wire-type image quality indicators
23.	ISO 19232-2:2013 Non-destructive testing — Image quality of radiographs — Part 2: Determination of the image quality value using step/hole-type image quality indicators
24.	ISO 19232-3:2013 Non-destructive testing — Image quality of radiographs — Part 3: Image quality classes
25.	ISO 19232-4:2013 Non-destructive testing — Image quality of radiographs — Part 4: Experimental evaluation of image quality values and image quality tables
26.	ISO 19232-5:2018 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
27.	ISO 20769-1:2018 Non-destructive testing — Radiographic inspection of corrosion and deposits in pipes by X- and gamma rays — Part 1: Tangential radiographic inspection

28.	ISO 20769-2:2018 Non-destructive testing — Radiographic inspection of corrosion and deposits in pipes by X- and gamma rays — Part 2: Double wall radiographic inspection
29.	ISO 21432:2019 Non-destructive testing — Standard test method for determining residual stresses by neutron diffraction
30.	ISO 23159:2020 Non-destructive testing — Gamma ray scanning method on process columns

Dentistry	
1.	ISO 3990:2023 Dentistry — Evaluation of antibacterial activity of dental restorative materials, luting materials, fissure sealants and orthodontic bonding or luting materials
2.	ISO 7405:2018 Dentistry — Evaluation of biocompatibility of medical devices used in dentistry
3.	ISO 3107:2022 Dentistry — Zinc oxide-eugenol cements and non-eugenol zinc oxide cements
4.	ISO 4049:2019 Dentistry — Polymer-based restorative materials
5.	ISO/TS 4640:2023 Dentistry — Test methods for tensile bond strength to tooth structure
6.	ISO 6872:2015+ Amd 1:2018 Dentistry — Ceramic materials
7.	ISO 6874:2015 Dentistry — Polymer-based pit and fissure sealants
8.	ISO 6876:2012 Dentistry — Root canal sealing materials
9.	ISO 6877:2021 Dentistry — Endodontic obturating materials
10.	ISO 7405:2018 Dentistry — Evaluation of biocompatibility of medical devices used in dentistry

11.	ISO/TS 4640:2023 Dentistry — Test methods for tensile bond strength to tooth structure
12.	ISO 9917-1:2007 Dentistry — Water-based cements — Part 1: Powder/liquid acid-base cements
13.	ISO 9917-2:2017 Dentistry — Water-based cements — Part 2: Resin-modified cements
14.	ISO 9693:2019 Dentistry — Compatibility testing for metal-ceramic and ceramic-ceramic systems
15.	ISO 10271:2020 Dentistry — Corrosion test methods for metallic materials
16.	ISO 14801:2016 Dentistry — Implants — Dynamic loading test for endosseous dental implants
17.	ISO 22674:2022 Dentistry — Metallic materials for fixed and removable restorations and appliances
18.	ISO 22794:2007 Dentistry — Implantable materials for bone filling and augmentation in oral and maxillofacial surgery — Contents of a technical file
19.	ISO 22803:2004 Dentistry — Membrane materials for guided tissue regeneration in oral and maxillofacial surgery — Contents of a technical file
20.	ISO 24234:2021 Dentistry — Dental amalgam

21.	ISO/TS 11405:2015 Dentistry — Testing of adhesion to tooth structure
22.	ISO 13116:2014 Dentistry — Test method for determining radio-opacity of materials
23.	ISO 29022:2013 Dentistry — Adhesion — Notched-edge shear bond strength test
24.	ISO 6873:2013 Dentistry — Gypsum products
25.	ISO 7491:2000 Dental materials — Determination of colour stability
26.	ISO 9333:2022 Dentistry — Brazing materials
27.	ISO 9693:2019 Dentistry — Compatibility testing for metal-ceramic and ceramic-ceramic systems
28.	ISO 10139-1:2018 Dentistry — Soft lining materials for removable dentures — Part 1: Materials for short-term use
29.	ISO 10139-2:2016 Dentistry — Soft lining materials for removable dentures — Part 2: Materials for long-term use
30.	ISO 10271:2020 Dentistry — Corrosion test methods for metallic materials
31.	ISO 10477:2020 Dentistry — Polymer-based crown and veneering materials

32.	ISO 13017:2020 Dentistry — Magnetic attachments
33.	ISO 13078-2:2016 Dentistry — Dental furnace — Part 2: Test method for evaluation of furnace programme via firing glaze
34.	ISO 13078-3:2023 Dentistry — Dental furnace — Part 3: Test method for the evaluation of high temperature sintering furnace measurement with a separate thermocouple
35.	ISO 13078:2013 Dentistry — Dental furnace — Test method for temperature measurement with separate thermocouple
36.	ISO 14233:2003 Dentistry — Polymer-based die materials
37.	ISO 14356:2003 Dentistry — Duplicating material
38.	ISO/TR 14569-1:2007 Dental materials — Guidance on testing of wear — Part 1: Wear by toothbrushing
39.	ISO/TS 14569-2:2001 Dental materials — Guidance on testing of wear — Part 2: Wear by two- and/or three body contact
40.	ISO 15854:2023 Dentistry — Casting and baseplate waxes
41.	ISO/TS 19736:2017 Dentistry — Bonding test between polymer teeth and denture base materials

