RS-01:2015 (E)

# 醫療儀器的規管

# Regulation of Medical Devices

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

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# 1. Introduction

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 Control Office (MDCO) believes that conformance with recognised medical device standards, in whole or in part, can provide assurance of safety and effectiveness 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 and effectiveness of their products in listing applications. It also helps MDCO to ensure consistency in reviewing the listing applications, and save the manpower 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

| | |
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| ISO 10993-1:2009 | Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process |
| ISO 10993-1:2009/ Cor1:2010 | Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process - *Technical Corrigendum 1* |
| ISO 10993-2:2006 | Biological evaluation of medical devices – Part 2: Animal welfare requirements |
| ISO 10993-3:2003 | Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity |
| ISO 10993-4:2002 | Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood |
| ISO 10993-4:2002/ Amd 1:2006 | Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood – *Amendment 1* |
| ISO 10993-5:2009 | Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity |
| ISO 10993-6:2007 | Biological evaluation of medical devices – Part 6: Tests for local effects after implantation |
| ISO 10993-7:2008 | Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals |

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| ISO 10993-7:2008 / Cor 1:2009 | Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals – *Technical Corrigendum 1* |
| ISO 10993-9:2009 | 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 10993-11:2006 | 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 10993-15:2000 | Biological evaluation of medical devices – Part 15: Identification and quantification of degradation products from metals and alloys |
| ISO 10993-16:2010 | 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 |

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| ISO 10993-18:2005 | Biological evaluation of medical devices – Part 18: Chemical characterization of materials |
| ISO 10993-19:2006 | Biological evaluation of medical devices – Part 19: Physico-chemical, morphological and topographical characterization of materials |
| ISO 10993-20:2006 | Biological evaluation of medical devices – Part 20: Principles and methods for immunotoxicology testing of medical devices |
| ISO/TR 15499: 2012 | Biological evaluation of medical devices – Guidance on the conduct of biological evaluation within a risk management process |

## 2.2 Clinical investigation

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| ISO 14155:2011 | Clinical investigation of medical devices for human subjects – Good clinical practice |
| ISO 14155:2001/ Cor 1:2011 | Clinical investigation of medical devices for human subjects – Good clinical practice – *Technical Corrigendum 1* |

## 2.3 Quality management system (QMS)

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|---|---|
| ISO 13485:2003 | Medical devices – Quality management systems – Requirements for regulatory purposes |
| ISO 13485:2003/ Cor 1:2009 | Medical devices – Quality management systems – Requirements for regulatory purposes – *Technical Corrigendum 1* |

## 2.4 Risk management

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|---|---|
| ISO 14971:2007 | Medical devices – Application of risk management to medical devices |

## 2.5 Symbols and labelling

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| ISO 15223-1:2012 | 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 | Information to be supplied by the manufacturer with 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)

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| ISO/TR 37137:2014 | Biological evaluation of medical devices – Guidance for absorbable implants |

## 3.2 Animal tissue and their derivatives (Biological evaluation)

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| ISO 22442-1:2007 | Medical devices utilizing animal tissues and their derivatives – Part 1: Application of risk management |
| ISO 22442-2:2007 | 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

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|---|---|
| ISO 13408-1:2011 | Aseptic processing of health care products – Part 1: General requirements |
| ISO 13408-1:2011/ Amd1:2013 | Aseptic processing of health care products – Part 1: General requirements – *Amendment 1* |

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|---|---|
| ISO 13408-2:2003 | Aseptic processing of health care products – Part 2: 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

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|---|---|
| IEC 60601-1:2005 +AMD1:2012 CSV Consolidated version (Ed. 3.1) | Medical electrical equipment – Part 1: General requirements for basic safety and essential performance |
| IEC 60601-1-2:2014 (Ed. 4.0) | Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests |
| IEC 60601-1-4:2006 (Ed. 3.0) | Medical electrical equipment – Part 1-4: General requirements for safety – Collateral standard: Programmable electrical medical systems |

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| IEC 60601-1-6:2013 (Ed. 3.1) | Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability |
| IEC 60601-1-8:2012 (Ed. 2.1) | 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 60601-1-9:2013 (Ed. 1.1) | Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral standard: Requirements for environmentally conscious design |
| IEC 60601-1-10:2013 (Ed 1.1) | 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 60601-1-11:2010 | 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

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| IEC 62366:2007 | Medical devices – Application of usability engineering to medical devices |

## 3.6 In vitro diagnostic (IVD) medical devices

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| 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 17511:2003 | In vitro diagnostic medical devices -- Measurement of quantities in biological samples -- Metrological traceability of values assigned to calibrators and control materials |
| 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 |

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| 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

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| ASTM F2503-13 | Standard practice for marking medical devices and other items for safety in the magnetic resonance environment |

## 3.8 Software

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| IEC 62304:2006 | 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

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| ISO 11135:2014 | Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices |
| 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 11137-2:2012 | Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose |
| ISO 11137-3:2006 | Sterilization of health care products – Radiation – Part 3: Guidance on dosimetric aspects |
| ISO 11138-1:2006 | Sterilization of health care products – Biological indicators – Part 1: General requirements |
| ISO 11138-2:2006 | Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes |
| ISO 11138-3:2006 | Sterilization of health care products – Biological indicators – Part 3: Biological indicators for moist heat sterilization processes |
| ISO 11138-4:2006 | Sterilization of health care products – Biological indicators – Part 4: Biological indicators for dry heat sterilization processes |

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| ISO 11138-5:2006 | Sterilization of health care products – Biological indicators – Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes |
| ISO 11139:2006 | Sterilization of health care products – Vocabulary |
| ISO 11140-1:2005 | 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 11607-1:2006 | Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems |
| ISO 11607-2:2006 | Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes |

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| ISO 11737-1:2006 | Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products |
| ISO 11737-1:2006/ Cor 1:2007 | Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products – *Technical Corrigendum 1* |
| ISO 11737-2:2009 | 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 14161:2009 | Sterilization of health care products – Biological indicators – Guidance for the selection, use and interpretation of results |
| 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 |

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| ISO 17664:2004 | Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable 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 18472:2006 | 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 25424:2009 | 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 – 07(2011) | 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 |

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| EN 556-2:2003 | Sterilization of medical devices – Requirements for medical devices to be designated “STERILE” – Part 2 Requirements for aseptically processed medical devices |

