RS-01:2021(E)

Medical Device Administrative Control System (MDACS)

List of Recognised Standards for Medical Devices

Recognised Standards: RS-01

中華人民共和國
香港特別行政區政府衞生署

Department of Health
The Government of the Hong Kong Special Administrative Region
The People's Republic of China

Revision History

Version Number	Date of Revision	Summary of Revisions	Reference Number
0	NIL	• First issue of RS-01	RS-01:2015(E)
1	12 May 2021	• Update document format; • Rename Medical Device Control Office to Medical Device Division, and • Update list of standards	RS-01:2021(E)

Table of Contents

1. Introduction

1.1 Medical devices listed under the Medical Device Administrative Control System (MDACS) are required to meet the Essential Principles of Safety and Performance of Medical Devices[1]. To determine whether a device meets these requirements, one way is to make use of standards issued by national and international standards writing organizations.

The Medical Device Division (MDD) believes that conformance with recognised medical device standards, in whole or in part, can provide assurance of safety and performance for those aspects of medical devices addressed by these standards. The list of recognised standards established provides a good reference for Local Responsible Persons (and their manufacturers) to demonstrate the safety, quality and performance of their products in listing applications. It also helps MDD to ensure consistency in reviewing the listing applications, and save the resources needed to review the actual test data for those aspects of the device addressed by the standards.

Nevertheless, not all requirements for listing a device may be addressed by recognised standards, especially for new types of devices and emerging technologies. In these cases, other supporting documentary evidence should be submitted for evaluation, which may involve relevant industrial or factory standards. Besides, it should be noted that conformance with certain recognised standards sometimes may not be sufficient to demonstrate a device's full compliance with the Essential Principles of Safety and Performance of Medical Devices for making regulatory decisions.

[1] Essential Principles of Safety and Performance of Medical Devices as described in the Technical Reference TR-004 Essential Principles of Safety and Performance of Medical Devices.

2. Basic Standards

2.1 Biological evaluation

ISO 10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO 10993-2:2006	Biological evaluation of medical devices – Part 2: Animal welfare requirements
ISO 10993-3:2014	Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
ISO 10993-4:2017	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood
ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
ISO 10993-6:2016	Biological evaluation of medical devices – Part 6: Tests for local effects after implantation
ISO 10993-7:2008/ Amd 1:2019	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals – Amendment 1: Applicability of allowable limits for neonates and infants
ISO 10993-7:2008/ Cor 1:2009	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals – *Technical Corrigendum 1*
ISO 10993-9:2019	Biological evaluation of medical devices – Part 9: Framework for identification and quantification of potential degradation products
ISO 10993-10:2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
ISO 10993-11:2017	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
ISO 10993-12:2012	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
ISO 10993-13:2010	Biological evaluation of medical devices – Part 13: Identification and quantification of degradation products from polymeric medical devices

ISO 10993-14:2001	Biological evaluation of medical devices – Part 14: Identification and quantification of degradation products from ceramics
ISO 10993-15:2019	Biological evaluation of medical devices – Part 15: Identification and quantification of degradation products from metals and alloys
ISO 10993-16:2017	Biological evaluation of medical devices – Part 16: Toxicokinetic study design for degradation products and leachables
ISO 10993-17:2002	Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances
ISO 10993-18:2020	Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process
ISO/TS 10993-19:2020	Biological evaluation of medical devices – Part 19: Physico-chemical, morphological and topographical characterization of materials
ISO/TS 10993-20:2006	Biological evaluation of medical devices – Part 20: Principles and methods for immunotoxicology testing of medical devices

2.2 Clinical investigation

ISO 14155:2020	Clinical investigation of medical devices for human subjects – Good clinical practice

2.3 Quality management system (QMS)

ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes

2.4 Risk management

ISO 14971:2019	Medical devices – Application of risk management to medical devices

2.5 Symbols and labelling

ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
ISO 15223-2:2010	Medical devices – Symbols to be used with medical Device labels, labeling, and information to be supplied – Part 2: Symbol development, selection and validation
EN 1041:2008 +A1:2013	Information supplied by the manufacturer of medical devices
EN 15986:2011	Symbol for use in the labelling of medical devices – Requirements for labelling of medical devices containing phthalates

3. Group Standards

3.1 Absorbable implants (Biological evaluation)

ISO/TR 37137:2014	Cardiovascular biological evaluation of medical devices – Guidance for absorbable implants

3.2 Animal tissue and their derivatives (Biological evaluation)

ISO 22442-1:2015	Medical devices utilizing animal tissues and their derivatives – Part 1: Application of risk management
ISO 22442-2:2015	Medical devices utilizing animal tissues and their derivatives – Part 2: Controls on sourcing, collection and handling
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
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

3.3 Aseptic processing of health care products

ISO 13408-1:2008	Aseptic processing of health care products – Part 1: General requirements
ISO 13408-1:2008/ Amd1:2013	Aseptic processing of health care products – Part 1: General requirements – *Amendment 1*
ISO 13408-2:2018	Aseptic processing of health care products – Part 2: Sterilizing filtration
ISO 13408-3:2006	Aseptic processing of health care products – Part 3: Lyophilization

ISO 13408-4:2005	Aseptic processing of health care products – Part 4: Clean-in-place technologies
ISO 13408-5:2006	Aseptic processing of health care products – Part 5: Sterilization in place
ISO 13408-6:2005	Aseptic processing of health care products – Part 6: Isolator systems
ISO 13408-6:2005/ Amd 1:2013	Aseptic processing of health care products – Part 6: Isolator systems – *Amendment 1*
ISO 13408-7:2012	Aseptic processing of health care products – Part 7: Alternative processes for medical devices and combination products

3.4 Electrical equipment

IEC 60601-1:2005 +Amd1:2012 +Amd2:2020 CSV Consolidated version (Ed. 3.2)	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014 (Ed. 4)	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
IEC 60601-1-2:2014 +Amd1:2020 CSV Consolidated version (Ed. 4.1)	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
IEC 60601-1-6:2010 +Amd1:2013 +Amd2:2020 CSV Consolidated version (Ed. 3.2)	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability

IEC 60601-1-8:2006 +Amd1:2012 +Amd2:2020 CSV Consolidated version (Ed. 2.2)	Medical electrical equipment – Part 1-8: General requirements for safety – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 60601-1-9:2007 +Amd1:2013 +Amd2:2020 CSV Consolidated version (Ed. 1.2)	Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral standard: Requirements for environmentally conscious design
IEC 60601-1-10:2007 +Amd1:2013 +Amd2:2020 CSV Consolidated version (Ed 1.2)	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
IEC 60601-1-11:2015 +Amd1:2020 CSV Consolidated version (Ed. 2.1)	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

3.5 Human factor engineering

IEC 62366-1:2015 (Ed. 1)	Medical devices – Part 1: Application of usability engineering to medical devices
IEC 62366-1:2015/ Amd1:2020 (Ed. 1)	Medical devices – Part 1: Application of usability engineering to medical devices – *Amendment 1*
IEC 62366-1:2015/ Cor 1:2016 (Ed. 1)	Medical devices – Part 1: Application of usability engineering to medical devices – *Technical Corrigendum 1*
IEC 62366-1:2015 +Amd1:2020 CSV Consolidated version (Ed. 1.1)	Medical devices – Part 1: Application of usability engineering to medical devices

3.6 In vitro diagnostic medical devices (IVDMD)

ISO 15193:2009	In vitro diagnostic medical devices – Measurement of quantities in samples of biological origin – Requirements for content and presentation of reference measurement procedures
ISO 15194:2009	In vitro diagnostic medical devices – Measurement of quantities in samples of biological origin – Requirements for certified reference materials and the content of supporting documentation
ISO 15198:2004	Clinical laboratory medicine – In vitro diagnostic medical devices – Validation of user quality control procedures by the manufacturer
ISO 17511:2020	In vitro diagnostic medical devices – Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples
ISO 18113-1:2009	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements
ISO 18113-2:2009	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 2: In vitro diagnostic reagents for professional use
ISO 18113-3:2009	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 3: In vitro diagnostic instruments for professional use
ISO 18113-4:2009	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 4: In vitro diagnostic reagents for self-testing
ISO 18113-5:2009	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) -- Part 5: In vitro diagnostic instruments for self-testing
ISO 18153:2003	In vitro diagnostic medical devices – Measurement of quantities in biological samples – Metrological traceability of values for catalytic concentration of enzymes assigned calibrators and control materials

ISO 19001:2013	In vitro diagnostic medical devices – Information supplied by the manufacturer with in vitro diagnostic reagents for staining in biology
ISO 23640:2011	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents

3.7 Magnetic resonance environment

ASTM F2503-20	Standard practice for marking medical devices and other items for safety in the magnetic resonance environment

3.8 Software

IEC 62304:2006	Medical device software – Software life cycle processes
IEC 62304:2006/ Amd 1:2015	Medical device software – Software life cycle processes – *Amendment 1*
IEC 62304:2006 +AMD1:2015 CSV Consolidated version (Ed. 1.1)	Medical device software – Software life cycle processes
IEC/TR 80002-1:2009	Medical device software – Part 1: Guidance on the application of ISO 14971 to medical device software
IEC/TR 80002-3:2014	Medical device software – Part 3: Process reference model of medical device software life cycle processes (IEC 62304)

3.9 Sterilization

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
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*
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
ISO 11137-1:2006/ Amd1:2013	Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices – *Amendment 1*
ISO 11137-1:2006/ Amd2:2018	Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices – *Amendment 2: Revision to 4.3.4 and 11.2*
ISO 11137-2:2013	Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose
ISO 11137-3:2017	Sterilization of health care products – Radiation – Part 3: Guidance on dosimetric aspects of development, validation and routine control
ISO 11138-1:2017	Sterilization of health care products – Biological indicators – Part 1: General requirements
ISO 11138-2:2017	Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes
ISO 11138-3:2017	Sterilization of health care products – Biological indicators – Part 3: Biological indicators for moist heat sterilization processes
ISO 11138-4:2017	Sterilization of health care products – Biological indicators – Part 4: Biological indicators for dry heat sterilization processes

ISO 11138-5:2017	Sterilization of health care products – Biological indicators – Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes
ISO 11138-7:2019	Sterilization of health care products – Biological indicators – Part 7: Guidance for the selection, use and interpretation of results
ISO 11139:2018	Sterilization of health care products – Vocabulary of terms used in sterilization and related equipment and process standards
ISO 11140-1:2014	Sterilization of health care products – Chemical indicators – Part 1: General requirements
ISO 11140-3:2007	Sterilization of health care products – Chemical indicators – Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test
ISO 11140-3:2007/ 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 – *Technical Corrigendum 1*
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 penetration
ISO 11140-5:2007	Sterilization of health care products – Chemical indicators – Part 5: Class 2 indicators for Bowie and Dick-type air removal tests
ISO 11607-1:2019	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2:2019	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
ISO 11737-1:2018	Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products
ISO 11737-2:2019	Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

ISO/TS 13004:2013	Sterilization of health care products – Radiation – Substantiation of selected sterilization dose: Method VDMaxSD
ISO 14160:2011	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
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
ISO 15882:2008	Sterilization of health care products – Chemical indicators – Guidance for selection, use and interpretation of results
ISO 17664:2017	Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices
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
ISO/TS 17665-2:2009	Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ISO 17665-1
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
ISO 18472:2018	Sterilization of health care products – Biological and chemical indicators – Test equipment
ISO 20857:2010	Sterilization of health care products – Dry heat – Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 25424:2018	Sterilization of medical devices – Low temperature steam and formaldehyde – Requirements for development, validation and routine control of a sterilization process for medical devices

ASTM F1980 – 16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
EN 556-1:2001 /AC:2006	Sterilization of medical devices – Requirements for medical devices to be designated “STERILE” – Part 1 Requirements for terminally sterilized medical devices
EN 556-2:2015	Sterilization of medical devices – Requirements for medical devices to be designated “STERILE” – Part 2 Requirements for aseptically processedmedical devices

4. Product Standards

4.1 Acoustics and hearing aid devices

4.1.1 Audiometric equipment

IEC 60645-1:2017	Electroacoustics – Audiometric equipment – Part 1: Equipment for pure-tone speech audiometry
IEC 60645-3:2007	Electroacoustics – Audiometric equipment – Part 3: Test signals of short duration
IEC 60645-5:2004	Electroacoustics – Audiometric equipment – Part 5: Instruments for the measurement of aural acoustic impedance/admittance
IEC 60645-6:2009	Electroacoustics – Audiometric equipment – Part 6: Instruments for the measurement of otoacoustic emissions
IEC 60645-7:2009	Electroacoustics – Audiometric equipment – Part 7: Instruments for the measurement of auditory brainstem responses
ISO 389-1:2017	Acoustics – Reference zero for the calibration of audiometric equipment – Part 1: Reference equivalent threshold sound pressure levels for pure tones and supra-aural earphones
ISO 389-2:1994	Acoustics – Reference zero for the calibration of audiometric equipment – Part 2: Reference equivalent threshold sound pressure levels for pure tones and insert earphones
ISO 389-3:2016	Acoustics — Reference zero for the calibration of audiometric equipment — Part 3: Reference equivalent threshold vibratory force levels for pure tones and bone vibrators
ISO 389-4:1994	Acoustics – Reference zero for the calibration of audiometric equipment – Part 4: Reference levels for narrow-band masking noise
ISO 389-5:2006	Acoustics – Reference zero for the calibration of audiometric equipment – Part 5: Reference equivalent threshold sound pressure levels for pure tones in the frequency range 8 kHz to 16 kHz