42.	ISO 20795-1:2013 Dentistry — Base polymers — Part 1: Denture base polymers
43.	ISO 20795-2:2013 Dentistry — Base polymers — Part 2: Orthodontic base polymers
44.	ISO 21563:2021 Dentistry — Hydrocolloid impression materials
45.	ISO 22112:2017 Dentistry — Artificial teeth for dental prostheses
46.	ISO 22598:2020 Dentistry — Colour tabs for intraoral tooth colour determination
47.	ISO 22674:2022 Dentistry — Metallic materials for fixed and removable restorations and appliances
48.	ISO 23401-1:2023 Dentistry — Chairside denture base relining materials — Part 1: Hard type materials
49.	ISO 28319:2018 Dentistry — Laser welding and filler materials
50.	ISO 1797:2017 Dentistry — Shanks for rotary and oscillating instruments
51.	ISO 3630-1:2019 Dentistry — Endodontic instruments — Part 1: General requirements
52.	ISO 3630-2:2023 Dentistry — Endodontic instruments — Part 2: Enlargers

53.	ISO 3630-3:2021 Dentistry — Endodontic instruments — Part 3: Compactors
54.	ISO 3630-4:2023 Dentistry — Endodontic instruments — Part 4: Auxiliary instruments
55.	ISO 3630-5:2020 Dentistry — Endodontic instruments — Part 5: Shaping and cleaning instruments
56.	ISO/TR 3630-6:2023 Dentistry — Endodontic instruments — Part 6: Numeric coding system
57.	ISO 3823-1:1997 Dental rotary instruments — Burs — Part 1: Steel and carbide burs
58.	ISO 3823-2:2003+ Amd 1:2008 Dentistry — Rotary bur instruments — Part 2: Finishing burs
59.	ISO 3964:2016+ Amd 1:2018 Dentistry — Coupling dimensions for handpiece connectors
60.	ISO 4865-1:2023 Dentistry — General requirements of hand instruments — Part 1: Non-hinged hand instruments
61.	ISO 6360-1:2004+ Cor 1:2007 Dentistry — Number coding system for rotary instruments — Part 1: General characteristics
62.	ISO 6360-2:2004+ Amd 1:2011 Dentistry — Number coding system for rotary instruments — Part 2: Shapes
63.	ISO 6360-3:2005

	Dentistry — Number coding system for rotary instruments — Part 3: Specific characteristics of burs and cutters
64.	ISO 6360-4:2004 Dentistry — Number coding system for rotary instruments — Part 4: Specific characteristics of diamond instruments
65.	ISO 6360-5:2007 Dentistry — Number coding system for rotary instruments — Part 5: Specific characteristics of root-canal instruments
66.	ISO 6360-6:2004 Dentistry — Number coding system for rotary instruments — Part 6: Specific characteristics of abrasive instruments
67.	ISO 6360-7:2006 Dentistry — Number coding system for rotary instruments — Part 7: Specific characteristics of mandrels and special instruments
68.	ISO 7492:2019 Dentistry — Dental explorer
69.	ISO 7711-1:2021 Dentistry — Diamond rotary instruments — Part 1: General requirements
70.	ISO 7711-2:2011 Dentistry — Rotary diamond instruments — Part 2: Discs
71.	ISO 7786:2001 Dental rotary instruments — Laboratory abrasive instruments
72.	ISO 7787-1:2016 Dentistry — Laboratory cutters — Part 1: Steel laboratory cutters

73.	ISO 7787-2:2020 Dentistry — Laboratory cutters — Part 2: Carbide laboratory cutters
74.	ISO 7787-3:2017 Dentistry — Laboratory cutters — Part 3: Carbide cutters for milling machines
75.	ISO 7787-4:2002 Dental rotary instruments — Cutters — Part 4: Miniature carbide laboratory cutters
76.	ISO 7885:2010 Dentistry — Sterile injection needles for single use
77.	ISO 8325:2023 Dentistry — Test methods for rotary instruments
78.	ISO 9168:2009 Dentistry — Hose connectors for air driven dental handpieces
79.	ISO 9173-1:2016 Dentistry — Extraction forceps — Part 1: General requirements
80.	ISO 9173-2:2010 Dentistry — Extraction forceps — Part 2: Designation
81.	ISO 9173-3:2014 Dentistry — Extraction forceps — Part 3: Design
82.	ISO 9873:2019 Dentistry — Intra-oral mirrors
83.	ISO 9997:2020 Dentistry — Cartridge syringes

84.	ISO 10323:2013 Dentistry — Bore diameters for rotary instruments such as discs and wheels
85.	ISO 11499:2014 Dentistry — Single-use cartridges for local anaesthetics
86.	ISO 13295:2007 Dentistry — Mandrels for rotary instruments
87.	ISO 13397-1:1995 Periodontal curettes, dental scalers and excavators — Part 1: General requirements
88.	ISO 13397-2:2005+Amd 1:2012 Dentistry — Periodontal curettes, dental scalers and excavators — Part 2: Periodontal curettes of Gr-type
89.	ISO 13397-3:1996 Periodontal curettes, dental scalers and excavators — Part 3: Dental scalers — H-type
90.	ISO 13397-5:2015 Dentistry — Periodontal curettes, dental scalers and excavators — Part 5: Jacquette scalers
91.	ISO 13504:2012 Dentistry — General requirements for instruments and related accessories used in dental implant placement and treatment
92.	ISO 14457:2017 Dentistry — Handpieces and motors
93.	ISO 15087-1:1999 Dental elevators — Part 1: General requirements