# 4. Product Standards

## 4.1 Acoustics and hearing aid devices

### (a) Audiometric equipment

| | |
|---|---|
| IEC 60645-1:2001 | Audiometers. Pure-tone audiometers |
| IEC 60645-2:1993 | Audiometers. Equipment for speech audiometry |
| IEC 60645-4:1994 | Audiometers. Equipment for extended high-frequency audiometry |
| ISO 389-1:1998 | Acoustics. Reference zero for the calibration of audiometric equipment. Reference equivalent threshold sound pressure levels for pure tones and supra-aural earphones |
| ISO 389-2:1994 | Reference zero for the calibration of audiometric equipment. Reference equivalent threshold sound pressure levels for pure tones and insert earphones |
| ISO 389-3:1994 | Electroacoustics. Audiometric equipment. Test signals of short duration |
| ISO 389-3:1994/ Cor 1:1995 | Electroacoustics. Audiometric equipment. Test signals of short duration – *Technical Corrigendum 1* |
| ISO 389-4:1994 | Acoustics. Reference zero for the calibration of audiometric equipment. Reference levels for narrow-band masking noise |
| ISO 389-5:2006 | Acoustics. Reference zero for the calibration of audiometric equipment. Reference equivalent threshold sound pressure levels for pure tones in the frequency range 8 kHz to 16 kHz |

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| ISO 389-6:2007 | Reference zero for the calibration of audiometric equipment. Reference threshold of hearing for test signals of short duration |
| ISO 389-7:2005 | Acoustics. Reference zero for the calibration of audiometric equipment. Reference threshold of hearing under free-field and diffuse-field listening conditions |
| ISO 389-8:2004 | Reference zero for the calibration of audiometric equipment. 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. 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 |

**(b) Hearing aids**

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|---|---|
| IEC 60318-1:2009 | Electroacoustics - Simulators of human head and ear - Part 1: Ear simulator for the measurement of supra-aural and circumaural earphones |

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| IEC 60318-3:1998 | 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 cm3 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 60318-7:2011 | Electroacoustics - Simulators of human head and ear - Part 7: Head and torso simulator for acoustic measurement of hearing aids |
| ISO 12124:2001 | Acoustics -- Procedures for the measurement of real-ear acoustical characteristics of hearing aids |

## 4.2 Anaesthetic, respiratory and reanimation equipment

### (a) Airways and related equipment

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|---|---|
| ISO 11712:2009 | Anaesthetic and respiratory equipment -- Supralaryngeal airways and connectors |
| ISO 11991:1995 | Guidance on airway management during laser surgery of upper airway |
| ISO 16628:2008 | Tracheobronchial tubes -- Sizing and marking |
| ISO 27427:2013 | Anaesthetic and respiratory equipment -- Nebulizing systems and components |

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| ISO 5361:2012 | Anaesthetic and respiratory equipment -- Tracheal tubes and connectors |
| ISO 5362:2006 | Anaesthetic reservoir bags |
| ISO 5364:2008 | Anaesthetic and respiratory equipment -- Oropharyngeal airways |
| ISO 5366-1:2000 | Anaesthetic and respiratory equipment -- Tracheostomy tubes -- Part 1: Tubes and connectors for use in adults |
| ISO 5366-3:2001 | Anaesthetic and respiratory equipment -- Tracheostomy tubes -- Part 3: Paediatric tracheostomy tubes |
| ISO 5366-3:2001/ Cor 1:2003 | Anaesthetic and respiratory equipment -- Tracheostomy tubes -- Part 3: Paediatric tracheostomy tubes- *Technical Corrigendum 1* |
| ISO 5367:2014 | Anaesthetic and respiratory equipment -- Breathing sets and connectors |
| ISO 7376:2009 | Anaesthetic and respiratory equipment -- Laryngoscopes for tracheal intubation |
| ISO 8836:2014 | Suction catheters for use in the respiratory tract |

**(b) Breathing attachments and anaesthetic machines**

| | |
|---|---|
| IEC 60601-2-13:2009 | Medical electrical equipment - Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems |
| ISO 11195:1995 | Gas mixers for medical use -- Stand-alone gas mixers |
| ISO 26825:2008 | Anaesthetic and respiratory equipment -- User-applied labels for syringes containing drugs |

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| | used during anaesthesia -- Colours, design and performance |
| ISO 5356-1:2004 | 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 5358:1992 | Anaesthetic machines for use with humans |
| ISO 5359:2014 | Anaesthetic and respiratory equipment -- Low-pressure hose assemblies for use with medical gases |
| ISO 5360:2012 | 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 80601-2-35:2009 | Medical electrical equipment -- Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use |
| ISO 80601-2-55:2011 | 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 |

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| ISO/TS 18835:2004 | Inhalational anaesthesia systems -- Draw-over vaporizers and associated equipment |
| CSA Z168.3-97 (R2011) | Anaesthetic Machines for Medical Use |

**(c) Lung ventilators and related equipment**

| | |
|---|---|
| IEC 60601-2-12:2011 | Medical electrical equipment - Part 2-12: Particular requirements for the safety of lung ventilators - Critical care ventilators |
| ISO 10651-2:2004 | Lung ventilators for medical use -- Particular requirements for basic safety and essential performance -- Part 2: Home care ventilators for ventilator-dependent patients |
| ISO 10651-3:1997 | Lung ventilators for medical use -- Part 3: Particular requirements for emergency and transport ventilators |
| 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 10651-6:2004 | Lung ventilators for medical use -- Particular requirements for basic safety and essential performance -- Part 6: Home-care ventilatory support devices |
| ISO 17510-2:2007 | Sleep apnoea breathing therapy -- Part 2: Masks and application accessories |
| ISO 18778:2005 | Respiratory equipment -- Infant monitors -- Particular requirements |

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| 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 23747:2007 | 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 80601-2-12:2011 | Medical electrical equipment -- Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators |
| ISO 80601-2-12:2011 / Cor 1:2011 | Medical electrical equipment -- Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators – *Technical Corrigendum 1* |
| ISO 80601-2-61:2011 | Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment |
| ISO 80601-267:2014 | Medical electrical equipment -- Part 2-67: Particular requirements for basic safety and essential performance of oxygen-conserving equipment |

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| ISO 80601-2-69:2014 | Medical electrical equipment -- Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator 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 8185:2007 | Respiratory tract humidifiers for medical use -- Particular requirements for respiratory humidification systems |
| 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 |

**(d) Medical gas systems**

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|---|---|
| ISO 10083:2006 | Oxygen concentrator supply systems for use with medical gas pipeline systems |
| ISO 10524-1:2006 | Pressure regulators for use with medical gases -- Part 1: Pressure regulators and pressure regulators with flow-metering devices |
| ISO 10524-2:2005 | Pressure regulators for use with medical gases -- Part 2: Manifold and line pressure regulators |