ISO 389-6:2007	Acoustics – Reference zero for the calibration of audiometric equipment – Part 6: Reference threshold of hearing for test signals of short duration
ISO 389-7:2019	Acoustics — Reference zero for the calibration of audiometric equipment — Part 7: Reference threshold of hearing under free-field and diffuse-field listening conditions
ISO 389-8:2004	Acoustics – Reference zero for the calibration of audiometric equipment – Part 8: Reference equivalent threshold sound pressure levels for pure tones and circumaural earphones
ISO 389-9:2009	Acoustics – Reference zero for the calibration of audiometric equipment – Part 9: Preferred test conditions for the determination of reference hearing threshold levels
BS EN 60645-3:2007	Electroacoustics. Audiometric equipment. Test signals of short duration
BS EN 60645-5:2005	Electroacoustics. Audiometric equipment. Instruments for the measurement of aural acoustic impedance/admittance
BS EN 60645-6:2010	Electroacoustics. Audiometric equipment. Instruments for the measurement of otoacoustic emissions
BS EN 60645-7:2010	Electroacoustics. Audiometric equipment. Instruments for the measurement of auditory brainstem responses

4.1.2 Hearing aids

IEC 60318-1:2009	Electroacoustics – Simulators of human head and ear – Part 1: Ear simulator for the measurement of supra-aural and circumaural earphones
IEC 60318-3:2014	Electroacoustics – Simulators of human head and ear – Part 3: Acoustic coupler for the calibration of supra-aural earphones used in audiometry
IEC 60318-4:2010	Electroacoustics – Simulators of human head and ear – Part 4: Occluded-ear simulator for the measurement of earphones coupled to the ear by means of ear inserts

IEC 60318-5:2006	Electroacoustics – Simulators of human head and ear – Part 5: 2 cm^3 coupler for the measurement of hearing aids and earphones coupled to the ear by means of ear inserts
IEC 60318-6:2007	Electroacoustics – Simulators of human head and ear – Part 6: Mechanical coupler for the measurement on bone vibrators
IEC TS 60318-7:2017	Electroacoustics – Simulators of human head and ear – Part 7: Head and torso simulator for acoustic measurement of hearing aids

4.2 Anaesthetic, respiratory and reanimation equipment

4.2.1 Airways and related equipment

ISO 11712:2009	Anaesthetic and respiratory equipment – Supralaryngeal airways and connectors
ISO 16628:2008	Tracheobronchial tubes – Sizing and marking
ISO 27427:2013	Anaesthetic and respiratory equipment – Nebulizing systems and components
ISO 5361:2016	Anaesthetic and respiratory equipment – Tracheal tubes and connectors
ISO 5362:2006	Anaesthetic reservoir bags
ISO 5364:2016	Anaesthetic and respiratory equipment -- Oropharyngeal airways
ISO 5367:2014	Anaesthetic and respiratory equipment – Breathing sets and connectors
ISO 7376:2020	Anaesthetic and respiratory equipment – Laryngoscopes for tracheal intubation
ISO 8836:2019	Suction catheters for use in the respiratory tract

4.2.2 Breathing attachments and anaesthetic machines

ISO 11195:2018	Gas mixers for medical use – Stand-alone gas mixers
ISO 18835:2015	Inhalational anaesthesia systems — Draw-over anaesthetic systems
ISO 26825:2008	Anaesthetic and respiratory equipment – User-applied labels for syringes containing drugs used during anaesthesia – Colours, design and performance
ISO 5356-1:2015	Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets
ISO 5356-2:2012	Anaesthetic and respiratory equipment – Conical connectors – Part 2: Screw-threaded weight-bearing connectors
ISO 5356-2:2012/ Amd 1:2019	Anaesthetic and respiratory equipment – Conical connectors – Part 2: Screw-threaded weight-bearing connectors – *Amendment 1*
ISO 5359:2014	Anaesthetic and respiratory equipment – Low-pressure hose assemblies for use with medical gases
ISO 5359:2014/ Amd 1:2017	Anaesthetic and respiratory equipment – Low-pressure hose assemblies for use with medical gases – *Amendment 1*
ISO 5360:2016	Anaesthetic vaporizers – Agent-specific filling systems
ISO 80601-2-13:2011	Medical electrical equipment – Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation
ISO 80601-2-13:2011/ Amd 1:2015	Medical electrical equipment – Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation – *Amendment 1*
ISO 80601-2-13:2011/ Amd 2:2018	Medical electrical equipment – Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation – *Amendment 2*
ISO 80601-2-55:2018	Medical electrical equipment – Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors

ISO 8835-7:2011	Inhalational anaesthesia systems – Part 7: Anaesthetic systems for use in areas with limited logistical supplies of electricity and anaesthetic gases
CSA Z168.3-97 (R2011)	Anaesthetic Machines for Medical Use

4.2.3 Lung ventilators and related equipment

ISO 10651-4:2002	Lung ventilators – Part 4: Particular requirements for operator-powered resuscitators
ISO 10651-5:2006	Lung ventilators for medical use – Particular requirements for basic safety and essential performance – Part 5: Gas-powered emergency resuscitators
ISO 17510:2015	Medical devices – Sleep apnoea breathing therapy – Masks and application accessories
ISO 18778:2005	Respiratory equipment – Infant monitors – Particular requirements
ISO 23328-1:2003	Breathing system filters for anaesthetic and respiratory use – Part 1: Salt test method to assess filtration performance
ISO 23328-2:2002	Breathing system filters for anaesthetic and respiratory use – Part 2: Non-filtration aspects
ISO 23747:2015	Anaesthetic and respiratory equipment – Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans
ISO 26782:2009	Anaesthetic and respiratory equipment – Spirometers intended for the measurement of time forced expired volumes in humans
ISO 26782:2009/ Cor 1:2009	Anaesthetic and respiratory equipment – Spirometers intended for the measurement of time forced expired volumes in humans – *Technical Corrigendum 1*

ISO 80601-2-12:2020	Medical electrical equipment – Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
ISO 80601-2-61:2017	Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
ISO 80601-2-67:2014	Medical electrical equipment – Part 2-67: Particular requirements for basic safety and essential performance of oxygen-conserving equipment
ISO 80601-2-70:2015	Medical Electrical Equipment – Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment
ISO 80601-2-72:2015	Medical electrical equipment – Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients
ISO 80601-2-74:2017	Medical electrical equipment – Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment
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
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
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
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

ISO/IEEE 11073-10404:2010	Health informatics – Personal health device communication – Part 10404: Device specialization – Pulse oximeter

4.2.4 Medical gas systems

ISO 10524-1:2018	Pressure regulators for use with medical gases – Part 1: Pressure regulators and pressure regulators with flow-metering devices
ISO 10524-2:2018	Pressure regulators for use with medical gases – Part 2: Manifold and line pressure regulators
ISO 10524-3:2019	Pressure regulators for use with medical gases – Part 3: Pressure regulators integrated with cylinder valves (VIPRs)
ISO 10524-4:2008	Pressure regulators for use with medical gases – Part 4: Low-pressure regulators
ISO 11117:2019	Gas cylinders – Valve protection caps and valve guards – Design, construction and tests
ISO 11197:2019	Medical supply units
ISO 15001:2010	Anaesthetic and respiratory equipment -- Compatibility with oxygen
ISO 15002:2008	Flow-metering devices for connection to terminal units of medical gas pipeline systems
ISO 15002:2008/ Amd 1:2018	Flow-metering devices for connection to terminal units of medical gas pipeline systems – *Amendment 1*
ISO 16571:2014	Systems for evacuation of plume generated by medical devices
ISO 18082:2014	Anaesthetic and respiratory equipment – Dimensions of non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases

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*
ISO 18777:2005	Transportable liquid oxygen systems for medical use – Particular requirements
ISO 19054:2005	Rail systems for supporting medical equipment
ISO 19054:2005/ Amd 1:2016	Rail systems for supporting medical equipment – *Amendment 1*
ISO 21969:2009	High-pressure flexible connections for use with medical gas systems
ISO 32:1977	Gas cylinders for medical use – Marking for identification of content
ISO 407:2004	Small medical gas cylinders – Pin-index yoke-type valve connections
ISO 7396-1:2016	Medical gas pipeline systems – Part 1: Pipeline systems for compressed medical gases and vacuum
ISO 7396-2:2007	Medical gas pipeline systems – Part 2: Anaesthetic gas scavenging disposal systems
ISO 9170-1:2017	Terminal units for medical gas pipeline systems – Part 1: Terminal units for use with compressed medical gases and vacuum
ISO 9170-2:2008	Terminal units for medical gas pipeline systems – Part 2: Terminal units for anaesthetic gas scavenging systems

4.2.5 Suction devices for hospital and emergency care use

ISO 10079-1:2015	Medical suction equipment – Part 1: Electrically powered suction equipment – Safety requirements

ISO 10079-1:2015/ Amd 1:2018	Medical suction equipment – Part 1: Electrically powered suction equipment – *Amendment 1: Changes to requirements for operating at extremes of temperature*
ISO 10079-2:2014	Medical suction equipment – Part 2: Manually powered suction equipment
ISO 10079-3:2014	Medical suction equipment – Part 3: Suction equipment powered from a vacuum or positive pressure gas source

4.2.6 Terminology and semantics

ISO 4135:2001	Anaesthetic and respiratory equipment – Vocabulary

4.3 Dentistry devices

4.3.1 Dental CAD/CAM systems

ISO 12836:2012	Dentistry – Digitizing devices for CAD/CAM systems for indirect dental restorations – Test methods for assessing accuracy

4.3.2 Dental equipment

IEC 80601-2-60:2019	Medical electrical equipment – Part 2-60: Particular requirements for basic safety and essential performance of dental equipment
ISO 10637:2018	Dentistry – Central suction source equipment
ISO 10650:2018	Dentistry – Powered polymerization activators
ISO 11143:2008	Dentistry – Amalgam separators
ISO 13897:2018	Dentistry – Dental amalgam reusable mixing-capsules
ISO 16954:2015	Dentistry – Test methods for dental unit waterline biofilm treatment

ISO 21530:2004	Dentistry – Materials used for dental equipment surfaces – Determination of resistance to chemical disinfectants
ISO 22052:2020	Dentistry – Central compressed air source equipment
ISO 4073:2009	Dentistry – Information system on the location of dental equipment in the working area of the oral health care provider
ISO 7488:2018	Dentistry — Mixing machines for dental amalgam
ISO 7493:2006	Dentistry – Operator's stool
ISO 7494-1:2018	Dentistry – Stationary dental units and dental patient chairs – Part 1: General requirements
ISO 7494-2:2015	Dentistry – Dental units – Part 2: Air, water, suction and wastewater systems
ISO 8282:1994	Dental equipment – Mercury and alloy mixers and dispensers
ISO 9680:2014	Dentistry – Operating lights
ISO 9687:2015	Dentistry – Graphical symbols for dental equipment
ISO 9687:2015/ Amd 1:2018	Dentistry – Graphical symbols for dental equipment – *Amendment 1*

4.3.3 Dental implants

ISO 10451:2010	Dentistry – Contents of technical file for dental implant systems
ISO 11953:2010	Dentistry – Implants – Clinical performance of hand torque instruments
ISO 14801:2016	Dentistry – Implants – Dynamic fatigue test for endosseous dental implants
ISO 16498:2013	Dentistry – Minimal dental implant data set for clinical use

ISO 22794:2007	Dentistry – Implantable materials for bone filling and augmentation in oral and maxillofacial surgery – Contents of a technical file
ISO 22803:2004	Dentistry – Membrane materials for guided tissue regeneration in oral and maxillofacial surgery – Contents of a technical file
ISO/TS 13498:2011	Dentistry – Torsion test of implant body/connecting part joints of endosseous dental implant systems

4.3.4 Dental instruments

ISO 10323:2013	Dentistry – Bore diameters for rotary instruments such as discs and wheels
ISO 11499:2014	Dentistry – Single-use cartridges for local anaesthetics
ISO 13295:2007	Dentistry – Mandrels for rotary instruments
ISO 13397-1:1995	Periodontal curettes, dental scalers and excavators – Part 1: General requirements
ISO 13397-2:2005	Dentistry – Periodontal curettes, dental scalers and excavators – Part 2: Periodontal curettes of Gr-type
ISO 13397-2:2005/ Amd 1:2012	Dentistry – Periodontal curettes, dental scalers and excavators – Part 2: Periodontal curettes of Gr-types – Amendment 1: Colour coding
ISO 13397-3:1996	Periodontal curettes, dental scalers and excavators – Part 3: Dental scalers – H-type
ISO 13397-4:1997	Periodontal curettes, dental scalers and excavators – Part 4: Dental excavators – Discoid-type
ISO 13504:2012	Dentistry – General requirements for instruments and related accessories used in dental implant placement and treatment
ISO 15087-1:1999	Dental elevators – Part 1: General requirements
ISO 15087-2:2000	Dental elevators – Part 2: Warwick James elevators