94.	ISO 15087-2:2000 Dental elevators — Part 2: Warwick James elevators
95.	ISO 15087-3:2000 Dental elevators — Part 3: Cryer elevators
96.	ISO 15087-4:2000 Dental elevators — Part 4: Coupland elevators
97.	ISO 15087-5:2000 Dental elevators — Part 5: Bein elevators
98.	ISO 15087-6:2000 Dental elevators — Part 6: Flohr elevators
99.	ISO 15098:2020 Dentistry — Dental tweezers
100.	ISO 16635-1:2013 Dentistry — Dental rubber dam technique — Part 1: Hole punch
101.	ISO 16635-2:2014 Dentistry — Dental rubber dam instruments — Part 2: Clamp forceps
102.	ISO 17509:2016 Dentistry — Torque transmitter for handpieces
103.	ISO 17937:2015 Dentistry — Osteotome
104.	ISO 18397:2016 Dentistry — Powered scaler

105.	ISO 18556:2016 Dentistry — Intraoral spatulas
106.	ISO 19490:2017 Dentistry — Sinus membrane elevator
107.	ISO 19715:2017 Dentistry — Filling instrument with contra angle
108.	ISO 20569:2018 Dentistry — Trephine burs
109.	ISO 20570:2018 Dentistry — Oral surgical scalpel handle
110.	ISO 20608:2018 Dentistry — Powder jet handpieces and powders
111.	ISO 21531:2009 Dentistry — Graphical symbols for dental instruments
112.	ISO 21533:2018 Dentistry — Reprocessable cartridge syringes for intraligamentary injections
113.	ISO 21671:2006+Amd 1:2011 Dentistry — Rotary polishers
114.	ISO 21672-1:2012 Dentistry — Periodontal probes — Part 1: General requirements
115.	ISO 21672-2:2012 Dentistry — Periodontal probes — Part 2: Designation

116.	ISO 21850-1:2020 Dentistry — Materials for dental instruments — Part 1: Stainless steel
117.	ISO 22569:2020 Dentistry — Multifunction handpieces
118.	ISO 22570:2020 Dentistry — Spoons and bone curettes
119.	ISO 23445:2021 Dentistry — Tissue punches
120.	ISO 23450:2021 Dentistry — Intraoral camera
121.	ISO 23940:2021 Dentistry — Excavators
122.	ISO 5467-1:2022 Dentistry — Mobile dental units and dental patient chairs — Part 1: General requirements
123.	ISO 7488:2018 Dentistry — Mixing machines for dental amalgam
124.	ISO 7493:2006 Dentistry — Operator's stool
125.	ISO 7494-1:2018 Dentistry — Stationary dental units and dental patient chairs — Part 1: General requirements
126.	ISO 7494-2:2022 Dentistry — Stationary dental units and dental patient chairs — Part 2: Air, water, suction and wastewater systems

127.	ISO 9680:2021 Dentistry — Operating lights
128.	ISO 9687:2015+ Amd 1:2018 Dentistry — Graphical symbols for dental equipment
129.	ISO 10637:2018 Dentistry — Central suction source equipment
130.	ISO 10650:2018 Dentistry — Powered polymerization activators
131.	ISO 11143:2008 Dentistry — Amalgam separators
132.	ISO 13897:2018 Dentistry — Dental amalgam reusable mixing-capsules
133.	ISO 16954:2015 Dentistry — Test methods for dental unit waterline biofilm treatment
134.	ISO 21530:2004 Dentistry — Materials used for dental equipment surfaces — Determination of resistance to chemical disinfectants
135.	ISO 22052:2020 Dentistry — Central compressed air source equipment
136.	ISO 23402-1:2020 Dentistry — Portable dental equipment for use in non-permanent healthcare environment — Part 1: General requirements
137.	IEC 80601-2-60:2019

	Medical electrical equipment — Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment
138.	ISO 10451:2010 Dentistry — Contents of technical file for dental implant systems
139.	ISO 11953:2010 Dentistry — Implants — Clinical performance of hand torque instruments
140.	ISO/TS 13498:2011 Dentistry — Torsion test of implant body/connecting part joints of endosseous dental implant systems
141.	ISO 14801:2016 Dentistry — Implants — Dynamic loading test for endosseous dental implants
142.	ISO 16498:2013 Dentistry — Minimal dental implant data set for clinical use
143.	ISO/TR 18130:2016 Dentistry — Screw loosening test using cyclic torsional loading for implant body/implant abutment connection of endosseous dental implants
144.	ISO 19429:2015 Dentistry — Designation system for dental implants
145.	ISO 22683:2022 Dentistry — Rotational adaptability test between implant body and implant abutment in dental implant system
146.	ISO 22794:2007 Dentistry — Implantable materials for bone filling and augmentation in oral and maxillofacial surgery — Contents of a technical file