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| ISO 10524-3:2005 | Pressure regulators for use with medical gases -- Part 3: Pressure regulators integrated with cylinder valves |
| ISO 10524-3:2005 | Filtration and information to be supplied by the manufacturer |
| ISO 10524-3:2005 / Amd 1:2013 | Filtration and information to be supplied by the manufacturer – *Amendment 1* |
| ISO 10524-4:2008 | Pressure regulators for use with medical gases -- Part 4: Low-pressure regulators |
| ISO 11117:2008 | Gas cylinders -- Valve protection caps and valve guards -- Design, construction and tests |
| ISO 11117:2008 / Cor1:2009 | Gas cylinders -- Valve protection caps and valve guards -- Design, construction and tests – *Technical Corrigendum 1* |
| ISO 11197:2004 | 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 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 18777:2005 | Transportable liquid oxygen systems for medical use -- Particular requirements |

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| ISO 19054:2005 | Rail systems for supporting medical equipment |
| 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 7396-1:2007 | Medical gas pipeline systems -- Part 1: Pipeline systems for compressed medical gases and vacuum |
| ISO 7396-1:2007/ Amd 1:2010 | Requirements for terminal units for vacuum fitted on medical supply units with operator-adjustable portions and connected to the pipeline through flexible hoses |
| ISO 7396-1:2007/ Amd 3:2013 | Terminology relating to alarm systems |
| ISO 7396-2:2007 | Medical gas pipeline systems -- Part 2: Anaesthetic gas scavenging disposal systems |
| ISO 9170-1:2008 | 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 |

**(e) Suction devices for hospital and emergency care use**

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|---|---|
| ISO 10079-1:1999 | Medical suction equipment -- Part 1: Electrically powered suction equipment -- Safety requirements |

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| 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 |

**(f) Terminology and semantics**

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|---|---|
| ISO 4135:2001 | Anaesthetic and respiratory equipment – Vocabulary |

## 4.3 Dentistry devices

**(a) Dental CAD/CAM systems**

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

**(b) Dental equipment**

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|---|---|
| ISO 11143:2008 | Dentistry -- Amalgam separators |
| ISO 11144:1995 | Dental equipment -- Connections for supply and waste lines |
| ISO 13897:2003 | Dentistry -- Amalgam capsules |
| ISO 13897:2003 / Cor1:2003 | Dentistry -- Amalgam capsules – *Technical Corrigendum 1* |
| ISO 21530:2004 | Dentistry -- Materials used for dental equipment surfaces -- Determination of resistance to chemical disinfectants |
| ISO 4073:2009 | Dentistry -- Information system on the location of dental equipment in the working area of the oral health care provider |

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|---|---|
| ISO 6875:2011 | Dentistry -- Patient chair |
| ISO 7488:1991 | Dental amalgamators |
| ISO 7493:2006 | Dentistry -- Operator's stool |
| ISO 7494-1:2011 | Dentistry -- Dental units -- Part 1: General requirements and test methods |
| ISO 7494-2:2003 | Dentistry -- Dental units -- Part 2: Water and air supply |
| 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/TS 11080:2009 | Dentistry -- Essential characteristics of test methods for the evaluation of treatment methods intended to improve or maintain the microbiological quality of dental unit procedural water |
| ISO/TS 22595-1:2006 | Dentistry -- Plant area equipment -- Part 1: Suction systems |
| ISO/TS 22595-2:2008 | Dentistry -- Plant area equipment -- Part 2: Compressor systems |
| IEC 80601-2-60:2012 | Medical electrical equipment -- Part 2-60: Particular requirements for basic safety and essential performance of dental equipment |
| ISO 11143:2008 | Dentistry -- Amalgam separators |
| ISO 11144:1995 | Dental equipment -- Connections for supply and waste lines |

**(c) 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 14801:2007 | 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/TR 11175:1993 | Dental implants -- Guidelines for developing dental implants |
| ISO/TS 13498:2011 | Dentistry -- Torsion test of implant body/connecting part joints of endosseous dental implant systems |
| ISO/TS 22911:2005 | Dentistry -- Preclinical evaluation of dental implant systems -- Animal test methods |

**(d) Dental instruments**

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|---|---|
| ISO 10323:2013 | Dentistry -- Bore diameters for rotary instruments such as discs and wheels |
| ISO 11499:2014 | Dentistry -- Single-use cartridges for local anaesthetics |

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|---|---|
| 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 | 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 15098-1:1999 | Dental tweezers -- Part 1: General requirements |
| ISO 15098-2:2000 | Dental tweezers -- Part 2: Meriam types |

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| ISO 15098-3:2000 | Dental tweezers -- Part 3: College types |
| ISO 15606:1999 | Dental handpieces -- Air-powered scalers and scaler tips |
| ISO 15635-2:2014 | Dentistry -- Dental rubber dam instruments -- Part 2: Clamp forceps |
| ISO 16635-1:2013 | Dentistry -- Dental rubber dam technique -- Part 1: Hole punch |
| ISO 1797-1:2011 | Dentistry -- Shanks for rotary instruments -- Part 1: Shanks made of metals |
| ISO 1797-2:1992 | Dental rotary instruments -- Shanks -- Part 2: Shanks made of plastics |
| ISO 1797-3:2013 | Dentistry -- Shanks for rotary instruments -- Part 3: Shanks made of ceramics |
| ISO 21531:2009 | Dentistry -- Graphical symbols for Dental instruments |
| ISO 21533:2003 | Dentistry -- Reusable cartridge syringes intended for intraligamentary injections |
| ISO 21533:2003/ Cor 1:2009 | Dentistry -- Reusable cartridge syringes intended for intraligamentary injections – *Technical Corrigendum 1* |
| ISO 2157:1992 | Dental rotary instruments -- Nominal diameters and designation code number |
| ISO 21671:2006 | Dentistry -- Rotary polishers |
| ISO 21671:2006/ Amd 1:2011 | Dentistry – Rotary polishers – *Amendment 1* |

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|---|---|
| ISO 21672-1:2012 | Dentistry -- Periodontal probes -- Part 1: General requirements |
| ISO 21672-2:2012 | Dentistry -- Periodontal probes -- Part 2: Designation |
| ISO 22374:2005 | Dentistry -- Dental handpieces -- Electrical-powered scalers and scaler tips |
| ISO 3630-1:2008 | Dentistry -- Root canal instruments -- Part 1: General requirements and test methods |
| ISO 3630-2:2013 | Dentistry -- Endodontic Instruments -- Part 2: Enlargers |
| ISO 3630-3:1994 | Dental root-canal instruments -- Part 3: Condensers, pluggers and spreaders |
| ISO 3630-4:2009 | Dentistry -Root canal instruments -- Part 4: Auxiliary instruments |
| ISO 3630-5:2011 | 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 3964:1982 | Dental handpieces -- Coupling dimensions |
| ISO 6360-1:2004 | Dentistry -- Number coding system for rotary instruments -- Part 1: General characteristics |