ISO 15087-3:2000	Dental elevators – Part 3: Cryer elevators
ISO 15087-4:2000	Dental elevators – Part 4: Coupland elevators
ISO 15087-5:2000	Dental elevators – Part 5: Bein elevators
ISO 15087-6:2000	Dental elevators – Part 6: Flohr elevators
ISO 15098:2020	Dentistry – Dental tweezers
ISO 16635-1:2013	Dentistry – Dental rubber dam technique – Part 1: Hole punch
ISO 1797:2017	Dentistry - Shanks for rotary and oscillating instruments
ISO 18397:2016	Dentistry – Powered scaler
ISO 21531:2009	Dentistry – Graphical symbols for Dental instruments
ISO 21533:2018	Dentistry - Reprocessable cartridge syringes for intraligamentary injections
ISO 2157:2016	Dentistry – Nominal diameters and designation code numbers for rotary instruments
ISO 21671:2006	Dentistry – Rotary polishers
ISO 21671:2006/ Amd 1:2011	Dentistry – Rotary polishers – *Amendment 1*
ISO 21672-1:2012	Dentistry – Periodontal probes – Part 1: General requirements
ISO 21672-2:2012	Dentistry – Periodontal probes – Part 2: Designation
ISO 3630-1:2008	Dentistry – Root canal instruments – Part 1: General requirements and test methods
ISO 3630-1:2019	Dentistry – Endodontic instruments – Part 1: General requirements
ISO 3630-2:2013	Dentistry – Endodontic Instruments – Part 2: Enlargers
ISO 3630-3:2015	Dental – root-canal instruments – Part 3: Condensers, pluggers and spreaders

ISO 3630-4:2009	Dentistry – Root canal instruments – Part 4: Auxiliary instruments
ISO 3630-5:2020	Dentistry – Endodontic instruments – Part 5: Shaping and cleaning instruments
ISO 3823-1:1997	Dental rotary instruments – Burs – Part 1: Steel and carbide burs
ISO 3823-2:2003	Dentistry – Rotary bur instruments – Part 2: Finishing burs
ISO 3823-2:2003/ Amd 1:2008	Dentistry – Rotary bur instruments – Part 2: Finishing burs – *Amendment 1*
ISO 3964:2016	Dentistry – Coupling dimensions for handpiece connectors
ISO 3964:2016/ Amd 1:2018	Dentistry – Coupling dimensions for handpiece connectors – *Amendment 1*
ISO 6360-1:2004	Dentistry – Number coding system for rotary instruments – Part 1: General characteristics
ISO 6360-1:2004/ Cor 1:2007	Dentistry – Number coding system for rotary instruments – Part 1: General characteristics – *Technical Corrigendum 1*
ISO 6360-2:2004	Dentistry – Number coding system for rotary instruments – Part 2: Shapes
ISO 6360-2:2004/ Amd 1:2011	Dentistry – Number coding system for rotary instruments – Part 2: Shapes – *Amendment 1*
ISO 6360-3:2005	Dentistry – Number coding system for rotary instruments – Part 3: Specific characteristics of burs and cutters
ISO 6360-4:2004	Dentistry – Number coding system for rotary instruments – Part 4: Specific characteristics of diamond instruments
ISO 6360-5:2007	Dentistry – Number coding system for rotary instruments – Part 5: Specific characteristics of root-canal instruments
ISO 6360-6:2004	Dentistry – Number coding system for rotary instruments – Part 6: Specific characteristics of abrasive instruments
ISO 6360-7:2006	Dentistry – Number coding system for rotary instruments – Part 7: Specific characteristics of mandrels and special instruments

ISO 7492:2019	Dentistry – Dental explorers
ISO 7711-1:1997	Dental rotary instruments – Diamond instruments – Part 1: Dimensions, requirements, marking and packaging
ISO 7711-1:1997/ Amd 1:2009	Dental rotary instruments – Diamond instruments – Part 1: Dimensions, requirements, marking and packaging – *Amendment 1*
ISO 7711-2:2011	Dentistry – Rotary diamond instruments – Part 2: Discs
ISO 7711-3:2004	Dentistry – Diamond rotary instruments – Part 3: Grit sizes, designation and colour code
ISO 7786:2001	Dental rotary instruments – Laboratory abrasive instruments
ISO 7787-1:2016	Dentistry – Laboratory cutters – Part 1: Steel laboratory cutters
ISO 7787-2:2020	Dentistry – Laboratory cutters – Part 2: Carbide laboratory cutters
ISO 7787-3:2017	Dentistry – Laboratory cutters – Part 3: Carbide cutters for milling machines
ISO 7787-4:2002	Dental rotary instruments – Cutters – Part 4: Miniature carbide laboratory cutters
ISO 7885:2010	Dentistry – Sterile injection needles for single use
ISO 8325:2004	Dentistry – Test methods for rotary instruments
ISO 9168:2009	Dentistry – Hose connectors for air driven dental handpieces
ISO 9173-1:2016	Dentistry – Extraction forceps – Part 1: General requirements and test methods
ISO 9173-2:2010	Dentistry – Extraction forceps – Part 2: Designation
ISO 9173-3:2014	Dentistry – Extraction forceps – Part 3: Design
ISO 9873:2019	Dentistry – Intra-oral mirrors
ISO 9997:2020	Dentistry – Cartridge syringes

4.3.5 Filling and restorative materials

ISO 13116:2014	Dentistry – Test Method for Determining Radio-Opacity of Materials
ISO 15841:2014	Dentistry – Wires for use in orthodontics
ISO 17304:2013	Dentistry – Polymerization shrinkage: Method for determination of polymerization shrinkage of polymer-based restorative materials
ISO 21606:2007	Dentistry – Elastomeric auxiliaries for use in orthodontics
ISO 24234:2015	Dentistry – Dental amalgam
ISO 27020:2019	Dentistry – Brackets and tubes for use in orthodontics
ISO 29022:2013	Dentistry – Adhesion – Notched-edge shear bond strength test
ISO 3107:2011	Dentistry – Zinc oxide/eugenol cements and zinc oxide/non-eugenol cements
ISO 4049:2019	Dentistry – Polymer-based restorative materials
ISO 6874:2015	Dentistry – Polymer-based pit and fissure sealants
ISO 6876:2012	Dentistry – Root canal sealing materials
ISO 6877:2006	Dentistry – Root-canal obturating points
ISO 7551:1996	Dental absorbent points
ISO 9917-1:2007	Dentistry – Water-based cements – Part 1: Powder/liquid acid-base cements
ISO 9917-2:2017	Dentistry – Water-based cements – Part 2: Resin-modified cements
ISO/TS 17988:2020	Dentistry – Corrosion test methods for dental amalgam

4.3.6 Oral care products

ISO 10873:2010	Dentistry – Denture adhesives
ISO 11609:2017	Dentistry – Dentifrices – Requirements, test methods and marking
ISO 16408:2015	Dentistry – Oral care products – Oral rinses
ISO 16409:2016	Dentistry – Oral care products – Manual interdental brushes
ISO 17730:2014	Dentistry – Fluoride varnishes
ISO 20126:2012	Dentistry – Manual toothbrushes – General requirements and test methods
ISO 20126:2012/ Amd 1:2018	Dentistry – Manual toothbrushes – General requirements and test methods – *Amendment 1*
ISO 20127:2020	Dentistry – Physical properties of powered toothbrushes
ISO 22254:2005	Dentistry – Manual toothbrushes – Resistance of tufted portion to deflection
ISO 28158:2018	Dentistry – Integrated dental floss and handles
ISO 28399:2020	Dentistry – External tooth bleaching products
ISO 28888:2013	Dentistry – Screening method for erosion potential of oral rinses on dental hard tissues

4.3.7 Prosthodontic materials

ISO 10139-1:2018	Dentistry – Soft lining materials for removable dentures – Part 1: Materials for short-term use
ISO 10139-2:2016	Dentistry – Soft lining materials for removable dentures – Part 2: Materials for long-term use
ISO 10271:2020	Dentistry – Corrosion test methods for metallic materials
ISO 10477:2018	Dentistry – Polymer-based crown and bridge materials

ISO 13017:2020	Dentistry – Magnetic attachments
ISO 13078:2013	Dentistry – Dental furnace – Test method for temperature measurement with separate thermocouple
ISO 14233:2003	Dentistry – Polymer-based die materials
ISO 14356:2003	Dentistry – Duplicating material
ISO 15854:2005	Dentistry – Casting and baseplate waxes
ISO 15912:2016	Dentistry – Refractory investment and die material
ISO 20795-1:2013	Dentistry – Base polymers – Part 1: Denture base polymers
ISO 20795-2:2013	Dentistry – Base polymers – Part 2: Orthodontic base polymers
ISO 21563:2013	Dentistry – Hydrocolloid impression materials
ISO 22112:2017	Dentistry – Artificial teeth for dental prostheses
ISO 22674:2016	Dentistry – Metallic materials for fixed and removable restorations and appliances
ISO 28319:2018	Dentistry – Laser welding and filler materials
ISO 4823:2015	Dentistry – Elastomeric impression materials
ISO 6872:2015	Dentistry – Ceramic materials
ISO 6872:2015/ Amd 1:2018	Dentistry – Ceramic materials – *Amendment 1*
ISO 6873:2013	Dentistry – Gypsum products
ISO 7491:2000	Dental materials – Determination of colour stability
ISO 9333:2006	Dentistry – Brazing materials

ISO 9693:2019	Dentistry – Compatibility testing for metal-ceramic and ceramic-ceramic systems
ISO/TR 14569-1:2007	Dental materials – Guidance on testing of wear – Part 1: Wear by toothbrushing
ISO/TR 28642:2016	Dentistry – Guidance on colour measurement
ISO/TS 14569-2:2001	Dental materials – Guidance on testing of wear – Part 2: Wear by two- and/or three body contact

4.3.8 Terminology

ISO 16059:2007	Dentistry – Required elements for codification used in data exchange
ISO 16443:2014	Dentistry – Vocabulary for dental implants systems and related procedure
ISO 1942:2009	Dentistry – Vocabulary
ISO 3950:2016	Dentistry – Designation system for teeth and areas of the oral cavity
ISO/TR 15300:2001	Dentistry – Application of OSI clinical codification to the classification and coding of dental products
ISO/TR 15599:2002	Digital codification of dental laboratory procedures
ISO/TR 15599:2002/ Cor 1:2003	Digital codification of dental laboratory procedures – *Technical Corrigendum 1*

4.4 Extracorporeal systems

IEC 60601-2-16:2018 (Ed.5)	Medical electrical equipment – Part 2-16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment
IEC 60601-2-39:2018 (Ed.3)	Medical electrical equipment – Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment
IECEE TRF 60601-2-39D:2019 (Ed. 4)	This Test Report Form applies to: IEC 60601-2-39:2018 for use in conjunction with IEC 60601-1:2005 or IEC 60601-1:2005, AMD1:2012
IEC/TR 62653:2013	Guidelines for the safe use of medical products in dialysis treatment
ISO 11658:2012	Cardiovascular implants and extracorporeal systems - Blood/tissue contact surface modifications for extracorporeal perfusion systems
ISO 11663:2014	Quality of dialysis fluid for haemodialysis and related therapies
ISO 12417-1:2015	Cardiovascular implants and extracorporeal systems – Vascular device-drug combination products – Part 1: General requirements
ISO 15674:2016	Cardiovascular implants and artificial organs – Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags
ISO 15674:2016/ Amd 1:2020	Cardiovascular implants and artificial organs – Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags – *Amendment 1: Connectors*
ISO 15675:2016	Cardiovascular implants and artificial organs – Cardiopulmonary bypass systems – Arterial blood line filters
ISO 15675:2016/ Amd 1:2020	Cardiovascular implants and artificial organs – Cardiopulmonary bypass systems – Arterial blood line filters – *Amendment 1: Connectors*
ISO 15676:2016	Cardiovascular implants and artificial organs – Requirements for single-use tubing packs for cardiopulmonary bypass and extracorporeal membrane oxygenation (ECMO)

ISO 23500-1:2019	Preparation and quality management of fluids for haemodialysis and related therapies – Part 1: General requirements
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
ISO 23500-3:2019	Preparation and quality management of fluids for haemodialysis and related therapies – Part 3: Water for haemodialysis and related therapies
ISO 23500-4:2019	Preparation and quality management of fluids for haemodialysis and related therapies – Part 4: Concentrates for haemodialysis and related therapies
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
ISO 8637-1:2017	Extracorporeal systems for blood purification — Part 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators
ISO 8637-2:2018	Extracorporeal systems for blood purification — Part 2: Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters
ISO 8637-3:2018	Extracorporeal systems for blood purification — Part 3: Plasmafilters
ISO/TR 12417-2:2017	Cardiovascular implants and extracorporeal systems – Vascular device-drug combination products – Part 2: Local regulatory information
ISO/TS 23810:2018	Cardiovascular implants and artificial organs – Checklist for preoperative extracorporeal circulation equipment setup