147.	ISO 22803:2004 Dentistry — Membrane materials for guided tissue regeneration in oral and maxillofacial surgery — Contents of a technical file
148.	ISO 5139:2023 Dentistry — Polymer-based composite machinable blanks
149.	ISO 12836:2015 Dentistry — Digitizing devices for CAD/CAM systems for indirect dental restorations — Test methods for assessing accuracy
150.	ISO 18618:2022 Dentistry — Interoperability of CAD/CAM systems
151.	ISO 18675:2022 Dentistry — Machinable ceramic blanks
152.	ISO 20896-1:2019 Dentistry — Digital impression devices — Part 1: Methods for assessing accuracy
153.	ISO/TR 20896-2:2023 Dentistry — Digital impression devices — Part 2: Methods for assessing accuracy for implanted devices
154.	ISO/TR 22710:2019 Dentistry — Vocabulary of process chain from dental CT to CAD/CAM for implant prosthetic restorations — Backward planning in the digital process chain
155.	ISO 23298:2023 Dentistry — Test methods for machining accuracy of computer-aided milling machines

Optical and Ophthalmic	
1.	ISO 7998:2005 Ophthalmic optics — Spectacle frames — Lists of equivalent terms and vocabulary
2.	ISO 8429:1986 Optics and optical instruments — Ophthalmology — Graduated dial scale
3.	ISO 8596:2017 Ophthalmic optics — Visual acuity testing — Standard and clinical optotypes and their presentation
4.	ISO 8596:2017/Amd 1:2019 Ophthalmic optics — Visual acuity testing — Standard and clinical optotypes and their presentation — Amendment 1
5.	ISO 8598-1:2014 Optics and optical instruments — Focimeters — Part 1: General purpose instruments
6.	ISO 8612:2009 Ophthalmic instruments — Tonometers
7.	ISO 8624:2020 Ophthalmic optics — Spectacle frames — Measuring system and vocabulary
8.	ISO 8980-1:2017 Ophthalmic optics — Uncut finished spectacle lenses — Part 1: Specifications for single-vision and multifocal lenses
9.	ISO 8980-2:2017 Ophthalmic optics — Uncut finished spectacle lenses — Part 2: Specifications for power-variation lenses

10.	ISO 8980-3:2022 Ophthalmic optics — Uncut finished spectacle lenses — Part 3: Transmittance specifications and test methods
11.	ISO 8980-4:2006 Ophthalmic optics — Uncut finished spectacle lenses — Part 4: Specifications and test methods for anti-reflective coatings
12.	ISO 8980-5:2005 Ophthalmic optics — Uncut finished spectacle lenses — Part 5: Minimum requirements for spectacle lens surfaces claimed to be abrasion-resistant
13.	ISO 9342-1:2023 Optics and optical instruments — Test lenses for calibration of focimeters — Part 1: Reference lenses for focimeters used for measuring spectacle lenses
14.	ISO 9342-2:2005 Optics and optical instruments — Test lenses for calibration of focimeters — Part 2: Test lenses for focimeters used for measuring contact lenses
15.	ISO 9394:2012 Ophthalmic optics — Contact lenses and contact lens care products — Determination of biocompatibility by ocular study with rabbit eyes
16.	ISO 9801:2009 Ophthalmic instruments — Trial case lenses
17.	ISO 10322-1:2016 Ophthalmic optics — Semi-finished spectacle lens blanks — Part 1: Specifications for single-vision and multifocal lens blanks
18.	ISO 10341:2012 Ophthalmic instruments — Refractor heads

19.	ISO 10342:2010 Ophthalmic instruments — Eye refractometers
20.	ISO 10343:2014 Ophthalmic instruments — Ophthalmometers
21.	ISO 10939:2017 Ophthalmic instruments — Slit-lamp microscopes
22.	ISO 10940:2009 Ophthalmic instruments — Fundus cameras
23.	ISO 10942:2022 Ophthalmic instruments — Direct ophthalmoscopes
24.	ISO 10943:2023 Ophthalmic instruments — Indirect ophthalmoscopes
25.	ISO 10944:2009 Ophthalmic instruments — Synoptophores
26.	ISO 11978:2017 Ophthalmic optics — Contact lenses and contact lens care products — Labelling
27.	ISO 11978:2017/Amd 1:2020 Ophthalmic optics — Contact lenses and contact lens care products — Labelling — Amendment 1

28.	ISO 11979-1:2018 Ophthalmic implants — Intraocular lenses — Part 1: Vocabulary
29.	ISO 11979-2:2014 Ophthalmic implants — Intraocular lenses — Part 2: Optical properties and test methods
30.	ISO 11979-3:2012 Ophthalmic implants — Intraocular lenses — Part 3: Mechanical properties and test methods
31.	ISO 11979-4:2008 Ophthalmic implants — Intraocular lenses — Part 4: Labelling and information
32.	ISO 11979-4:2008/Amd 1:2012 Ophthalmic implants — Intraocular lenses — Part 4: Labelling and information — Amendment 1
33.	ISO 11979-5:2020 Ophthalmic implants — Intraocular lenses — Part 5: Biocompatibility
34.	ISO 11979-6:2014 Ophthalmic implants — Intraocular lenses — Part 6: Shelf-life and transport stability testing
35.	ISO 11979-7:2018 Ophthalmic implants — Intraocular lenses — Part 7: Clinical investigations of intraocular lenses for the correction of aphakia
36.	ISO 11979-8:2017 Ophthalmic implants — Intraocular lenses — Part 8: Fundamental requirements