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|---|---|
| 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 7492:1997 | Dental explorers |
| ISO 7711-1:1997 | Dental rotary instruments -- Diamond instruments -- Part 1: Dimensions, requirements, marking and packaging |

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| 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 7787-1:1984 | Dental rotary instruments -- Cutters -- Part 1: Steel laboratory cutters |
| ISO 7787-2:2000 | Dental rotary instruments -- Cutters -- Part 2: Carbide laboratory cutters |
| ISO 7787-3:1991 | Dental rotary instruments -- Cutters -- Part 3: Carbide laboratory 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 9173-1:2006 | 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 9873:1998 | Dental hand instruments -- Reusable mirrors and handles |
| ISO 9873:1998/ Cor 1:2000 | Dental hand instruments -- Reusable mirrors and handles – *Technical Corrigendum 1* |
| ISO 9997:1999 | Dental cartridge syringes |

**(e) 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 27020:2010 | 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 4049:2009 | Dentistry -- Polymer-based restorative materials |
| ISO 6874:2005 | Dentistry -- Polymer-based pit and fissure sealants |
| ISO 6876:2012 | Dentistry -- Root canal sealing materials |

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|---|---|
| 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 9917-2:2010 | Dentistry -- Water-based cements -- Part 2: Resin-modified cements |
| ISO/TS 11405:2015 | Dental materials -- Testing of adhesion to tooth structure |
| ISO/TS 17988:2014 | Dentistry -- Corrosion test methods for dental amalgam |

**(f) Prosthodontic materials**

| | |
|---|---|
| ISO 10139-1:2005 | Dentistry -- Soft lining materials for removable dentures -- Part 1: Materials for short-term use |
| ISO 10139-1:2005/ Cor 1:2006 | Dentistry -- Soft lining materials for removable dentures -- Part 1: Materials for short-term use – *Technical Corrigendum 1* |
| ISO 10139-2:2009 | Dentistry -- Soft lining materials for removable dentures -- Part 2: Materials for long-term use |
| ISO 10271:2011 | Dentistry -- Corrosion test methods for metallic materials |
| ISO 10477:2004 | Dentistry -- Polymer-based crown and bridge materials |
| ISO 13017:2012 | 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 15912:2006 | Dentistry -- Casting investments and refractory die materials |
| ISO 15912:2006/ Amd 1:2011 | Requirement and test method for adequacy of expansion of Type 1 and Type 2 materials |
| 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 22112:2005 | Dentistry -- Artificial teeth for dental prostheses |
| ISO 22674:2006 | Dentistry -- Metallic materials for fixed and removable restorations and appliances |
| ISO 28319:2010 | Dentistry -- Laser welding |
| ISO 4823:2000 | Dentistry -- Elastomeric impression materials |
| ISO 6872:2008 | Dentistry -- Ceramic materials |
| ISO 6873:2013 | Dentistry -- Gypsum products |
| ISO 7491:2000 | Dental materials -- Determination of colour stability |
| ISO 9333:2006 | Dentistry -- Brazing materials |

| | |
|---|---|
| ISO 9693:1999/ Amd 1:2005 | Metal-ceramic dental restorative systems |
| ISO 9693-1:2012 | Dentistry -- Compatibility testing -- Part 1: Metal-ceramic systems |
| ISO/TR 14569-1:2007 | Dental materials -- Guidance on testing of wear -- Part 1: Wear by toothbrushing |
| ISO/TR 28642:2011 | 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 |

**(g) 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 3950:2009 | 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 60601-2-16:2012 | Medical electrical equipment - Part 2-16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment |
| IEC 60601-2-39:2007 (Ed.2) | Medical electrical equipment - Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment |
| IEC/TRF 60601-2-39: 2008 (Ed.3) | This Test Report Form applies to IEC 60601-2-39:2007 (Second edition) for use in conjunction with IEC 60601-1:2005 (Third Edition) |
| 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 12417:2011 | Cardiovascular implants and extracorporeal systems -- Vascular device-drug |
| ISO 13958:2014 | Concentrates for haemodialysis and related therapies |
| ISO 13959:2014 | Water for haemodialysis and related therapies |
| ISO 13960:2010 | Cardiovascular implants and extracorporeal systems – Plasmafilters |
| ISO 15674:2009 | Cardiovascular implants and artificial organs -- Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags |

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|---|---|
| ISO 15675:2009 | Cardiovascular implants and artificial organs -- Cardiopulmonary bypass systems -- Arterial blood line filters |
| ISO 15676:2005 | Cardiovascular implants and artificial organs -- Requirements for single-use tubing packs for cardiopulmonary bypass and extracorporeal membrane oxygenation (ECMO) |
| ISO 23500:2014 | Guidance for the preparation and quality management of fluids for haemodialysis and related therapies |
| ISO 26722:2014 | Water treatment equipment for haemodialysis applications and related therapies |
| ISO 8637:2010 | Cardiovascular implants and extracorporeal systems -- Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators |
| ISO 8637:2010 / Amd 1:2013 | Revision to Figure 2 -- Main fitting dimensions of dialysis fluid inlet and outlet ports |
| ISO 8638:2010 | Cardiovascular implants and extracorporeal systems -- Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters |
| ISO/TS 23810:2012 | Cardiovascular implants and artificial organs -- Checklist for preoperative extracorporeal circulation equipment setup |

## 4.5 Hospital equipment

### (a) Heating equipment

| | |
|---|---|
| IEC 60601-2-35:2009 | Medical electrical equipment - Part 2-35: Particular requirements for the safety of blankets, pads and mattresses, intended for heating in medical use |
| IEC 80601-2-35:2009 | Medical electrical equipment -- Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use |

### (b) Medical beds

| | |
|---|---|
| IEC 60601-2-38:1996 | Medical electrical equipment - Part 2-38: Particular requirements for the safety of electrically operated hospital 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 /Cor1:2010 | Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds – *Technical Corrigendum 1* |
| 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/TRF 60601-2-38:2011 (Ed. 3) | This Test Report Form applies to IEC 60601-2-38:1996 (First Edition) + A1: 1999 for use with IEC 60601:1988 + A1:91 + A2:95 |

**(c) Medical face masks**

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|---|---|
| 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) |

**(d) Medical gloves**

| | |
|---|---|
| ISO 10282:2014 | Single-use sterile rubber surgical gloves – Specification |
| ISO 11193-1:2008 | Single-use medical examination gloves - Part 1: Specification for gloves made from rubber latex or rubber solution |
| ISO 11193-1:2008/ Amd 1:2012 | Single-use medical examination gloves - Part 1: Specification for gloves made from rubber latex or rubber solution – *Amendment 1* |
| 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 455-1:2000 | Medical gloves for single use - Part 1: Requirements and testing for freedom from holes |
| EN 455-2:2009 + A2:2013 | Medical gloves for single use - Part 2: Requirements and testing for physical properties |