4.5 Hospital equipment

4.5.1 Heating equipment

IEC 60601-2-35:2020	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

4.5.2 Medical beds

IEC 60601-2-52:2009	Medical electrical equipment – Part 2-52: Particular requirements for the basic safety and essential performance of medical beds
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*
IEC 60601-2-52:2009 +Amd1:2015 CSV Consolidated version (Ed. 1.1)	Medical electrical equipment – Part 2-52: Particular requirements for the basic safety and essential performance of medical beds
IEC 60601-2-52:2009/ Cor1:2010	Medical electrical equipment – Part 2-52: Particular requirements for the basic safety and essential performance of medical beds – T*echnical Corrigendum 1*
IECEE TRF 60601-2-38D:2020 (Ed. 4.0)	This Test Report Form applies to: IEC 60601-2-38:1996, AMD1:1999 for use in conjunction with IEC 60601-1:1988, AMD1:1991, AMD2:1995
IECEE TRF 60601-2-52B:2017 (Ed. 2)	This Test Report Form applies to: IEC 60601-2-52:2009, AMD1:2015 for use with IEC 60601-1:2005

4.5.3 Medical face masks

EN14683:2019 + AC:2019	Medical face masks - Requirements and test methods
ASTM F2100:20	Standard Specification for Performance of Materials Used in Medical Face Masks

YY 0469-2011	醫用外科口罩
ISO 22609:2004	Clothing for protection against infectious agents – Medical face masks – Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)

4.5.4 Medical gloves

ISO 10282:2014	Single-use sterile rubber surgical gloves – Specification
ISO 11193-1:2020	Single-use medical examination gloves – Part 1: Specification for gloves made from rubber latex or rubber solution
ISO 11193-2:2006	Single-use medical examination gloves – Part 2: Specification for gloves made from poly (vinyl chloride)
ISO 12243:2003	Medical gloves made from natural rubber latex – Determination if water-extractable protein using the modified Lowry method
ISO 12243:2003/ Amd 1:2012	Medical gloves made from natural rubber latex – Determination if water-extractable protein using the modified Lowry method – *Amendment 1*
ISO 21171:2006	Medical gloves – Determination of removable surface powder
EN 455-1:2020	Medical gloves for single use – Part 1: Requirements and testing for freedom from holes
EN 455-2:2015	Medical gloves for single use – Part 2: Requirements and testing for physical properties
EN 455-3: 2015	Medical gloves for single use – Part 3: Requirements and testing for biological evaluation
EN 455-4:2009	Medical gloves for single use – Part 4: Requirements and testing for shelf life determination

4.5.5 Operating tables

IEC 60601-2-46:2016 (Ed. 3.0)	Medical electrical equipment – Part 2-46: Particular requirements for basic safety and essential performance of operating tables
IECEE TRF 60601-2-46E:2017	This Test Report Form applies to: IEC 60601-2-46:2016 for use in conjunction with IEC 60601-1:2005, AMD1:2012

4.5.6 Other medical equipment

ISO 23907-1:2019	Sharps injury protection – Requirements and test methods – Part 1: Single-use sharps containers
ISO 23907-2:2019	Sharps injury protection – Requirements and test methods – Part 2: Reusable sharps containers

4.6 Implants for surgery, prosthetics and orthotics devices

4.6.1 Implants for surgery (Active implants)

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
IEC 60601-2-4:2010	Medical electrical equipment – Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators
IEC 60601-2-4:2010 +Amd1:2018 CSV Consolidated version (Ed. 3.1)	Medical electrical equipment – Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators
ISO 11318:2002	Cardiac defibrillators – Connector assembly DF-1 for implantable defibrillators – Dimensions and test requirements
ISO 14117:2019	Active implantable medical devices – Electromagnetic compatibility – EMC test protocols for implantable cardiac

	pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices
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
ISO 14708-2:2019	Implants for surgery – Active implantable medical devices – Part 2: Cardiac pacemakers
ISO 14708-3:2017	Implants for surgery – Active implantable medical devices – Part 3: Implantable neurostimulators
ISO 14708-4:2008	Implants for surgery – Active implantable medical devices – Part 4: Implantable infusion pumps
ISO 14708-5:2020	Implants for surgery – Active implantable medical devices – Part 5: Circulatory support devices
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)
ISO 14708-7:2019	Implants for surgery – Active implantable medical devices – Part 7: Particular requirements for cochlear implant systems
ISO 27185:2012	Cardiac rhythm management devices – Symbols to be used with cardiac rhythm management device labels, and information to be supplied – General requirements
ISO 27186:2010	Active implantable medical devices – Four-pole connector system for implantable cardiac rhythm management devices – Dimensional and test requirements
ISO 5841-2:2014	Implants for surgery – Cardiac pacemakers – Part 2: Reporting of clinical performance of populations of pulse generators or leads
ISO 5841-3:2013	Implants for surgery – Cardiac pacemakers – Part 3: Low-profile connectors (IS-1) for implantable pacemakers
ISO/TS 10974:2018	Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device
AAMI TIR41:2011	Active Implantable Medical Devices – Guidance for Designation

(R2020)	of Left Ventricle and Implantable Cardioverter Defibrillator Lead Connectors and Pulse Generator Connector Cavities for Implantable Pacemakers and Implantable Cardioverter Defibrillators

4.6.2 Implants for surgery (Bone and joint replacements)

ISO 14242-1:2014	Implants for surgery – Wear of total hip-joint prostheses – Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test
ISO 14242-1:2014/ Amd 1:2018	Implants for surgery – Wear of total hip-joint prostheses – Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test – *Amendment 1*
ISO 14242-2:2016	Implants for surgery – Wear of total hip-joint prostheses – Part 2: Methods of measurement
ISO 14242-3:2009	Implants for surgery – Wear of total hip-joint prostheses – Part 3: Loading and displacement parameters for orbital bearing type wear testing machines and corresponding environmental conditions for test
ISO 14242-3:2009/ Amd 1:2019	Implants for surgery – Wear of total hip-joint prostheses – Part 3: Loading and displacement parameters for orbital bearing type wear testing machines and corresponding environmental conditions for test – *Amendment 1*
ISO 14243-1:2009	Implants for surgery – Wear of total knee-joint prostheses – Part 1: Loading and displacement parameters for wear-testing machines with load control and corresponding environmental conditions for test
ISO 14243-1:2009/ Amd 1:2020	Implants for surgery – Wear of total knee-joint prostheses – Part 1: Loading and displacement parameters for wear-testing machines with load control and corresponding environmental conditions for test – *Amendment 1*
ISO 14243-2:2016	Implants for surgery – Wear of total knee-joint prostheses – Part 2: Methods of measurement
ISO 14243-3:2014	Implants for surgery – Wear of total knee-joint prostheses – Part 3: Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test

ISO 14243-3:2014/ Amd 1:2020	Implants for surgery – Wear of total knee-joint prostheses – Part 3: Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test – *Amendment 1*
ISO 14879-1:2020	Implants for surgery – Total knee-joint prostheses – Part 1: Determination of endurance properties of knee tibial trays
ISO 16087:2013	Implants for surgery – Roentgen stereophotogrammetric analysis for the assessment of migration of orthopaedic implants
ISO 17853:2011	Wear of implant materials – Polymer and metal wear particles – Isolation and characterization
ISO 21534:2007	Non-active surgical implants – Joint replacement implants – Particular requirements
ISO 21535:2007	Non-active surgical implants – Joint replacement implants – Specific requirements for hip-joint replacement implants
ISO 21536:2007	Non-active surgical implants – Joint replacement implants – Specific requirements for knee-joint replacement implants
ISO 21536:2007/ Amd1:2014	Non-active surgical implants – Joint replacement implants – Specific requirements for knee-joint replacement implants – *Amendment 1*
ISO 7206-1:2008	Implants for surgery – Partial and total hip joint prostheses – Part 1: Classification and designation of dimensions
ISO 7206-2:2011	Implants for surgery – Partial and total hip joint prostheses – Part 2: Articulating surfaces made of metallic, ceramic and plastics materials
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 – *Amendment 1*
ISO 7206-4:2010	Implants for surgery – Partial and total hip joint prostheses – Part 4: Determination of endurance properties and performance of stemmed femoral components
ISO 7206-4:2010/Amd 1:2016	Implants for surgery – Partial and total hip joint prostheses – Part 4: Determination of endurance properties and performance of stemmed femoral components – *Amendment 1*

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
ISO 7206-10:2018	Implants for surgery – Partial and total hip-joint prostheses – Part 10: Determination of resistance to static load of modular femoral heads
ISO 7207-1:2007	Implants for surgery – Components for partial and total knee joint prostheses – Part 1: Classification, definitions and designation of dimensions
ISO 7207-2:2011	Implants for surgery – Components for partial and total knee joint prostheses – Part 2: Articulating surfaces made of metal, ceramic and plastics materials
ISO 7207-2:2011/ Amd 1:2016	Implants for surgery – Components for partial and total knee joint prostheses – Part 2: Articulating surfaces made of metal, ceramic and plastics materials – *Amendment 1*
ISO 7207-2:2011/ Amd 2:2020	Implants for surgery – Components for partial and total knee joint prostheses – Part 2: Articulating surfaces made of metal, ceramic and plastics materials – *Amendment 2*

4.6.3 Implants for surgery (Cardiovascular implants)

ISO 25539-1:2017	Cardiovascular implants – Endovascular devices – Part 1: Endovascular prostheses
ISO 25539-2:2020	Cardiovascular implants – Endovascular devices – Part 2: Vascular stents
ISO 25539-3:2011	Cardiovascular implants – Endovascular devices – Part 3: Vena cava filters
ISO 5840-1:2015	Cardiovascular implants – Cardiac valve prostheses – Part 1: General requirements
ISO 5840-2:2015	Cardiovascular implants – Cardiac valve prostheses – Part 2: Surgically implanted heart valve substitutes
ISO 5840-3:2013	Cardiovascular implants – Cardiac valve prostheses – Part 3: Heart valve substitutes implanted by transcatheter techniques

ISO 7198:2016	Cardiovascular implants and extracorporeal systems – Vascular prostheses – Tubular vascular grafts and vascular patches
ISO 7199:2016	Cardiovascular implants and artificial organs – Blood-gas exchangers (oxygenators)
ISO 7199:2016/ Amd 1:2020	Cardiovascular implants and artificial organs – Blood-gas exchangers (oxygenators) – *Amendment 1: Connectors*
ISO/TS 17137:2019	Cardiovascular implants and extracorporeal systems – Cardiovascular absorbable implants
AAMI TIR42:2010	Evaluation of particulates associated with vascular medical devices
ASTM F2079 - 09(2017)	Standard test method for measuring intrinsic elastic recoil of balloon-expandable stents
ASTM F2081 - 06(2017)	Standard guide for characterization and presentation of the dimensional attributes of vascular stents
ASTM F2914-12	Standard guide for identification of shelf-life test attributes for endovascular devices
BS EN ISO 7198:2017	Cardiovascular implants and extracorporeal systems. Vascular prostheses. Tubular vascular grafts and vascular patches

4.6.4 Implants for surgery (General requirements)

ISO 14630:2012	Non-active surgical implants – General requirements
ISO 16061:2015	Instrumentation for use in association with non-active surgical implants – General requirements
ASTM F138 - 19	Standard specification for wrought 18 Chromium-14 Nickel-2.5 Molybdenum stainless steel bar and wire for surgical implants (UNS S31673)
ASTM F2119 - 07(2013)	Standard test method for evaluation of MR Image artifacts from passive implants
ASTM F2129 - 19a	Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices

4.6.5 Implants for surgery (Materials)

ISO 13175-3:2012	Implants for surgery – Calcium phosphates – Part 3: Hydroxyapatite and beta-tricalcium phosphate bone substitutes
ISO 13179-1:2014	Implants for surgery – Plasma-sprayed unalloyed titanium coatings on metallic surgical implants – Part 1: General requirements
ISO 13356:2015	Implants for surgery – Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)
ISO 13779-2:2018	Implants for surgery – Hydroxyapatite – Part 2: Thermally sprayed coatings of hydroxyapatite
ISO 13779-3:2018	Implants for surgery – Hydroxyapatite – Part 3: Chemical analysis and characterization of crystallinity and phase purity
ISO 13779-4:2018	Implants for surgery – Hydroxyapatite – Part 4: Determination of coating adhesion strength
ISO 13779-6:2015	Implants for surgery – Hydroxyapatite – Part 6: Powders
ISO 13781:2017	Implants for surgery – Homopolymers, copolymers and blends on poly(lactide) – In vitro degradation testing
ISO 13782:2019	Implants for surgery – Metallic materials – Unalloyed tantalum for surgical implant applications
ISO 14949:2001	Implants for surgery – Two-part addition-cure silicone elastomers
ISO 15309:2013	Implants for surgery – Differential scanning calorimetry of poly ether ether ketone (PEEK) polymers and compounds for use in implantable medical devices
ISO 15374:1998	Implants for surgery – Requirements for production of forgings
ISO 16402:2008	Implants for surgery – Acrylic resin cement – Flexural fatigue testing of acrylic resin cements used in orthopaedics
ISO 16428:2005	Implants for surgery – Test solutions and environmental conditions for static and dynamic corrosion tests on implantable materials and medical devices
ISO 16429:2004	Implants for surgery – Measurements of open-circuit potential to

	assess corrosion behaviour of metallic implantable materials and medical devices over extended time periods
ISO 20160:2006	Implants for surgery – Metallic materials – Classification of microstructures for alpha+beta titanium alloy bars
ISO 23317:2014	Implants for surgery – In vitro evaluation for apatite-forming ability of implant materials
ISO 5832-1:2016	Implants for surgery – Metallic materials – Part 1: Wrought stainless steel
ISO 5832-11:2014	Implants for surgery – Metallic materials – Part 11: Wrought titanium 6-aluminium 7-niobium alloy
ISO 5832-12:2019	Implants for surgery – Metallic materials – Part 12: Wrought cobalt-chromium-molybdenum alloy
ISO 5832-14:2019	Implants for surgery – Metallic materials – Part 14: Wrought titanium 15-molybdenum 5-zirconium 3-aluminium alloy
ISO 5832-2:2018	Implants for surgery – Metallic materials – Part 2: Unalloyed titanium
ISO 5832-3:2016	Implants for surgery – Metallic materials – Part 3: Wrought titanium 6-aluminium 4-vanadium alloy
ISO 5832-4:2014	Implants for surgery – Metallic materials – Part 4: Cobalt-chromium-molybdenum casting alloy
ISO 5832-5:2005	Implants for surgery – Metallic materials – Part 5: Wrought cobalt-chromium-tungsten-nickel alloy
ISO 5832-6:1997	Implants for surgery – Metallic materials – Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy
ISO 5832-7:2016	Implants for surgery – Metallic materials – Part 7: Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy
ISO 5832-9:2019	Implants for surgery – Metallic materials – Part 9: Wrought high nitrogen stainless steel
ISO 5833:2002	Implants for surgery – Acrylic resin cements