37.	ISO 11981:2017 Ophthalmic optics — Contact lenses and contact lens care products — Determination of physical compatibility of contact lens care products with contact lenses
38.	ISO 11987:2012 Ophthalmic optics — Contact lenses — Determination of shelf-life
39.	ISO 12865:2006 Ophthalmic instruments — Retinoscopes
40.	ISO 12867:2010 Ophthalmic instruments — Trial frames
41.	ISO 14534:2011 Ophthalmic optics — Contact lenses and contact lens care products — Fundamental requirements
42.	ISO 14729:2001 Ophthalmic optics — Contact lens care products — Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses
43.	ISO 14730:2014 Ophthalmic optics — Contact lens care products — Antimicrobial preservative efficacy testing and guidance on determining discard date
44.	ISO 14889:2013/Amd 1:2017 Ophthalmic optics — Spectacle lenses — Fundamental requirements for uncut finished lenses — Amendment 1
45.	ISO 15253:2021 Ophthalmic optics and instruments — Optical and electro-optical devices for enhancing low vision

46.	ISO 15798:2022 Ophthalmic implants — Ophthalmic viscosurgical devices
47.	ISO 16034:2002 Ophthalmic optics — Specifications for single-vision ready-to-wear near- vision spectacles
48.	ISO 16672:2020 Ophthalmic implants — Ocular endotamponades
49.	ISO 16971:2015 Ophthalmic instruments — Optical coherence tomograph for the posterior segment of the human eye
50.	ISO 18189:2016 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
51.	ISO 18259:2014 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
52.	ISO 18369-1:2017 Ophthalmic optics — Contact lenses — Part 1: Vocabulary, classification system and recommendations for labelling specifications
53.	ISO 18369-3:2017 Ophthalmic optics — Contact lenses — Part 3: Measurement methods
54.	ISO 18369-4:2017 Ophthalmic optics — Contact lenses — Part 4: Physicochemical properties of contact lens materials

55.	ISO 19045:2015 Ophthalmic optics — Contact lens care products — Method for evaluating Acanthamoeba encystment by contact lens care products
56.	ISO 19980:2021 Ophthalmic instruments — Corneal topographers
57.	ISO 21987:2017 Ophthalmic optics — Mounted spectacle lenses
58.	ISO 22665:2012 Ophthalmic optics and instruments - Instruments to measure axial distances in the eye

Health Informatics	
1.	IEC/TR 80001-2-3:2012 Application of risk management for IT-networks incorporating medical devices — Part 2-3: Guidance for wireless networks
2.	IEC/TR 80001-2-4:2012 Application of risk management for IT-networks incorporating medical devices — Part 2-4: General implementation guidance for Healthcare Delivery Organizations
3.	IEC/TR 80001-2-5:2014 Application of risk management for IT-networks incorporating medical devices — Part 2-5: Application guidance — Guidance for distributed alarm systems
4.	IEC/TR 80001-2-8:2016 Application of risk management for IT-networks incorporating medical devices — Part 2-8: Application guidance — Guidance on standards for establishing the security capabilities identified in IEC 80001-2-2
5.	IEC/TR 80001-2-9:2017 Application of risk management for IT-networks incorporating medical devices — Part 2-9: Application guidance — Guidance for use of security assurance cases to demonstrate confidence in IEC/TR 80001-2-2 security capabilities
6.	IEC/TR 80001-2-6:2014 Application of risk management for IT-networks incorporating medical devices — Part 2-6: Application guidance — Guidance for responsibility agreements
7.	IEC/TR 80001-2-7:2015 Application of risk management for IT-networks incorporating medical devices — Application guidance — Part 2-7: Guidance for healthcare delivery organizations (HDOs) on how to self-assess their conformance with IEC 80001-1
8.	IEC 82304-1:2016 Health software — Part 1: General requirements for product safety

Assistive Products	
1.	ISO 19894:2019 Walking trolleys — Requirements and test methods
2.	ISO 7176-1:2014 Wheelchairs — Part 1: Determination of static stability
3.	ISO 7176-5:2008 Wheelchairs — Part 5: Determination of dimensions, mass and manoeuvring space
4.	ISO 7176-8:2014 Wheelchairs -- part 8: requirements and test methods for static, impact and fatigue strengths
5.	ISO 7176-11:2012 Wheelchairs — Part 11: Test dummies
6.	ISO 7176-13:1989 Wheelchairs — Part 13: Determination of coefficient of friction of test surfaces
7.	ISO 7176-15:1996 Wheelchairs — Part 15: Requirements for information disclosure, documentation and labelling
8.	ISO 7176-16:2012 Wheelchairs -- part 16: resistance to ignition of postural support devices
9.	ISO 7176-19:2008/AMD 1:2015 Wheelchairs — Part 19: Wheeled mobility devices for use as seats in motor vehicles- Amendment 1: Annex G

10.	ISO 7176-21:2009 Wheelchairs -- part 21: requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
11.	ISO 7176-25:2022 Wheelchairs Part 25: Lead-acid batteries and chargers for powered wheelchairs. Requirements and test methods
12.	ISO 21856:2022 Assistive products — General requirements and test methods
13.	ISO/TR 11548-1:2001 Communication aids for blind persons — Identifiers, names and assignation to coded character sets for 8-dot Braille characters — Part 1: General guidelines for Braille identifiers and shift marks
14.	ISO/TR 11548-2:2001 Communication aids for blind persons — Identifiers, names and assignation to coded character sets for 8-dot Braille characters — Part 2: Latin alphabet based character sets
15.	ISO 20342-1:2022 Assistive products for tissue integrity when lying down — Part 1: General requirements
16.	ISO/TR 20342-7:2021 Assistive products for tissue integrity when lying down — Part 7: Foam properties, characteristics and performance
17.	ISO 21801-1:2020 Cognitive accessibility — Part 1: General guidelines
18.	ISO 21801-2:2022 Cognitive accessibility — Part 2: Reporting