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| EN 455-3:2006 | 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 |

**(e) Operating tables**

| | |
|---|---|
| IEC 60601-2-46:2010 (Ed.2.0) | Medical electrical equipment - Part 2-46: Particular requirements for basic safety and essential performance of operating tables |
| IEC/TRF 60601-2-46:2011 (Ed.3) | This test report form applies to IEC 60601-2-46:2010 (Second Edition) for use in conjunction with IEC 60601-1:2005 (Third Edition) |

**(f) Other medical equipment**

| | |
|---|---|
| ISO 23907:2012 | Sharps injury protection -- Requirements and test methods -- Sharps containers |

## 4.6 Implants for surgery, prosthetics and orthotics devices

**(a) Implants for surgery (Active implants)**

| | |
|---|---|
| IEC 60601-2-31:2011 | 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 |
| ISO 11318:2002 | Cardiac defibrillators -- Connector assembly DF-1 for implantable defibrillators -- Dimensions and test requirements |

| | |
|---|---|
| ISO 14117:2012 | 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 14708-2:2012 | Implants for surgery -- Active implantable medical devices -- Part 2: Cardiac pacemakers |
| ISO 14708-3:2008 | 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 14708-5:2010 | Implants for surgery - Active implantable medical devices - Part 5: Circulatory support devices |
| ISO 14708-6:2010 | Implants for surgery -- Active implantable medical devices -- Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators) |
| ISO 14708-7:2013 | 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 10974:2012 | Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device |
| AAMI ANSI TIR41:2011 | Technical information report active implantable guidance for designation of left ventricle and implantable cardioverter defibrillator lead connectors and pulse generator connector cavities for implantable pacemakers and implantable cardioverter defibrillators |

**(b) Implants for surgery (Bone and joint replacements)**

| | |
|---|---|
| ISO 13243-2:2009 | Implants for surgery -- Wear of total knee-joint prostheses -- Part 2: Methods of measurement |
| 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 14242-2:2000 | 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 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 14243-3:2014 | 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 14879-1:2000 | 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 |

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|---|---|
| ISO 21536:2007 | Non-active surgical implants -- Joint replacement implants -- Specific requirements for knee-joint replacement implants |
| ISO 21536:2007 / Amd 1:2014 | 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 7206-10:2003 | Implants for surgery -- Partial and total hip-joint prostheses -- Part 10: Determination of resistance to static load of modular femoral heads |
| 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 7206-4:2010 | Implants for surgery -- Partial and total hip joint prostheses -- Part 4: Determination of endurance properties and performance of stemmed femoral components |
| ISO 7206-6:2013 | 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 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 |

**(c) Implants for surgery (Cardiovascular implants)**

| | |
|---|---|
| ISO 25539-1:2003 | Cardiovascular implants - Endovascular devices - Part 1: Endovascular prostheses |
| ISO 25539-1:2003/ Amd 1:2005 | Test methods |
| ISO 25539-2:2012 | Cardiovascular implants -- Endovascular devices -- Part 2: Vascular stents |
| ISO 25539-3:2011 | Cardiovascular implants - Endovascular devices - Part 3: Vena cava filters |
| ISO 5840:2005 | Cardiovascular implants - Cardiac valve prostheses |
| ISO 5840-3:2013 | Cardiovascular implants - Cardiac valve prostheses - Part 3: Heart valve substitutes implanted by transcatheter techniques |
| ISO 7198:1998 | Cardiovascular implants - Tubular vascular prostheses |
| ISO 7199:2009 | Cardiovascular implants and artificial organs -- Blood-gas exchangers (oxygenators) |
| ISO 7199:2009 / Amd 1:2012 | Clarifications for test methodologies, labelling, and sampling schedule |
| ISO/TS 15539:2000 | Cardiovascular implants -- Endovascular prostheses |
| ISO/TS 17137:2014 | Cardiovascular implants and extracorporeal systems -- Cardiovascular absorbable implants |
| AAMI ANSI ASTM F2914-12 | Standard guide for identification of shelf-life test attributes for endovascualar devices |

| | |
|---|---|
| AAMI TIR42:2010 | Evaluation of particulates associated with vascular medical devices |
| ASTM F2079 - 09(2013) | Standard test method for measuring intrinsic elastic recoil of balloon-expandable stents |
| ASTM F2081 - 06(2013) | Standard guide for characterization and presentation of the dimensional attributes of vascular stents |
| EN 12006-2:1998/ A1:2009 | Non active surgical implants - Particular requirements for cardiac and vascular implants - Part 2: Vascular prostheses including cardiac valve conduits |

**(d) Implants for surgery (General requirements)**

| | |
|---|---|
| ISO 14630:2012 | Non-active surgical implants- General requirements |
| ISO 16061:2008 | Instrumentation for use in association with non-active surgical implants -- General requirements |
| ASTM F2129 - 08 | Standard test method for conducting cyclic potentiodynamic polarization measurements to determine the corrosion susceptibility of small implant devices |
| ASTM F138 - 13 | 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 |

**(e) 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 13356:2008 | Implants for surgery -- Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP) |
| ISO 13779-1:2008 | Implants for surgery -- Hydroxyapatite -- Part 1: Ceramic hydroxyapatite |
| ISO 13779-2:2008 | Implants for surgery -- Hydroxyapatite -- Part 2: Coatings of hydroxyapatite |
| ISO 13779-3:2008 | Implants for surgery -- Hydroxyapatite -- Part 3: Chemical analysis and characterization of crystallinity and phase purity |
| ISO 13779-4:2002 | Implants for surgery -- Hydroxyapatite -- Part 4: Determination of coating adhesion strength |
| ISO 13779-6:2015 | Implants for surgery -- Hydroxyapatite -- Part 6: Powders |
| ISO 13781:1997 | Poly(L-lactide) resins and fabricated forms for surgical implants -- In vitro degradation testing |
| ISO 13782:1996 | 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 |

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| ISO 15374:1998 | Implants for surgery -- Requirements for production of forgings |
| ISO 15814:1999 | Implants for surgery -- Copolymers and blends based on polylactide -- In vitro degradation testing |
| 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 5832-1:2007 | Implants for surgery -- Metallic materials -- Part 1: Wrought stainless steel |
| ISO 5832-1:2007 / Cor 1:2007 | Implants for surgery -- Metallic materials -- Part 1: Wrought stainless steel – *Technical Corrigendum 1* |
| ISO 5832-11:2014 | Implants for surgery -- Metallic materials -- Part 11: Wrought titanium 6-aluminium 7-niobium alloy |
| ISO 5832-12:2007 | Implants for surgery -- Metallic materials -- Part 12: Wrought cobalt-chromium-molybdenum alloy |