ISO 5834-1:2019	Implants for surgery – Ultra-high-molecular-weight polyethylene – Part 1: Powder form
ISO 5834-3:2019	Implants for surgery – Ultra-high-molecular-weight polyethylene – Part 3: Accelerated ageing methods
ISO 5834-4:2019	Implants for surgery – Ultra-high-molecular-weight polyethylene – Part 4: Oxidation index measurement method
ISO 5834-5:2019	Implants for surgery – Ultra-high-molecular-weight polyethylene – Part 5: Morphology assessment method
ISO 6474-1:2019	Implants for surgery – Ceramic materials – Part 1: Ceramic materials based on high purity alumina
ISO 6474-2:2019	Implants for surgery – Ceramic materials – Part 2: Composite materials based on a high-purity alumina matrix with zirconia reinforcement
ISO 9583:1993	Implants for surgery – Non-destructive testing – Liquid penetrant inspection of metallic surgical implants
ISO 9584:1993	Implants for surgery – Non-destructive testing – Radiographic examination of cast metallic surgical implants

4.6.6 Implants for surgery (Neurosurgical implants)

ISO 7197:2006	Neurosurgical implants – Sterile, single-use hydrocephalus shunts and components
ISO 7197:2006/ Cor 1:2007	Neurosurgical implants – Sterile, single-use hydrocephalus shunts and components – *Technical Corrigendum 1*
ISO 9713:2002	Neurosurgical implants – Self-closing intracranial aneurysm clips

4.6.7 Implants for surgery (Osteosynthesis and spinal devices)

ISO 10334:1994	Implants for surgery – Malleable wires for use as sutures and other surgical applications
ISO 12189:2008	Implants for surgery – Mechanical testing of implantable spinal devices – Fatigue test method for spinal implant assemblies using an anterior support
ISO 14602:2010	Non-active surgical implants – Implants for osteosynthesis – Particular requirements
ISO 15142-1:2003	Implants for surgery – Metal intramedullary nailing systems – Part 1: Intramedullary nails
ISO 15142-2:2003	Implants for surgery – Metal intramedullary nailing systems – Part 2: Locking components
ISO 15142-3:2003	Implants for surgery – Metal intramedullary nailing systems – Part 3: Connection devices and reamer diameter measurements
ISO 18192-1:2011	Implants for surgery – Wear of total intervertebral spinal disc prostheses – Part 1: Loading and displacement parameters for wear testing and corresponding environmental conditions for test
ISO 18192-1:2011/ Amd 1:2018	Implants for surgery – Wear of total intervertebral spinal disc prostheses – Part 1: Loading and displacement parameters for wear testing and corresponding environmental conditions for test – *Amendment 1*
ISO 18192-2:2010	Implants for surgery – Wear of total intervertebral spinal disc prostheses – Part 2: Nucleus replacements
ISO 5835:1991	Implants for surgery – Metal bone screws with hexagonal drive connection, spherical under-surface of head, asymmetrical thread – Dimensions
ISO 5836:1988	Implants for surgery – Metal bone plates – Holes corresponding to screws with asymmetrical thread and spherical under-surface
ISO 5837-1:1985	Implants for surgery – Intramedullary nailing systems – Part 1: Intramedullary nails with cloverleaf or V-shaped cross-section

ISO 5838-1:2013	Implants for surgery – Metallic skeletal pins and wires – Part 1: General requirements
ISO 5838-2:1991	Implants for surgery – Skeletal pins and wires – Part 2: Steinmann skeletal pins – Dimensions
ISO 5838-3:1993	Implants for surgery – Skeletal pins and wires – Part 3: Kirschner skeletal wires
ISO 6475:1989	Implants for surgery – Metal bone screws with asymmetrical thread and spherical under-surface – Mechanical requirements and test methods
ISO 8319-1:1996	Orthopaedic instruments – Drive connections – Part 1: Keys for use with screws with hexagon socket heads
ISO 8319-2:1986	Orthopaedic instruments – Drive connections – Part 2: Screwdrivers for single slot head screws, screws with cruciate slot and cross-recessed head screws
ISO 8615:1991	Implants for surgery – Fixation devices for use in the ends of the femur in adults
ISO 8827:1988	Implants for surgery – Staples with parallel legs for orthopaedic use – General requirements
ISO 9268:1988	Implants for surgery – Metal bone screws with conical under-surface of head – Dimensions
ISO 9269:1988	Implants for surgery – Metal bone plates – Holes and slots corresponding to screws with conical under-surface
ISO 9585:1990	Implants for surgery – Determination of bending strength and stiffness of bone plates
ISO 9714-1:2012	Orthopaedic drilling instruments – Part 1: Drill bits, taps and countersink cutters

4.6.8 Implants for surgery (Tissue-engineered medical products)

ISO/TR 16379:2014	Tissue-engineered medical products – Evaluation of anisotropic structure of articular cartilage using DT (Diffusion Tensor)-MR Imaging

4.6.9 Prosthetics and orthotics

ISO 10328:2016	Prosthetics – Structural testing of lower-limb prostheses – Requirements and test methods
ISO 13404:2007	Prosthetics and orthotics – Categorization and description of external orthoses and orthotic components
ISO 13405-1:2015	Prosthetics and orthotics – Classification and description of prosthetic components – Part 1: Classification of prosthetic components
ISO 13405-2:2015	Prosthetics and orthotics – Classification and description of prosthetic components – Part 2: Description of lower limb prosthetic components
ISO 13405-3:2015	Prosthetics and orthotics – Classification and description of prosthetic components – Part 3: Description of upper limb prosthetic components
ISO 15032:2000	Prostheses – Structural testing of hip units
ISO 22523:2006	External limb prostheses and external orthoses – Requirements and test methods
ISO 22675:2006	Prosthetics – Testing of ankle-foot devices and foot units – Requirements and test methods
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
ISO 29782:2008	Prostheses and orthoses – Factors to be considered when specifying a prosthesis for a person who has had a lower limb amputation

ISO 29783-1:2008	Prosthetics and orthotics – Vocabulary – Part 1: Normal gait
ISO 29783-2:2015	Prosthetics and orthotics – Vocabulary – Part 2: Prosthetic gait
ISO 29783-3:2016	Prosthetics and orthotics — Vocabulary — Part 3: Pathological gait (excluding prosthetic gait)
ISO 8548-1:1989	Prosthetics and orthotics – Limb deficiencies – Part 1: Method of describing limb deficiencies present at birth
ISO 8548-2:2020	Prosthetics and orthotics – Limb deficiencies – Part 2: Method of describing lower limb amputation stumps
ISO 8548-3:1993	Prosthetics and orthotics – Limb deficiencies – Part 3: Method of describing upper limb amputation stumps
ISO 8548-4:1998	Prosthetics and orthotics – Limb deficiencies – Part 4: Description of causal conditions leading to amputation
ISO 8548-5:2003	Prosthetics and orthotics – Limb deficiencies – Part 5: Description of the clinical condition of the person who has had an amputation
ISO 8549-1:2020	Prosthetics and orthotics – Vocabulary – Part 1: General terms for external limb prostheses and external orthoses
ISO 8549-2:2020	Prosthetics and orthotics – Vocabulary – Part 2: Terms relating to external limb prostheses and wearers of these prostheses
ISO 8549-3:2020	Prosthetics and orthotics – Vocabulary – Part 3: Terms relating to external orthoses
ISO 8549-4:2020	Prosthetics and orthotics – Vocabulary – Part 4: Terms relating to limb amputation
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
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

ISO/TS 16955:2016	Prosthetics – Quantification of physical parameters of ankle foot devices and foot units

4.7 Ophthalmic equipment

IEC 80601-2-58:2014 +Amd 1:2016 CSV Consolidated version (Ed. 2.1)	Medical electrical equipment – Part 2-58: Particular requirements for basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery
ISO 10322-1:2016	Ophthalmic optics – Semi-finished spectacle lens blanks – Part 1: Specifications for single-vision and multifocal lens blanks
ISO 10322-2:2016	Ophthalmic optics – Semi-finished spectacle lens blanks – Part 2: Specifications for progressive power lens blanks
ISO 10341:2012	Ophthalmic instruments – Refractor heads
ISO 10342:2010	Ophthalmic instruments – Eye refractometers
ISO 10343:2014	Ophthalmic instruments — Ophthalmometers
ISO 10685-1:2011	Ophthalmic optics – Spectacle frames and sunglasses electronic catalogue and identification – Part 1: Product identification and electronic catalogue product hierarchy
ISO 10685-2:2016	Ophthalmic optics – Spectacle frames and sunglasses electronic catalogue and identification – Part 2: Commercial information
ISO 10685-3:2012	Ophthalmic optics – Spectacle frames and sunglasses electronic catalogue and identification – Part 3: Technical information
ISO 10936-2:2010	Optics and photonics – Operation microscopes – Part 2: Light hazard from operation microscopes used in ocular surgery
ISO 10938:2016	Ophthalmic optics – Chart displays for visual acuity measurement – Printed, projected and electronic
ISO 10939:2017	Ophthalmic instruments – Slit-lamp microscopes

ISO 10940:2009	Ophthalmic instruments – Fundus cameras
ISO 10942:2006	Ophthalmic instruments – Direct ophthalmoscopes
ISO 10943:2011	Ophthalmic instruments – Indirect ophthalmoscopes
ISO 10944:2009	Ophthalmic instruments – Synoptophores
ISO 11380:1994	Optics and optical instruments – Ophthalmic optics – Formers
ISO 11381:2016	Ophthalmic optics – Spectacle frames – Screw threads
ISO 11978:2017	Ophthalmic optics – Contact lenses and contact lens care products – Labelling
ISO 11978:2017/Amd 1	Ophthalmic optics – Contact lenses and contact lens care products – Labelling – *Amendment 1*
ISO 11979-1:2018	Ophthalmic implants – Intraocular lenses – Part 1: Vocabulary
ISO 11979-2:2014	Ophthalmic implants – Intraocular lenses – Part 2: Optical properties and test methods
ISO 11979-3:2012	Ophthalmic implants – Intraocular lenses – Part 3: Mechanical properties and test methods
ISO 11979-4:2008	Ophthalmic implants – Intraocular lenses – Part 4: Labelling and information
ISO 11979-4:2008/ Amd 1:2012	Ophthalmic implants – Intraocular lenses – Part 4: Labelling and information – *Amendment 1*
ISO 11979-5:2020	Ophthalmic implants – Intraocular lenses – Part 5: Biocompatibility
ISO 11979-6:2014	Ophthalmic implants – Intraocular lenses – Part 6: Shelf-life and transport stability testing
ISO 11979-7:2018	Ophthalmic implants – Intraocular lenses – Part 7: Clinical investigations of intraocular lenses for the correction of aphakia
ISO 11979-8:2017	Ophthalmic implants – Intraocular lenses – Part 8: Fundamental requirements

ISO 11979-10:2018	Ophthalmic implants – Intraocular lenses – Part 10: Clinical investigations of intraocular lenses for correction of ametropia in phakic eyes
ISO 11980:2012	Ophthalmic optics – Contact lenses and contact lens care products – Guidance for clinical investigations
ISO 11981:2017	Ophthalmic optics – Contact lenses and contact lens care products – Determination of physical compatibility of contact lens care products with contact lenses
ISO 11986:2017	Ophthalmic optics – Contact lenses and contact lens care products – Determination of preservative uptake and release
ISO 11987:2012	Ophthalmic optics – Contact lenses – Determination of shelf-life
ISO 12865:2006	Ophthalmic instruments – Retinoscopes
ISO 12866:1999	Ophthalmic instruments – Perimeters
ISO 12866:1999/ Amd 1:2008	Ophthalmic instruments – Perimeters – *Amendment 1*
ISO 12867:2010	Ophthalmic instruments – Trial frames
ISO 12870:2016	Ophthalmic optics – Spectacle frames – Requirements and test methods
ISO 13212:2014	Ophthalmic optics – Contact lens care products – Guidelines for determination of shelf-life
ISO 13666:2019	Ophthalmic optics – Spectacle lenses – Vocabulary
ISO 14534:2011	Ophthalmic optics – Contact lenses and contact lens care products – Fundamental requirements
ISO 14729:2001	Ophthalmic optics – Contact lens care products – Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses
ISO 14729:2001/ Amd 1:2010	Ophthalmic optics – Contact lens care products – Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses – *Amendment 1*