19.	ISO 21802:2019 Assistive products — Guidelines on cognitive accessibility — Daily time management
20.	ISO 23600:2007 Assistive products for persons with vision impairments and persons with vision and hearing impairments — Acoustic and tactile signals for pedestrian traffic lights
21.	ISO 24415-2:2011 Tips for assistive products for walking — Requirements and test methods — Part 2: Durability of tips for crutches
22.	ISO 7176-2:2017 Wheelchairs — Part 2: Determination of dynamic stability of electrically powered wheelchairs
23.	ISO 7176-4:2008 Wheelchairs — Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range
24.	ISO 7176-6:2018 Wheelchairs — Part 6: Determination of maximum speed of electrically powered wheelchairs
25.	ISO 7176-10:2008 Wheelchairs — Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs
26.	ISO 7176-22:2014 Wheelchairs — Part 22: Set-up procedures
27.	ISO 7176-26:2007 Wheelchairs — Part 26: Vocabulary

28.	ISO 7176-28:2012 Wheelchairs — Part 28: Requirements and test methods for stair-climbing devices
29.	ISO 7176-30:2018 Wheelchairs — Part 30: Wheelchairs for changing occupant posture — Test methods and requirements
30.	ISO 7176-31:2023 Wheelchairs — Part 31: Lithium-ion battery systems and chargers for powered wheelchairs — Requirements and test methods
31.	ISO 7176-32:2022 Wheelchairs — Part 32: Test method for wheelchair castor assembly durability
32.	ISO 10542-1:2012 Technical systems and aids for disabled or handicapped persons — Wheelchair tiedown and occupant-restraint systems — Part 1: Requirements and test methods for all systems
33.	ISO 10542-1:2012/Amd 1:2021 Technical systems and aids for disabled or handicapped persons — Wheelchair tiedown and occupant-restraint systems — Part 1: Requirements and test methods for all systems — Amendment 1: Annexes K, L, M
34.	ISO 10542-1:2012/Cor 1:2013 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
35.	ISO 10865-1:2012 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

36.	ISO 10865-2:2015 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
37.	ISO/TR 13570-1:2005 Wheelchairs — Part 1: Guidelines for the application of the ISO 7176 series on wheelchairs
38.	ISO/TR 13570-2:2014 Wheelchairs — Part 2: Typical values and recommended limits of dimensions, mass and manoeuvring space as determined in ISO 7176-5
39.	ISO 16840-1:2006 Wheelchair seating — Part 1: Vocabulary, reference axis convention and measures for body segments, posture and postural support surfaces
40.	ISO 16840-2:2018 Wheelchair seating — Part 2: Determination of physical and mechanical characteristics of seat cushions intended to manage tissue integrity
41.	ISO 16840-3:2022 Wheelchair seating — Part 3: Determination of static, impact, and repetitive load strengths for postural support devices
42.	ISO 16840-4:2009 Wheelchair seating — Part 4: Seating systems for use in motor vehicles
43.	ISO 16840-6:2015 Wheelchair seating — Part 6: Simulated use and determination of the changes in properties of seat cushions

44.	ISO/TR 16840-9:2015 Wheelchair seating — Part 9: Clinical interface pressure mapping guidelines for seating
45.	ISO 16840-10:2021 Wheelchair seating — Part 10: Resistance to ignition of postural support devices — Requirements and test method
46.	ISO 16840-11:2022 Wheelchair seating — Part 11: Determination of dissipation characteristics of sensible perspiration into seat cushions
47.	ISO 16840-12:2021 Wheelchair seating — Part 12: Envelopment and immersion characterization of seat cushions using a dual semispherical indenter
48.	ISO 16840-13:2021 Wheelchair seating — Part 13: Determination of the lateral stability property of a seat cushion
49.	ISO/TS 16840-14:2023 Wheelchair seating — Part 14: Concepts related to managing external forces to maintain tissue integrity
50.	ISO 9999:2022 Assistive products — Classification and terminology
51.	ISO 8669-1:1988 Urine collection bags — Part 1: Vocabulary
52.	ISO 8670-1:1988 Ostomy collection bags — Part 1: Vocabulary

53.	ISO 8670-2:1996 Ostomy collection bags — Part 2: Requirements and test methods
54.	ISO 11948-1:1996 Urine-absorbing aids — Part 1: Whole-product testing
55.	ISO 12505-1:2014 Skin barrier for ostomy aids — Test methods — Part 1: Size, surface pH and water-absorbency
56.	ISO 12505-2:2016 Skin barrier for ostomy aids — Test methods — Part 2: Wet integrity and adhesive strength
57.	ISO 15621:2017 Absorbent incontinence aids for urine and/or faeces — General guidelines on evaluation
58.	ISO 16021:2000 Urine-absorbing aids — Basic principles for evaluation of single-use adult-incontinence-absorbing aids from the perspective of users and caregivers
59.	ISO 17190-1:2020 Urine-absorbing aids for incontinence — Polyacrylate superabsorbent powders — Part 1: Test method for determination of pH
60.	ISO 17190-2:2021 Urine-absorbing aids for incontinence — Polyacrylate superabsorbent powders — Part 2: Test method for determination of the amount of residual acrylate monomers
61.	ISO 17190-3:2020 Urine-absorbing aids for incontinence — Polyacrylate superabsorbent powders — Part 3: Test method for determination of the particle size distribution by sieve fractionation