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| ISO 5832-12:2007/ Cor 1:2008 | Implants for surgery -- Metallic materials -- Part 12: Wrought cobalt-chromium-molybdenum alloy – *Technical Corrigendum 1* |
| ISO 5832-14:2007 | Implants for surgery -- Metallic materials -- Part 14: Wrought titanium 15-molybdenum 5-zirconium 3-aluminium alloy |
| ISO 5832-2:1999 | Implants for surgery -- Metallic materials -- Part 2: Unalloyed titanium |
| ISO 5832-3:1996 | 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 5832-7:1994 | Implants for surgery -- Metallic materials -- Part 7: Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy |
| ISO 5832-8:1997 | Implants for surgery -- Metallic materials -- Part 8: Wrought cobalt-nickel-chromium-molybdenum-tungsten-iron alloy |
| ISO 5832-9:2007 | Implants for surgery -- Metallic materials -- Part 9: Wrought high nitrogen stainless steel |
| ISO 5833:2002 | Implants for surgery -- Acrylic resin cements |
| ISO 5834-1:2005 | Implants for surgery -- Ultra-high-molecular-weight polyethylene -- Part 1: Powder form |

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| ISO 5834-1:2005 / Cor 1:2007 | Implants for surgery -- Ultra-high-molecular-weight polyethylene -- Part 1: Powder form – *Technical Corrigendum 1* |
| ISO 5834-3:2005 | Implants for surgery -- Ultra-high-molecular-weight polyethylene -- Part 3: Accelerated ageing methods |
| ISO 5834-4:2005 | Implants for surgery -- Ultra-high-molecular-weight polyethylene -- Part 4: Oxidation index measurement method |
| ISO 5834-5:2005 | Implants for surgery -- Ultra-high-molecular-weight polyethylene -- Part 5: Morphology assessment method |
| ISO 6474-1:2010 | Implants for surgery -- Ceramic materials -- Part 1: Ceramic materials based on high purity alumina |
| ISO 6474-2:2012 | 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 |

**(f) Implants for surgery (Neurosurgical implants)**

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|---|---|
| ISO 7197:2006 | Neurosurgical implants -- Sterile, single-use hydrocephalus shunts and components |
| ISO 9713:2002 | Neurosurgical implants -- Self-closing intracranial aneurysm clips |

**(g) Implants for surgery (Osteosynthesis and spinal devices)**

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|---|---|
| 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 18192-2:2010 | 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 |

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| 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 |

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| 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 |

**(h) Implants for surgery (Tissue-engineered medical products)**

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

**(i) Prosthetics and orthotics**

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| ISO 10328:2006 | 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 |

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| 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 8548-1:1989 | Prosthetics and orthotics -- Limb deficiencies -- Part 1: Method of describing limb deficiencies present at birth |
| ISO 8548-2:1993 | 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 |

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| SO 8548-5:2003 | Prosthetics and orthotics -- Limb deficiencies -- Part 5: Description of the clinical condition of the person who has had an amputation |
| ISO 8549-1:1989 | Prosthetics and orthotics -- Vocabulary -- Part 1: General terms for external limb prostheses and external orthoses |
| ISO 8549-2:1989 | Prosthetics and orthotics -- Vocabulary -- Part 2: Terms relating to external limb prostheses and wearers of these prostheses |
| ISO 8549-3:1989 | Prosthetics and orthotics -- Vocabulary -- Part 3: Terms relating to external orthoses |
| ISO 8549-4:2014 | Prosthetics and orthotics -- Vocabulary -- Part 4: Terms relating to limb amputation |
| ISO 8551:2003 | 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/CD 29783-3 | Prosthetics and orthotics -- Vocabulary -- Part 3: Pathological gait |
| ISO/DIS 16955:2 | Prosthetics -- Quantification of physical parameters of ankle foot devices and foot units |
| 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 |

## 4.7 Ophthalmic equipment

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| IEC 80601-2-58:2014 | 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 10322-1:2006 | Ophthalmic optics -- Semi-finished spectacle lens blanks -- Part 1: Specifications for single-vision and multifocal lens blanks |
| ISO 10322-2:2006 | 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 10685-2:2012 | 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 |

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| ISO 10938:1998 | Ophthalmic instruments -- Chart projectors |
| ISO 10939:2007 | 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 11381:1994 | Optics and optical instruments -- Ophthalmic optics -- Screw threads |
| ISO 11978:2014 | Ophthalmic optics -- Contact lenses and contact lens care products – Labelling |
| ISO 11979-1:2012 | 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* |

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| ISO 11979-5:2006 | Ophthalmic implants -- Intraocular lenses -- Part 5: Biocompatibility |
| ISO 11979-6:2014 | Ophthalmic implants -- Intraocular lenses -- Part 6: Shelf-life and transport stability testing |
| ISO 11979-7:2014 | Ophthalmic implants -- Intraocular lenses -- Part 7: Clinical investigations |
| ISO 11979-8:2006 | Ophthalmic implants -- Intraocular lenses -- Part 8: Fundamental requirements |
| ISO 11979-8:2006/ Amd 1:2011 | Ophthalmic implants – Intraocular lenses – Part 8: Fundamental requirements – *Amendment 1* |
| ISO 11979-9:2006 | Ophthalmic implants -- Intraocular lenses -- Part 9: Multifocal intraocular lenses |
| ISO 11979-9:2006/ Amd 1:2014 | Ophthalmic implants -- Intraocular lenses -- Part 9: Multifocal intraocular lenses – *Amendment 1* |
| ISO 11979-10:2006 | Ophthalmic implants -- Intraocular lenses -- Part 10: Phakic intraocular lenses |
| ISO 11979-10:2006/ Amd 1:2014 | Ophthalmic implants -- Intraocular lenses -- Part 10: Phakic intraocular lenses – *Amendment 1* |
| ISO 11980:2012 | Ophthalmic optics -- Contact lenses and contact lens care products -- Guidance for clinical investigations |
| ISO 11981:2009 | Ophthalmic optics -- Contact lenses and contact lens care products -- Determination of physical compatibility of contact lens care products with contact lenses |

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| ISO 11985:1997 | Ophthalmic optics -- Contact lenses -- Ageing by exposure to UV and visible radiation (in vitro method) |
| ISO 11986:2010 | 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 12864:1997 | Ophthalmic optics -- Contact lenses -- Determination of scattered light |
| 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 12870:2012 | Ophthalmic optics -- Spectacle frames -- Requirements and test methods |
| ISO 13212:2014 | Ophthalmic optics -- Contact lens care products -- Guidelines for determination of shelf-life |
| ISO 13666:2012 | 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 |

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| 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 15004-1:2006 | 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* |