ISO 14730:2014	Ophthalmic optics – Contact lens care products – Antimicrobial preservative efficacy testing and guidance on determining discard date
ISO 14889:2013	Ophthalmic optics – Spectacle lenses – Fundamental requirements for uncut finished lenses
ISO 14889:2013/ Amd 1:2017	Ophthalmic optics – Spectacle lenses – Fundamental requirements for uncut finished lenses – *Amendment 1*
ISO 15004-1:2020	Ophthalmic instruments – Fundamental requirements and test methods – Part 1: General requirements applicable to all ophthalmic instruments
ISO 15004-2:2007	Ophthalmic instruments – Fundamental requirements and test methods – Part 2: Light hazard protection
ISO 15254:2009	Ophthalmic optics and instruments – Electro-optical devices for enhancing low vision
ISO 15752:2010	Ophthalmic instruments – Endoilluminators – Fundamental requirements and test methods for optical radiation safety
ISO 15798:2013	Ophthalmic implants – Ophthalmic viscosurgical devices
ISO 16034:2002	Ophthalmic optics – Specifications for single-vision ready-to-wear near-vision spectacles
ISO 16034:2002/ Cor 1:2006	Ophthalmic optics – Specifications for single-vision ready-to-wear near- vision spectacles – *Technical Corrigendum 1*
ISO 16671:2015	Ophthalmic implants – Irrigating solutions or ophthalmic surgery
ISO 16671:2015/ Amd 1:2017	Ophthalmic implants – Irrigating solutions for ophthalmic surgery – *Amendment 1*
ISO 16672:2020	Ophthalmic implants – Ocular endotamponades
ISO 16971:2015	Ophthalmic instruments – Optical coherence tomograph for the posterior segment of the human eye

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
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
ISO 18369-1:2017	Ophthalmic optics – Contact lenses – Part 1: Vocabulary, classification system and recommendations for labelling specifications
ISO 18369-2:2017	Ophthalmic optics – Contact lenses – Part 2: Tolerances
ISO 18369-3:2017	Ophthalmic optics – Contact lenses – Part 3: Measurement methods
ISO 18369-4:2017	Ophthalmic optics – Contact lenses – Part 4: Physicochemical properties of contact lens materials
ISO 19045:2015	Ophthalmic optics – Contact lens care products – Method for evaluating Acanthamoeba encystment by contact lens care products
ISO 19980:2012	Ophthalmic instruments – Corneal topographers
ISO 21987:2017	Ophthalmic optics – Mounted spectacle lenses
ISO 24157:2008	Ophthalmic optics and instruments – Reporting aberrations of the human eye
ISO 24157:2008/ Amd 1:2020	Ophthalmic optics and instruments – Reporting aberrations of the human eye – *Amendment 1*
ISO 7998:2005	Ophthalmic optics – Spectacle frames – Lists of equivalent terms and vocabulary
ISO 8429:1986	Optics and optical instruments – Ophthalmology – Graduated dial scale
ISO 8596:2017	Ophthalmic optics – Visual acuity testing – Standard and clinical optotype and its presentation

ISO 8596:2017/ Amd 1:2019	Ophthalmic optics – Visual acuity testing – Standard and clinical optotypes and their presentation – *Amendment 1*
ISO 8598-1:2014	Optics and optical instruments – Focimeters – Part 1: General purpose instruments
ISO 8612:2009	Ophthalmic instruments – Tonometers
ISO 8624:2020	Ophthalmic optics – Spectacle frames – Measuring system and vocabulary
ISO 8980-1:2017	Ophthalmic optics – Uncut finished spectacle lenses – Part 1: Specifications for single-vision and multifocal lenses
ISO 8980-2:2017	Ophthalmic optics – Uncut finished spectacle lenses – Part 2: Specifications for power-variation power lenses
ISO 8980-3:2013	Ophthalmic optics – Uncut finished spectacle lenses – Part 3: Transmittance specifications and test methods
ISO 8980-4:2006	Ophthalmic optics – Uncut finished spectacle lenses – Part 4: Specifications and test methods for anti-reflective coatings
ISO 8980-5:2005	Ophthalmic optics – Uncut finished spectacle lenses – Part 5: Minimum requirements for spectacle lens surfaces claimed to be abrasion-resistant
ISO 9342-1:2005	Optics and optical instruments – Test lenses for calibration of focimeters – Part 1: Test lenses for focimeters used for measuring spectacle lenses
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
ISO 9394:2012	Ophthalmic optics – Contact lenses and contact lens care products – Determination of biocompatibility by ocular study with rabbit eyes
ISO 9801:2009	Ophthalmic instruments – Trial case lenses
ISO/TR 18476:2017	Ophthalmic optics and instruments – Free form technology – Spectacle lenses and measurement

ISO/~~D~~TR 19498:2015	Ophthalmic optics and instruments – Correlation of optotypes
ISO/TR 20824:2007	Ophthalmic instruments – Background for light hazard specification in ophthalmic instrument standards
ISO/TR 22979:2017	Ophthalmic implants – Intraocular lenses – Guidance on assessment of the need for clinical investigation of intraocular lens design modifications
ISO/TR 28980:2007	Ophthalmic optics – Spectacle lenses – Parameters affecting lens power measurement
ISO/TS 24348:2014	Ophthalmic optics – Spectacle frames – Method for the simulation of wear and detection of nickel release from metal and combination spectacle frames
ANSI Z80.12-2007 (R2017)	Multifocal Intraocular Lenses
ANSI Z80.13-2007 (R2017)	Phakic Intraocular Lenses
ANSI Z80.17-2013 (R2018)	Ophthalmics – Focimeters
ANSI Z80.18-2016	Ophthalmics – Contact Lens Care Products: Vocabulary, Performance Specifications, and Test Methodology
ANSI Z80.20-2016	Ophthalmics – Contact Lenses – Standard Terminology, Tolerances, Measurements and Physicochemical Properties
ANSI Z80.30-2018	Ophthalmics – Toric Intraocular Lenses
ANSI Z80.7-2013 (R2018)	Ophthalmic Optics – Intraocular Lenses

4.8 Sterilization and disinfection devices

4.8.1 Chemical disinfectants and antiseptics

EN 14348:2005	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)
EN 14561:2006	Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants in the medical area including instrument disinfectants – Test method and requirements (Phase 2, Step 2)
EN 14563:2008	Chemical disinfectants and antiseptics – Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area – Test methods and requirements (Phase 2, Step 2)

4.8.2 Sterilizing equipment

ISO 15883-1:2006	Washer-disinfectors – Part 1: General requirements, terms and definitions and tests
ISO 15883-1:2006/ Amd 1:2014	Washer-disinfectors – Part 1: General requirements, terms and definitions and tests – *Amendment 1*
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.
ISO 15883-3:2006	Washer-disinfectors – Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers
ISO 15883-4:2018	Washer-disinfectors – Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes

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
ISO/TS 15883-5:2005	Washer-disinfectors – Part 5: Test soils and methods for demonstrating cleaning efficacy
EN 13060:2014	Small steam sterilizers
EN 14180:2014	Sterilizers for medical purposes – Low temperature steam and formaldehyde sterilizers – Requirements and testing
EN 285:2015	Sterilization – Steam sterilizers – Large sterilizers

4.9 Surgical instruments

4.9.1 Electro-optical systems

ISO 11810:2015	Lasers and laser-related equipment – Test method and classification for the laser resistance of surgical drapes and/or patient protective covers – Primary ignition, penetration, flame spread and secondary ignition

4.9.2 Electrosurgical equipment

IEC 60601-2-2:2017 (Ed.6)	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
IEC 60601-2-41:2009/ +Amd1:2013 CSV Consolidated version (Ed.2.1)	Medical electrical equipment – Part 2-41: Particular requirements for the safety of surgical luminaires and luminarires for diagnosis
IECEE TRF 60601-2-2F:2014 (Ed.5)	This Test Report Form applies to: IEC 60601-2-2: 2009 (Fifth Edition) + C1:2014 for use in conjunction with IEC 60601-1:2005 (Third Edition)

4.9.3 Microscopes and endoscopes

IEC 60601-2-18:2009 (Ed.3)	Medical electrical equipment – Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
ISO 10936-1:2017	Optics and photonics – Operation microscopes – Part 1: Requirements and test methods
ISO 8600-1:2015	Endoscopes – Medical endoscopes and endotherapy devices – Part 1: General requirements
ISO 8600-2:2015	Endoscopes – Medical endoscopes and endotherapy devices – Part 2: Particular requirements for rigid bronchoscopes
ISO 8600-3:2019	Endoscopes – Medical endoscopes and endotherapy devices – Part 3: Determination of field of view and direction of view of endoscopes with optics
ISO 8600-4:2014	Endoscopes – Medical endoscopes and endotherapy devices – Part 4: Determination of maximum width of insertion portion
ISO 8600-5:2005	Optics and photonics – Medical endoscopes and endotherapy devices – Part 5: Determination of optical resolution of rigid endoscopes with optics
ISO 8600-6:2005	Optics and photonics – Medical endoscopes and endotherapy devices – Part 6: Vocabulary
ISO 8600-7:2012	Endoscopes – Medical endoscopes and endotherapy devices – Part 7: Basic requirements for medical endoscopes of water-resistant type

4.9.4 Surgical instruments

ISO 13402:1995	Surgical and dental hand instruments – Determination of resistance against autoclaving, corrosion and thermal exposure
ISO 7151:1988	Surgical instruments – Non-cutting, articulated instruments – General requirements and test methods

ISO 7153-1:2016	Surgical instruments – Materials – Part 1: Metals
ISO 7740:1985	Instruments for surgery – Scalpels with detachable blades – Fitting dimensions
ISO 7741:1986	Instruments for surgery – Scissors and shears – General requirements and test methods

4.10 Syringes, needles and catheters

4.10.1 Syringes, needles and catheters

ISO 11040-1:2015	Prefilled syringes – Part 1: Glass cylinders for dental local anaesthetic cartridges
ISO 11040-2:2011	Prefilled syringes – Part 2: Plunger stoppers for dental local anaesthetic cartridges
ISO 11040-3:2012	Prefilled syringes – Part 3: Seals for dental local anaesthetic cartridges
ISO 11040-4:2015	Prefilled syringes – Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling
ISO 11040-4:2015/ Amd 1:2020	Prefilled syringes – Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling — *Amendment 1*
ISO 11040-5:2012	Prefilled syringes – Part 5: Plunger stoppers for injectables
ISO 11040-6:2019	Prefilled syringes – Part 6: Plastic barrels for injectables and sterilized subassembled syringes ready for filling
ISO 11608-1:2014	Needle-based injection systems for medical use – Requirements and test methods – Part 1: Needle-based injection systems
ISO 11608-2:2012	Needle-based injection systems for medical use – Requirements and test methods – Part 2: Needles

ISO 11608-3:2012	Needle-based injection systems for medical use – Requirements and test methods – Part 3: Finished containers
ISO 11608-4:2006	Pen-injectors for medical use – Part 4: Requirements and test methods for electronic and electromechanical pen-injectors
ISO 11608-5:2012	Needle-based injection systems for medical use – Requirements and test methods – Part 5: Automated functions
ISO 13926-1:2018	Pen systems – Part 1: Glass cylinders for pen-injectors for medical use
ISO 13926-2:2017	Pen systems – Part 2: Plunger stoppers for pen-injectors for medical use
ISO 13926-3:2019	Pen systems – Part 3: Seals for pen-injectors for medical use
ISO 14972:1998	Sterile obturators for single use with over-needle peripheral intravascular catheters
ISO 17218:2014	Sterile acupuncture needles for single use
ISO 23908:2011	Sharps injury protection – Requirements and test methods – Sharp protection features for single-use hypothermic needles, introducers for catheters and needles used for blood sampling
ISO 6009:2016	Hypodermic needles for single use – Colour coding for identification
ISO 7864:2016	Sterile hypodermic needles for single use – Requirements and test methods
ISO 7886-1:2017	Sterile hypodermic syringes for single use – Part 1: Syringes for manual use
ISO 7886-2:2020	Sterile hypodermic syringes for single use – Part 2: Syringes for use with power-driven syringe pumps
ISO 7886-3:2020	Sterile, hypodermic syringes for single use – Part 3: Auto-disable syringes for fixed-dose immunization
ISO 7886-4:2018	Sterile~~,~~ hypodermic syringes for single use – Part 4: Syringes with re-use prevention feature

ISO 80369-7:2016	Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications
ISO 8537:2016	Sterile single-use syringes, with or without needle, for insulin
ISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods

4.10.2 Syringes, needles and catheters (Cardiovascular)

ISO 10555-1:2013	Intravascular catheters – Sterile and single-use catheters – Part 1: General requirements
ISO 10555-1:2013/ Amd 1:2017	Intravascular catheters – Sterile and single-use catheters – Part 1: General requirements – *Amendment 1*
ISO 10555-3:2013	Intravascular catheters – Sterile and single-use catheters – Part 3: Central venous catheters
ISO 10555-4:2013	Intravascular catheters – Sterile and single-use catheters – Part 4: Balloon dilatation catheters
ISO 10555-5:2013	Intravascular catheters – Sterile and single-use catheters – Part 5: Over-needle peripheral catheters
ISO 11070:2014	Sterile, single-use intravascular catheter introducers, dilators and guidewires
ISO 11070:2014/AMD 1:2018	Sterile single-use intravascular introducers, dilators and guidewires – *Amendment 1*

4.11 Therapeutic/diagnostic equipment

4.11.1 Blood pressure monitors

IEC 60601-2-23:2011 (Ed. 3)	Medical electrical equipment – Part 2-23: Particular requirements for the basic safety and essential performance~~,~~ of transcutaneous partial pressure monitoring equipment
IEC 60601-2-34:2011 (Ed.3)	Medical electrical equipment – Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment
IEC 80601-2-30:2018	Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
IECEE TRF 60601-2-23D:2017 (Ed. 4)	This Test Report Form applies to: IEC 60601-2-23:2011 for use with IEC 60601-1:2005
IECEE TRF 60601-2-34D:2018 (Ed. 5)	This Test Report Form applies to: IEC 60601-2-34:2011
ISO 80601-2-30:2018	Medical electrical equipment – Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers
ISO 81060-1:2007	Non-invasive sphygmomanometers – Part 1: Requirements and test methods for non-automated measurement type
ISO 81060-2:2018	Non-invasive sphygmomanometers – Part 2: Clinical investigation of intermittent automated measurement type
ISO 81060-2:2018/ Amd 1:2020	Non-invasive sphygmomanometers – Part 2: Clinical investigation of intermittent automated measurement type – *Amendment 1*
ISO/IEEE 11073-10407:2010	Health informatics – Personal health device communication – Part 10407: Device specialization – Blood pressure monitor

4.11.2 Electrocardiogram (ECG)

IEC 60601-2-25:2011 (Ed.2)	Medical electrical equipment – Part 2-25: Particular requirements for basic safety and essential performance of electrocardiographs
IEC 60601-2-27:2011 (Ed.3)	Medical electrical equipment – Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
IECEE TRF 60601-2-25E:2020 (Ed. 4)	This Test Report Form applies to: IEC 60601-2-25:2011 for use in conjunction with IEC 60601-1:2005
IECEE TRF 60601-2-27E:2020 (Ed. 4)	This Test Report Form applies to: IEC 60601-2-27:2011 for use in conjunction with IEC 60601-1:2005
IECEE TRF 60601-2-51C:2020 (Ed. 3)	This Test Report Form applies to IEC 60601-2-51: 2003 (First Edition) for use in conjunction with IEC 60601-1:1988, AMD1:1991, AMD2:1995
ANSI/AAMI/IEC 60601-2-27:2011 (R2016)	Medical Electrical Equipment – Part 2-27: Particular Requirements for the Basic Safety and Essential Performance of Electrocardiographic Monitoring Equipment
ANSI/AAMI EC53:2013	ECG trunk cables and patient leadwires

4.11.3 Electroencephalogram (EEG)

IEC 80601-2-26:2019	Medical electrical equipment – Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalograph
IECEE TRF 60601-2-26E:2020 (Ed. 5)	This Test Report Form applies to: IEC 60601-2-26:2012 for use in conjunction with IEC 60601-1:2005
IECEE TRF 80601-2-26A:2020 (Ed. 1)	This Test Report Form applies to: IEC 80601-2-26:2019 for use in conjunction with IEC 60601-1:2005, AMD1:2012

4.11.4 Electromyogram (EMG)

IEC 60601-2-40:2016 (Ed. 2)	Medical electrical equipment – Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment
IECEE TRF 60601-2-40B:2006 (Ed.2)	This Test Report Form applies to IEC 60601-2-40: 1998 (First Edition) for use in conjunction with IEC 60601-1:1988 + A1:1991 + A2:1995

4.11.5 Infant incubators

IEC 60601-2-19:2020 (Ed. 3)	Medical electrical equipment – Part 2-19: Particular requirements for basic safety and essential performance of infant incubators
IEC 60601-2-20:2020 (Ed. 3)	Medical electrical equipment – Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators
IEC 60601-2-21:2020 (Ed. 3)	Medical electrical equipment – Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers
IEC 60601-2-50:2020 (Ed. 3)	Medical electrical equipment – Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment

IECEE TRF 60601-2-19D:2019 (Ed.4)	This Test Report Form applies to: IEC 60601-2-19: 2009, AMD1:2016 for use in conjunction with IEC 60601-1:2005, AMD1:2012
IECEE TRF 60601-2-20D:2019 (Ed.4)	This Test Report Form applies to: IEC 60601-2-20:2009, AMD1:2016 for use in conjunction with IEC 60601-1:2005, AMD1:2012, COR1:2014
IECEE TRF 60601-2-21D:2019 (Ed.4)	This Test Report Form applies to: IEC 60601-2-21:2009, AMD1:2016 for use in conjunction with IEC 60601-1:2005, AMD1:2012
IECEE TRF 60601-2-50C:2011 (Ed.3)	This Test Report Form applies to IEC 60601-2-50: 2009 (Second Edition) for use in conjunction with IEC 60601-1:2005 (Third Edition)

4.11.6 Lasers

IEC 60601-2-22:2019	Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
IEC 60825-1:2014 (Ed. 3)	Safety of laser products – Part 1: Equipment classification and requirements
IEC 60825-2:2004 +Amd1:2006 +Amd2:2010 CSV Consolidated version (Ed. 3.2)	Safety of laser products – Part 2: Safety of optical fibre communication systems (OFCS)
IEC 60825-4:2006 +Amd1:2008 +Amd2:2011 CSV Consolidated version (Ed. 2.2)	Safety of laser products – Part 4: Laser guards
IEC 60825-12:2019 (Ed.2)	Safety of laser products – Part 12: Safety of free space optical communication systems used for transmission of information
IEC TR 60825-13:2011 (Ed. 2)	Safety of laser products – Part 13: Measurements for classification of laser products

IEC TR 60825-14:2004 (Ed. 1)	Safety of laser products – Part 14: A user's guide
IEC TR 60825-17:2015 (Ed. 2)	Safety of laser products – Part 17: Safety aspects for use of passive optical components and optical cables in high power optical fibre communication systems
IEC TR 60825-3:2008 (Ed. 2)	Safety of laser products – Part 3: Guidance for laser displays and shows
IEC TR 60825-5:2019 (Ed. 3)	Safety of laser products – Part 5: Manufacturer's checklist for IEC 60825-1
IEC TR 60825-8:2006 (Ed. 2)	Safety of laser products – Part 8: Guidelines for the safe use of laser beams on humans
ISO 11145:2018	Optics and photonics – Lasers and laser-related equipment – Vocabulary and symbols
ISO 11146-1:2005	Lasers and laser-related equipment – Test methods for laser beam widths, divergence angles and beam propagation ratios – Part 1: Stigmatic and simple astigmatic beams
ISO 11146-2:2005	Lasers and laser-related equipment – Test methods for laser beam widths, divergence angles and beam propagation ratios – Part 2: General astigmatic beams
ISO 11151-1:2015	Lasers and laser-related equipment – Standard optical components – Part 1: Components for the UV, visible and near-infrared spectral ranges
ISO 11151-2:2015	Lasers and laser-related equipment – Standard optical components – Part 2: Components for the infrared spectral range
ISO 11252:2013	Lasers and laser-related equipment – Laser device – Minimum requirements for documentation
ISO 11551:2019	Optics and photonics – Lasers and laser-related equipment – Test method for absorptance of optical laser components
ISO 11554:2017	Optics and photonics – Lasers and laser-related equipment – Test methods for laser beam power, energy and temporal characteristics

ISO 11670:2003	Lasers and laser-related equipment – Test methods for laser beam parameters – Beam positional stability
ISO 11670:2003/ Cor 1:2004	Lasers and laser-related equipment – Test methods for laser beam parameters – Beam positional stability – *Technical Corrigendum 1*
ISO 11810:2015	Lasers and laser-related equipment – Test method and classification for the laser resistance of surgical drapes and/or patient protective covers – Primary ignition, penetration, flame spread and secondary ignition
ISO 11990:2018	Lasers and laser-related equipment – Determination of laser resistance of tracheal tube shaft and tracheal tube cuffs
ISO 12005:2003	Lasers and laser-related equipment – Test methods for laser beam parameters – Polarization
ISO 13694:2018	Optics and photonics – Lasers and laser-related equipment – Test methods for laser beam power (energy) density distribution
ISO 13695:2004	Optics and photonics – Lasers and laser-related equipment – Test methods for the spectral characteristics of lasers
ISO 13697:2006	Optics and photonics – Lasers and laser-related equipment – Test methods for specular reflectance and regular transmittance of optical laser components
ISO 15367-1:2003	Lasers and laser-related equipment – Test methods for determination of the shape of a laser beam wavefront – Part 1: Terminology and fundamental aspects
ISO 15367-2:2005	Lasers and laser-related equipment – Test methods for determination of the shape of a laser beam wavefront – Part 2: Shack-Hartmann sensors
ISO 17526:2003	Optics and optical instruments – Lasers and laser-related equipment – Lifetime of lasers
ISO 17915:2018	Optics and photonics – Measurement method of semiconductor lasers for sensing

ISO 21254-1:2011	Lasers and laser-related equipment – Test methods for laser-induced damage threshold – Part 1: Definitions and general principles
ISO 21254-2:2011	Lasers and laser-related equipment – Test methods for laser-induced damage threshold – Part 2: Threshold determination
ISO 21254-3:2011	Lasers and laser-related equipment – Test methods for laser-induced damage threshold – Part 3: Assurance of laser power (energy) handling capabilities
ISO 24013:2006	Optics and photonics – Lasers and laser-related equipment – Measurement of phase retardation of optical components for polarized laser radiation
ISO/TR 11146-3:2004	Lasers and laser-related equipment – Test methods for laser beam widths, divergence angles and beam propagation ratios – Part 3: Intrinsic and geometrical laser beam classification, propagation and details of test methods
ISO/TR 11146-3:2004/ Cor 1:2005	Lasers and laser-related equipment – Test methods for laser beam widths, divergence angles and beam propagation ratios – Part 3: Intrinsic and geometrical laser beam classification, propagation and details of test methods – *Technical Corrigendum 1*
ISO/TR 21254-4:2011	Lasers and laser-related equipment – Test methods for laser-induced damage threshold – Part 4: Inspection, detection and measurement
ISO/TR 22588:2005	Optics and photonics – Lasers and laser-related equipment – Measurement and evaluation of absorption-induced effects in laser optical components
ANSI Z136.1 and Z136.2 Combination Set	Safe Use of Lasers and Safe Use of Optical Fiber Communication Systems Utilizing Laser Diode and LED Sources
ANSI Z136.1 and Z136.3 Combination Set	Safe Use of Lasers and Safe Use of Lasers in Health Care Facilities
ANSI Z136.1 and Z136.4 Combination Set	Safe Use of Lasers and Laser Safety Measurements for Hazard Evaluation

ANSI Z136.1 and Z136.5 Combination Set	Safe Use of Lasers and Safe Use of Lasers in Educational Institutions
ANSI Z136.1 and Z136.6 Combination Set	Safe Use of Lasers and Safe Use of Lasers Outdoors
ANSI Z136.1 and Z136.7 Combination Set	Safe Use of Lasers and Testing and Labelling of Laser Protective Equipment
ANSI Z136.1 and Z136.8 Combination Set	Safe Use of Lasers and Safe Use of Lasers in Research, Development, or Testing
ANSI Z136.1 and Z136.9 Combination Set	Safe Use of Lasers and Safe Use of Lasers in Manufacturing Environments
ANSI Z136.3-2018	Safe Use of Lasers in Health Care
ANSI Z136.4-2010	American National Standard Recommended Practice for Laser Safety Measurements for Hazard Evaluation
ANSI Z136.5-2020	Safe Use of Lasers in Educational Institutions
ANSI Z136.6-2015	Safe Use of Lasers Outdoors
ANSI Z136.8-2012	American National Standard for Safe Use of Lasers in Research, Development, or Testing

4.11.7 Lithotripsy equipment

IEC 60601-2-36:2014 (Ed.2)	Medical electrical equipment – Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy

4.11.8 Magnetic resonance imaging (MRI) equipment

IEC 60601-2-33:2010 +AMD1:2013 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
IEC 60601-2-33:2010 +Amd1:2013 +Amd2:2015 CSV Consolidated version (Ed. 3.2)	Medical electrical equipment – Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis

4.11.9 Microwave therapy equipment

IEC 60601-2-3:2012 (Ed.3)	Medical electrical equipment – Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment
IEC 60601-2-3:2012 +Amd1:2016 CSV Consolidated version (Ed.3.1)	Medical electrical equipment – Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment
IEC 60601-2-6:2012 (Ed.2.0)	Medical electrical equipment – Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment
IEC 60601-2-6:2012 +Amd1:2016 CSV Consolidated version (Ed.2.1)	Medical electrical equipment – Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment
IECEE TRF 60601-2-3D:2019 (Ed. 5)	This Test Report Form applies to: IEC 60601-2-3:2012, AMD1:2016 for use in conjunction with IEC 60601-1:2005, AMD1:2012
IECEE TRF 60601-2-6D:2017 (Ed. 4)	This Test Report Form applies to: IEC 60601-2-6: 2012, AMD1:2016 for use in conjunction with for use with IEC 60601-1:2005 and with IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012

4.11.10 Nerve and muscle simulators

IEC 60601-2-10:2012 (Ed.2)	Medical electrical equipment – Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
IEC 60601-2-10:2012 +Amd1:2016 CSV Consolidated version (Ed.2.1)	Medical electrical equipment – Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators

4.11.11 Patient monitoring equipment

IEC 80601-2-49:2018 (Ed.1)	Medical electrical equipment – Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors
IEC 80601-2-59:2017 (Ed.2)	Medical electrical equipment – Part 2-59: Particular requirements for basic safety and essential performance of screening thermographs for human febrile temperature screening
ISO/TR 13154:2017	Medical electrical equipment – Deployment, implementation and operational guidelines for identifying febrile humans using a screening thermograph

4.11.12 Radiographic equipment (Brachytherapy)

IEC 60601-2-17:2013 (Ed.3)	Medical electrical equipment – Part 2-17: Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment
ISO 21439:2009	Clinical dosimetry – Beta radiation sources for brachytherapy

4.11.13 Radiographic equipment (Gamma Beam)

IEC 60601-2-11:2013 (Ed.3)	Medical electrical equipment – Part 2-11: Particular requirements for the basic safety and essential performance of gamma beam therapy equipment
IEC/TRF 60601-2-11D:2014	This test report applies to IEC 60601-2-11:2013 (Third Edition)

4.11.14 Radiographic equipment (X-Ray)

IEC 60601-1-3:2008 +Amd1:2013 CSV Consolidated version	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-2-1:2009 +Amd1:2014 CSV Consolidated version (Ed.3.1)	Medical electrical equipment – Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV
IEC 60601-2-28:2017 (Ed.3)	Medical electrical equipment – Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
IEC 60601-2-43:2010 (Ed.2)	Medical electrical equipment – Part 2-43: Particular requirements for basic safety and essential performance of X-ray equipment for interventional procedures
IEC 60601-2-43:2010 +Amd1:2017+Amd2:2019 CSV Consolidated version (Ed. 2.2)	Medical electrical equipment – Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures
IEC 60601-2-44:2009 +Amd1:2012 CSV Consolidated version (Ed.3.1)	Medical electrical equipment – Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography
IEC 60601-2-44:2009 +Amd1:2012+Amd2:2016 CSV Consolidated version (Ed.3.2)	Medical electrical equipment – Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography

IEC 60601-2-45:2011 (Ed.3)	Medical electrical equipment – Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices
IEC 60601-2-45:2011 +Amd1:2015 CSV Consolidated version (Ed.3.1)	Medical electrical equipment – Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices
IEC 60601-2-54:2009 (Ed.1)	Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
IEC 60601-2-54:2009 +Amd1:2015+Amd2:2018 CSV Consolidated version (Ed.1.2)	Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
IEC 60601-2-63:2012 +Amd1:2017 CSV Consolidated version (Ed.1.1)	Medical electrical equipment – Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment
IEC 60601-2-65:2012 +Amd1:2017 CSV Consolidated version (Ed.1.1)	Medical electrical equipment – Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment
IEC 60601-2-8:2010 (Ed.2)	Medical electrical equipment – Part 2-8: Particular requirements for basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV
IEC 60601-2-8:2010 +Amd1:2015 CSV Consolidated version (Ed.2.1)	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
IECEE TRF 60601-2-1H:2019 (Ed. 7)	This Test Report Form applies to: IEC 60601-2-1:2009 for use in conjunction with IEC 60601-1:2005
IECEE TRF 60601-2-28E:2017 (Ed. 5)	This Test Report Form applies to: IEC 60601-2-28:2010 for use in conjunction with IEC 60601-1:2005

IECEE TRF 60601-2-43F:2020 (Ed. 6)	This Test Report Form applies to: IEC 60601-2-43:2010, AMD1:2017, AMD2:2019 for use in conjunction with IEC 60601-1:2005, AMD1:2012
IECEE TRF 60601-2-45E:2017 (Ed. 5)	This Test Report Form applies to: IEC 60601-2-45:2011, AMD1:2015 for use with IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012 (or IEC 60601-1:2012 reprint)
IECEE TRF 60601-2-54G:2019 (Ed. 7)	This Test Report Form applies to: IEC 60601-2-54:2009, AMD1:2015 for use in conjunction with IEC 60601-1:2005, AMD1:2012
IECEE TRF 60601-2-63B:2017 (Ed. 2)	This Test Report Form applies to: IEC 60601-2-63:2012, AMD1:2017 for use in conjunction with IEC 60601-1:2005, AMD1:2012
IECEE TRF 60601-2-65B:2017 (Ed. 2)	This Test Report Form applies to: IEC 60601-2-65:2012, AMD1:2017 for use in conjunction with IEC 60601-1:2005, AMD1:2012
IECEE TRF 60601-2-8D:2016 (Ed. 4)	This Test Report applies to: IEC 60601-2-8:2010 (Second Edition) + A1 for use with IEC 60601-1:2005 (Third Edition) + CORR.1:2006 + CORR.2:2007 + A1:2012
ISO 3665:2011	Photography – Intra-oral dental radiographic film and film packets – Manufacturer specifications
ISO 5799:1991	Photography – Direct-exposing medical and dental radiographic film/process systems – Determination of ISO speed and ISO average gradient

4.11.15 Radiotherapy stimulators

IEC 60601-2-29:2008 (Ed.3)	Medical electrical equipment – Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy stimulators

4.11.16 Thermometers

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
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*

4.11.17 Ultrasonic monitoring/therapy equipment

IEC 60601-2-37:2007 (Ed.2)	Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnosis and monitoring equipment
IEC 60601-2-37:2007 +Amd1:2015 CSV Consolidated version (Ed.2.1)	Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC 60601-2-5:2009 (Ed.3)	Medical electrical equipment – Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment
IECEE TRF 60601-2-37F:2016 (Ed. 6)	This Test Report Form applies to: IEC 60601-2-37 (ed.2), am1 for use in conjunction with IEC60601-1 (ed.3), am1 with Corr1 and Corr2
IECEE TRF 60601-2-5E:2018 (Ed. 6)	This Test Report Form applies to: IEC 60601-2-5:2009 for use with IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012

4.11.18 Transfusion, infusion and injection equipment

IEC 60601-2-24:2012 (Ed.2)	Medical electrical equipment – Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers
ISO 10985:2009	Caps made of aluminium-plastics combinations for infusion bottles and injection vials – Requirements and test methods
ISO 1135-3:2016	Transfusion equipment for medical use – Part 3: Blood-taking sets for single use
ISO 1135-4:2015	Transfusion equipment for medical use – Part 4: Transfusion sets for single use, gravity feed
ISO 1135-5:2015	Transfusion equipment for medical use – Part 5: Transfusion sets for single use with pressure infusion apparatus
ISO 11418-1:2016	Containers and accessories for pharmaceutical preparations – Part 1: Drop-dispensing glass bottles
ISO 11418-2:2016	Containers and accessories for pharmaceutical preparations – Part 2: Screw-neck glass bottles for syrups
ISO 11418-3:2016	Containers and accessories for pharmaceutical preparations – Part 3: Screw-neck glass bottles (veral) for solid and liquid dosage forms
ISO 11418-3:2016/ Amd 1:2017	Containers and accessories for pharmaceutical preparations – Part 3: Screw-neck glass bottles (veral) for solid and liquid dosage forms – *Amendment 1*
ISO 11418-5:2015	Containers and accessories for pharmaceutical preparations – Part 5: Dropper assemblies
ISO 11418-7:2016	Containers and accessories for pharmaceutical preparations – Part 7: Screw-neck vials made of glass tubing for liquid dosage forms
ISO 15010:1998	Disposable hanging devices for transfusion and infusion bottles – Requirements and test methods

ISO 15137:2005	Self-adhesive hanging devices for infusion bottles and injection vials – Requirements and test methods
ISO 15375:2010	Medical infusion bottles – Suspension devicesfor multiple use – Requirements and test methods
ISO 15747:2018	Plastic containers for intravenous injections
ISO 15759:2005	Medical infusion equipment – Plastics caps with inserted elastomeric liner for containers manufactured by the blow-fill-seal (BFS) process
ISO 21649:2006	Needle-free injectors for medical use – Requirements and test methods
ISO 22413:2010	Transfer sets for pharmaceutical preparations – Requirements and test methods
ISO 28620:2020	Medical devices – Non-electrically driven portable infusion devices
ISO 3826-1-:2019	Plastics collapsible containers for human blood and blood components – Part 1: Conventional containers
ISO 3826-2:2008	Plastics collapsible containers for human blood and blood components – Part 2: Graphical symbols for use on labels and instruction leaflets
ISO 3826-3:2006	Plastics collapsible containers for human blood and blood components – Part 3: Blood bag systems with integrated features
ISO 6710:2017	Single-use containers for human venous blood specimen collection
ISO 8362-1:2018	Injection containers and accessories – Part 1: Injection vials made of glass tubing
ISO 8362-2:2015	Injection containers and accessories – Part 2: Closures for injection vials
ISO 8362-3:2001	Injection containers and accessories – Part 3: Aluminium caps for injection vials

ISO 8362-4:2011	Injection containers and accessories – Part 4: Injection vials made of moulded glass
ISO 8362-5:2016	Injection containers and accessories – Part 5: Freeze drying closures for injection vials
ISO 8362-6:2010	Injection containers and accessories – Part 6: Caps made of aluminium-plastics combinations for injection vials
ISO 8362-7:2006	Injection containers and accessories – Part 7: Injection caps made of aluminium-plastics combinations without overlapping plastics part
ISO 8536-1:2011	Infusion equipment for medical use – Part 1: Infusion glass bottles
ISO 8536-2:2010	Infusion equipment for medical use – Part 2: Closures for infusion bottles
ISO 8536-3:2009	Infusion equipment for medical use – Part 3: Aluminium caps for infusion bottles
ISO 8536-4:2019	Infusion equipment for medical use – Part 4: Infusion sets for single use, gravity feed
ISO 8536-5:2004	Infusion equipment for medical use – Part 5: Burette infusion sets for single use, gravity feed
ISO 8536-6:2016	Infusion equipment for medical use – Part 6: Freeze drying closures for infusion bottles
ISO 8536-7:2009	Infusion equipment for medical use – Part 7: Caps made of aluminium-plastics combinations for infusion bottles
ISO 8536-8:2015	Infusion equipment for medical use – Part 8: Infusion sets for single use with pressure infusion apparatus
ISO 8536-9:2015	Infusion equipment for medical use – Part 9: Fluid lines for single use with pressure infusion equipment
ISO 8536-10:2015	Infusion equipment for medical use – Part 10: Accessories for fluid lines for single use with pressure infusion equipment

ISO 8536-11:2015	Infusion equipment for medical use – Part 11: Infusion filters for single use with pressure infusion equipment
ISO 8536-12:2007	Infusion equipment for medical use – Part 12: Check valves
ISO 8536-12:2007/ Amd 1:2012	Infusion equipment for medical use – Part 12: Check valves – *Amendment 1*
ISO 8871-1:2003	Elastomeric parts for parenterals and for devices for pharmaceutical use – Part 1: Extractables in aqueous autoclavates
ISO 8871-2:2020	Elastomeric parts for parenterals and for devices for pharmaceutical use – Part 2: Identification and characterization
ISO 8871-3:2003	Elastomeric parts for parenterals and for devices for pharmaceutical use – Part 3: Determination of released-particle count
ISO 8871-3:2003/ Amd 1:2018	Elastomeric parts for parenterals and for devices for pharmaceutical use – Part 3: Determination of released-particle count – *Amendment 1*
ISO 8871-4:2006	Elastomeric parts for parenterals and for devices for pharmaceutical use – Part 4: Biological requirements and test methods
ISO 8871-5:2016	Elastomeric parts for parenterals and for devices for pharmaceutical use – Part 5: Functional requirements and testing
ISO 8872:2003	Aluminium caps for transfusion, infusion and injection bottles – General requirements and test methods
ISO 9187-1:2010	Injection equipment for medical use – Part 1: Ampoules for injectables
ISO 9187-2:2010	Injection equipment for medical use – Part 2: One-point-cut (OPC) ampoules

5. Product Standards (In Vitro Diagnostic Medical Devices (IVDMD))

5.1 Glucose meters

ISO 15197:2013	In vitro diagnostic test systems – Requirements for blood – glucose monitoring systems for self-testing in managing diabetes mellitus
ISO/IEEE 11073-10417:2017	Health informatics – Personal health device communication – Part 10417: Device specialization – Glucose meter