62.	ISO 17190-4:2020 Urine-absorbing aids for incontinence — Polyacrylate superabsorbent powders — Part 4: Test method for estimation of the moisture content as weight loss upon heating
63.	ISO 17190-5:2020 Urine-absorbing aids for incontinence — Polyacrylate superabsorbent powders — Part 5: Test method for determination of the free swell capacity in saline by gravimetric measurement
64.	ISO 17190-6:2020 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
65.	ISO 17190-7:2020 Urine-absorbing aids for incontinence — Polyacrylate superabsorbent powders — Part 7: Test method for gravimetric determination of absorption against pressure
66.	ISO 17190-8:2020 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
67.	ISO 17190-9:2020 Urine-absorbing aids for incontinence — Polyacrylate superabsorbent powders — Part 9: Test method for gravimetric determination of flow rate and bulk density
68.	ISO 17190-10:2020 Urine-absorbing aids for incontinence — Polyacrylate superabsorbent powders — Part 10: Test method for determination of extractable polymer content by potentiometric titration
69.	ISO 17190-11:2001 Urine-absorbing aids for incontinence — Test methods for characterizing polymer-based absorbent materials — Part 11: Determination of content of respirable particles

70.	ISO 17191:2004 Urine-absorbing aids for incontinence — Measurement of airborne respirable polyacrylate superabsorbent materials — Determination of dust in collection cassettes by sodium atomic absorption spectrometry
71.	ISO 22748:2021 Absorbent incontinence products for urine and/or faeces — Product type names and illustrations2466
72.	ISO 24669:2021 Water-absorbent polyacrylate in urine absorbing products — Requirements
73.	ISO 17049:2013 Accessible design — Application of braille on signage, equipment and appliances
74.	ISO 17069:2020 Accessible design — Consideration and assistive products for accessible meeting
75.	ISO 19029:2016 Accessible design — Auditory guiding signals in public facilities

Medical Face Masks	
1.	EN 14683:2019+AC: 2019 Medical face masks Requirements and test methods
2.	ASTM F2100 – 19e1 Standard specification for performance of materials used in medical face masks
3.	GSO ISO 22609:2009 Clothing for protection against infectious agents - Medical face masks - Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)
4.	ASTM F2101 – 14 Standard test method for evaluating the Bacterial Filtration Efficiency (BFE) of medical face mask materials, using a biological aerosol of staphylococcus aureus
5.	ASTM F2299 ASTM F2299/F2299M – 03(2017) Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
6.	EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing and marking
7.	NFPA 702 Standard for Classification of the Flammability of Wearing Apparel
8.	ASTM F1862/F1862M – 17 Standard test method for resistance of medical face masks to penetration by synthetic blood (horizontal projection of fixed volume at a known velocity)
9.	EN 143:2007 RESPIRATORY PROTECTIVE DEVICES - PARTICLE FILTERS - REQUIREMENTS, TESTING, MARKING

10.	ASTM F2100 – 19 Standard Specification For Performance Of Materials Used In Medical Face Masks
11.	16 CFR Part 1610—STANDARD FOR THE FLAMMABILITY OF CLOTHING TEXTILES

Personal Protective Equipment for Medical Purpose	
1.	ISO 4007:2018 Personal protective equipment — Eye and face protection — Vocabulary
2.	ISO 4849:1981 Personal eye-protectors — Specifications
3.	EN 166/2002 Personal eye protection
4.	OSHA 1910.133 Eye and face protection

Complementary and Alternative Medicine	
1.	ISO 5227:2022 Traditional Chinese medicine — Safety controls for cupping devices
2.	ISO 19611:2017 Traditional Chinese medicine — Air extraction cupping device
3.	ISO 22213:2020 Traditional Chinese medicine — Glass cupping device
4.	ISO 17218:2014 Sterile acupuncture needles for single use
5.	ISO 18746:2016 Traditional Chinese medicine — Sterile intradermal acupuncture needles for single use
6.	ISO 22236:2020 Traditional Chinese medicine —Thread-embedding acupuncture needle for single use
7.	ISO 20308:2017 Traditional Chinese medicine — Gua Sha instruments

Contraception	
1.	ISO 16037:2002/Amd 1:2011 Rubber condoms for clinical trials — Measurement of physical properties — Amendment 1
2.	ISO 19671:2018 Additional lubricants for male natural rubber latex condoms — Effect on condom strength
3.	ISO/TR 19969:2018 Guidance on sample handling for determination of bursting volume and pressure, and testing for freedom from holes for male condom
4.	ISO/TR 24484:2023 Female condoms — Use of ISO 25841 and the quality management of female condoms
5.	ISO 25841:2017 Female condoms — Requirements and test methods
6.	ISO 25841:2017/Amd 1:2020 Female condoms — Requirements and test methods — Amendment 1
7.	ISO 29942:2011 Prophylactic dams — Requirements and test methods