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| ISO 16284:2006 | Ophthalmic optics -- Information interchange for ophthalmic optical equipment |
| ISO 16671:2003 | Ophthalmic implants -- Irrigating solutions for ophthalmic surgery |
| ISO 16672:2003 | Ophthalmic implants -- Ocular endotamponades |
| 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 18369-1:2006 | Ophthalmic optics -- Contact lenses -- Part 1: Vocabulary, classification system and recommendations for labelling specifications |
| ISO 18369-1:2006/ Amd 1:2009 | Ophthalmic optics -- Contact lenses -- Part 1: Vocabulary, classification system and recommendations for labelling specifications – *Amendment 1* |
| ISO 18369-2:2012 | Ophthalmic optics -- Contact lenses -- Part 2: Tolerances |
| ISO 18369-3:2006 | Ophthalmic optics -- Contact lenses -- Part 3: Measurement methods |
| ISO 18369-4:2006 | Ophthalmic optics -- Contact lenses -- Part 4: Physicochemical properties of contact lens materials |
| ISO 19980:2012 | Ophthalmic instruments -- Corneal topographers |
| ISO 21987:2009 | Ophthalmic optics -- Mounted spectacle lenses |
| ISO 24157:2008 | Ophthalmic optics and instruments -- Reporting aberrations of the human eye |

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| ISO 24348:2014 | Ophthalmic optics -- Spectacle frames -- Method for the simulation of wear and detection of nickel release from metal and combination spectacle frames |
| 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 8596:2009 | Ophthalmic optics -- Visual acuity testing -- Standard optotype and its presentation |
| ISO 8598-1:2014 | Optics and optical instruments -- Focimeters -- Part 1: General purpose instruments |
| ISO 8612:2009 | Ophthalmic instruments – Tonometers |
| ISO 8624:2011 | Ophthalmic optics -- Spectacle frames -- Measuring system and terminology |
| ISO 8980-1:2004 | Ophthalmic optics -- Uncut finished spectacle lenses -- Part 1: Specifications for single-vision and multifocal lenses |
| ISO 8980-1:2004/ Cor 1:2006 | Ophthalmic optics -- Uncut finished spectacle lenses -- Part 1: Specifications for single-vision and multifocal lenses – *Technical Corrigendum 1* |
| ISO 8980-2:2004 | Ophthalmic optics -- Uncut finished spectacle lenses -- Part 2: Specifications for progressive power lenses |
| ISO 8980-2:2004/ Cor 1:2006 | Ophthalmic optics -- Uncut finished spectacle lenses -- Part 2: Specifications for progressive power lenses – *Technical Corrigendum 1* |

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| 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/DIS 19045 | Ophthalmic optics -- Contact lens care products -- Method for evaluating Acanthamoeba encystment by contact lens care products |
| ISO/DTR 19497 | Ophthalmic optics -- History of standardization activities for abrasion resistance of spectacle lenses |
| ISO/DTR 19498 | Ophthalmic optics and instruments -- Correlation of optotypes |

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| ISO/FDIS 16971 | Ophthalmic instruments -- Optical coherence tomograph for the posterior segment of the human eye |
| ISO/TR 20824:2007 | Ophthalmic instruments -- Background for light hazard specification in ophthalmic instrument standards |
| ISO/TR 22979:2006 | 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 19979:2014 | Ophthalmic optics -- Contact lenses -- Hygienic management of multipatient use trial contact lenses |
| ISO/WD 18189 | Ophthalmic optics -- Contact lenses and contact lens care products -- Cytotoxicity testing of contact lenses and contact lens care solutions |
| ISO/WD TR 18476 | Ophthalmic optics and instruments -- Free form technology -- Spectacle lenses and measurement |
| ANSI Z80.12-2007 (R2012) | Multifocal Intraocular Lenses |
| ANSI Z80.13-2007 (R2012) | Phakic Intraocular Lenses |
| ANSI Z80.17-2013 | Ophthalmics – Focimeters |
| ANSI Z80.18-2010 | Ophthalmics - Contact Lens Care Products: Vocabulary, Performance Specifications and Test Methodology |

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| ANSI Z80.20-2010 | Ophthalmics - Contact Lenses - Standard Terminology, Tolerances, Measurements and Physicochemical Properties |
| ANSI Z80.25-1996 (R2002) | Ophthalmics - Instruments: Fundamental Requirements and Test Methods |
| ANSI Z80.30-2010 | Ophthalmics - Toric Intraocular Lenses |
| ANSI Z80.7-2013 | Ophthalmic Optics - Intraocular Lenses |

## 4.8 Sterilization and disinfection devices

### (a) Chemical disinfectants and antiseptics

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| 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) |

**(b) Sterilizing equipment**

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| ISO 15883-1:2006 | Washer-disinfectors - Part 1: General requirements, terms and definitions and tests |
| ISO 15883-1:2006/ Amd 1:2004 | 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 15883-4:2008 | 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-critical medical devices and healthcare equipment |
| ISO/TS 15883-5:2005 | Washer-disinfectors -- Part 5: Test soils and methods for demonstrating cleaning efficacy |
| EN 13060:2004/ A2:2010 | Small steam sterilizers |
| EN 14180:2014 | Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing |
| EN 285:2006/A2:2009 | Sterilization - Steam sterilizers - Large sterilizers |

## 4.9 Surgical instruments

### (a) Electro-optical systems

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| ISO 11810-1:2005 | Lasers and laser-related equipment -- Test method and classification for the laser resistance of surgical drapes and/or patient protective covers -- Part 1: Primary ignition and penetration |
| ISO 11810-2:2007 | Lasers and laser-related equipment -- Test method and classification for the laser-resistance of surgical drapes and/or patient-protective covers -- Part 2: Secondary ignition |

### (b) Electrosurgical equipment

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| IEC 60601-2-2:2009 (Ed.5) | 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/ A1:2013 (Ed.2.1) | Medical electrical equipment - Part 2-41: Particular requirements for the safety of surgical luminaires and luminarires for diagnosis |
| IEC/TRF 60601-2-2:2014 (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) |

### (c) Microscopes and endoscopes

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| IEC 60601-2-18:2009 | Medical electrical equipment - Part 2-18: Particular requirements for basic safety and essential performance of endoscopic equipment |
| 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 |

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| ISO 10936-1:2000 | Optics and optical instruments -- Operation microscopes -- Part 1: Requirements and test methods |
| ISO 8600-1:2013 | Endoscopes -- Medical endoscopes and endotherapy devices -- Part 1: General requirements |
| ISO 8600-2:2002 | Optics and optical instruments -- Medical endoscopes and endoscopic accessories -- Part 2: Particular requirements for rigid bronchoscopes |
| ISO 8600-3:1997 | Optics and optical instruments -- Medical endoscopes and endoscopic accessories -- Part 3: Determination of field of view and direction of view of endoscopes with optics |
| ISO 8600-3:1997/ Amd 1:2003 | Optics and optical instruments -- Medical endoscopes and endoscopic accessories -- Part 3: Determination of field of view and direction of view of endoscopes with optics – *Amendment 1* |
| 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 |