Other	
1.	EN 60645-4:1995 Audiometers - Part 4: Equipment for extended high-frequency audiometry
2.	ISO 14698-1:2003 Cleanrooms and associated controlled environments -- biocontamination control -- part 1: general principles and methods
3.	ISO 14698-2:2003 + COR 1:2004 Cleanrooms and associated controlled environments -- biocontamination control -- part 2: evaluation and interpretation of biocontamination data
4.	ISO 14644-1:1999 Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration
5.	ISO 14644-2:2015 Cleanrooms and associated controlled environments — Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
6.	ISO 14644-3:2019 Cleanrooms and associated controlled environments — Part 3: Test methods
7.	ISO 14644-4:2001 Cleanrooms and associated controlled environments -- part 4: design, construction and start-up
8.	ISO 14644-5:2004 Cleanrooms and associated controlled environments -- part 5: operations
9.	ISO 14644-6:2007 Cleanrooms and associated controlled environments -- part 6: vocabulary

10.	ISO 14644-7:2004 Cleanrooms and associated controlled environments -- part 7: separative devices (clean air hoods, gloveboxes, isolators and mini-environments)
11.	ISO 14644-8:2013 Cleanrooms and associated controlled environments -- part 8: classification of air cleanliness by chemical concentration (ACC)
12.	ISO 14644-9:2012 Cleanrooms and associated controlled environments -- part 9: classification of surface cleanliness by particle concentration
13.	ISO 14644-10:2013 Cleanrooms and associated controlled environments -- part 10: classification of surface cleanliness by chemical concentration
14.	IEC 60529:1989+AMD1:1999+AMD2:2013 Degrees of protection provided by enclosures (IP Code)
15.	IEC 60825-1:2014 Safety of laser products - Part 1: Equipment classification and requirements
16.	IEC 61000-3-2:2018+AMD1:2020 Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤16 A per phase)
17.	IEC 61000-3-3:2013+AMD1:2017 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
18.	IEC 61000-4-2:2008 Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test

19.	IEC 61000-4-3:2006+AMD1:2007+AMD2:2010 Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test
20.	IEC 61000-4-4:2012 Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test
21.	IEC 61000-4-5:2014+AMD1:2017 Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test
22.	IEC 61000-4-6:2013 Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields
23.	IEC 61000-4-8:2009 Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test
24.	IEC 61000-4-11:2020 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
25.	CISPR 11:2015+AMD1:2016+AMD2:2019 Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement
26.	ISO 22609:2020 Clothing for protection against infectious agents -- medical face masks -- test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)

27.	ISO 386:1977 Liquid-in-glass laboratory thermometers -- principles of design, construction and use
28.	ASTM F2100 – 11(2018) Standard specification for performance of materials used in medical face masks
29.	IEC 81001-5-1:2021 Health software and health IT systems safety, effectiveness and security
30.	ISO 11117:2019 Gas cylinders.Valve protection caps and guards. Design, construction and tests
31.	ISO 22882:2016 Castors and wheels — Requirements for castors for hospital beds
32.	ISO 22610:2018 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
33.	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
34.	ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices
35.	ISO 10282:2023 Single-use sterile rubber surgical gloves Specification
36.	ISO 11193-1:2020 Single-use medical examination gloves Part 1: Specification for gloves made from rubber latex or rubber solution

37.	ISO 11193-2:2006 Single-use medical examination gloves Part 2: Specification for gloves made from poly(vinyl hloride)
38.	EN 455-1:2020+A1:2022 Medical gloves for single use - Part 1: Requirements and testing for freedom from holes
39.	EN 455-2:2015 Medical gloves for single use - Part 2: Requirements and testing for physical properties
40.	EN 455-3:2023 Medical gloves for single use - Part 3: Requirements and testing for biological evaluation
41.	EN 455-4:2009 Medical gloves for single use - Part 4: Requirements and testing for shelf life determination
42.	ISO 7886-1:2017 Sterile hypodermic syringes for single use Part 1: Syringes for manual use
43.	ISO 7886-2:2020 Sterile hypodermic syringes for single use Part 2: Syringes for use with power-driven syringe pumps
44.	ISO 7886-3:2020 Sterile hypodermic syringes for single use Part 3: Auto-disabled syringes for fixed-dose immunization
45.	ISO 7886-4:2018 Sterile hypodermic syringes for single use Part 4: Syringes with re-use prevention feature

Annex (1): Changing to Previous Documents

Number and date of previous version	Descriptions
MDS-G44 V1.0 2019/12/16 MDS-G46 V3.0 2020/06/17 MDS – G47 V1.0 2020/04/20 MDS – G004 V1.1 2022/12/14 MDS – G005 V1.1 2022/12/14 MDS – G006 V1.1 2022/12/14	• Update and merge the following documents: – SFDA Recognized Standards (Supporting Medical Device Premarket Submissions) – Guidance on Requirements for Medical Masks - Recognized Standards – Guidance on Requirements for Ventilators, Ventilator Tubing Connectors, and Ventilator Accessories – Recognized Standards. – Guidance for Requirements of Surgical and Medical Examination Gloves - Recognized Standards – Guidance for Requirements of sterile single-use hypodermic syringes - Recognized Standards – Guidance for Requirements of blood glucose metering devices and strips for home use - Recognized Standards