**(d) Surgical instruments**

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| 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 7153-1:1991 | Surgical instruments -- Metallic materials -- Part 1: Stainless steel |
| ISO 7153-1:1991 / Amd 1:1999 | Surgical instruments -- Metallic materials -- Part 1: Stainless steel – *Amendment 1* |
| 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

**(a) Syringes, needles and catheters**

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|---|---|
| ISO 11040-1:1992 | 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 11040-4:2007 | Prefilled syringes -- Part 4: Glass barrels for injectables |

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| ISO 11040-5:2012 | Prefilled syringes -- Part 5: Plunger stoppers for injectables |
| ISO 11040-6:2012 | Prefilled syringes -- Part 6: Plastic barrels for injectables |
| 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 13926-1:2004 | Pen systems -- Part 1: Glass cylinders for pen-injectors for medical use |
| ISO 13926-2:2011 | Pen systems -- Part 2: Plunger stoppers for pen-injectors for medical use |
| ISO 13926-3:2012 | 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 |

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|---|---|
| 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 594-1:1986 | Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment -- Part 1 General requirements |
| ISO 594-2:1998 | Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 2: Lock fittings |
| ISO 6009:1992 | Hypodermic needles for single use -- Colour coding for identification |
| ISO 7864:1993 | Sterile hypodermic needles for single use |
| ISO 7886-1:1993 | Sterile hypodermic syringes for single use -- Part 1: Syringes for manual use |
| ISO 7886-1:1993 / Cor 1:1995 | Sterile hypodermic syringes for single use -- Part 1: Syringes for manual use – *Technical Corrigendum 1* |
| ISO 7886-2:1996 | Sterile hypodermic syringes for single use -- Part 2: Syringes for use with power-driven syringe pumps |
| ISO 7886-3:2005 | Sterile, hypodermic syringes for single use - Part 3: Autodisable syringes for fixed-dose immunization |
| ISO 7886-4:2006 | Sterile, hypodermic syringes for single use - Part 4: Syringes with reuse prevention feature |
| ISO 8537:2007 | Sterile single-use syringes, with or without needle, for insulin |

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| ISO 9626:1991 | Stainless steel needle tubing for the manufacture of medical devices |
| ISO 9626:1991 / Amd 1:2001 | Stainless steel needle tubing for the manufacture of medical devices – *Amendment 1* |
| ISO 11040-1:1992 | 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 11040-4:2007 | Prefilled syringes -- Part 4: Glass barrels for injectables |
| ISO 11040-5:2012 | Prefilled syringes -- Part 5: Plunger stoppers for injectables |

**(b) Syringes, needles and catheters (Cardiovascular)**

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|---|---|
| ISO 10555-1:2013 | Intravascular catheters -- Sterile and single-use catheters -- Part 1: General requirements |
| 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 catheterscondition, and intended for single use |
| 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 |

## 4.11 Therapeutic/diagnostic equipment

### (a) Blood pressure monitors

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|---|---|
| IEC 60601-2-23:2011 (Ed. 3) | Medical electrical equipment. Part 2-23: Particular requirements for the safety , including essential performance, of transcutaneous partial pressure monitoring equipment |
| IEC 60601-2-30:2009/ A1:2013 (Ed. 1.1) | Medical electrical equipment. Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood 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/TRF 60601-2-23:2012 (Ed.3) | This test report form applies to IEC 60601-2-23:2011 (Third Edition) for use with IEC 60601-1:2005 (Third Edition) |
| IEC/TRF 60601-2-34:2012 (Ed. 3) | This test report form applies to IEC 60601-2-34 (Third Edition):2011 |
| ISO 80601-2-30:2009 | Medical electrical equipment -- Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers |
| ISO 80601-2-30:2009 / Amd 1:2013 | Medical electrical equipment -- Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers – *Amendment 1* |
| ISO 81060-1:2007 | Non-invasive sphygmomanometers -- Part 1: Requirements and test methods for non-automated measurement type |

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| ISO 81060-2:2013 | Non-invasive sphygmomanometers -- Part 2: Clinical investigation of automated measurement type |
| ISO/IEEE 11073-10407:2010 | Health informatics -- Personal health device communication -- Part 10407: Device specialization -- Blood pressure monitor |

**(b) 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 |
| IEC 60601-2-51:2003 | Medical electrical equipment - Part 2-51: Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs |
| IEC/TRF 60601-2-25:2013 (Ed. 3) | This Test Report Form applies to IEC 60601-2-25:2011 (Second Edition) for use in conjunction with IEC 60601-1:2005 (Third Edition) |
| IEC/TRF 60601-2-27:2012 (ed. 2) | IEC/TRF 60601-2-27:2012 (ed. 2)<br>This Test Report Form applies to IEC 60601-2-27: 2011 (Third Edition) for use in conjunction with IEC 60601-1:2005 + CORR. 1 (2006) + CORR. 2 (2007) |
| IEC/TRF 60601-2-51:2006 (Ed. 2) | This Test Report Form applies to IEC 60601-2-51: 2003 (First Edition) for use in conjunction with IEC 60601-1:1988 + A1:1991 + A2:1995 |
| AAMI ANSI EC13:2002 | Cardiac monitors, heart rate meters, and alarms |

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| AAMI EC53:2013 | ECG trunk cables and patient leadwires |

**(c) Electroencephalogram (EEG)**

| | |
|---|---|
| IEC 60601-2-26:2012 (Ed.3) | Medical electrical equipment. Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs |
| IEC/TRF 60601-2-26:2013 (Ed. 4) | This Test Report Form applies to IEC 60601-2-26:2012 (Third Edition) for use in conjunction with IEC 60601-1:2005 (Third Edition) |

**(d) Electromyogram (EMG)**

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| IEC 60601-2-40:1998 | Medical electrical equipment - Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment |
| IEC/TRF 60601-2-40:2006 (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 |

**(e) Infant incubators**

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|---|---|
| IEC 60601-219:2009 (Ed.2) | Medical electrical equipment - Part 2-19: Particular requirements for basic safety and essential performance of infant incubators |
| IEC 60601-2-20:2009 (Ed.2) | Medical electrical equipment - Part 2-20: Particular requirements for the safety of transport incubators |
| IEC 60601-2-21:2009 (Ed.2) | Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers |
| IEC 60601-2-50:2009 (Ed.2) | Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment |

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| IEC/TRF 60601-2-19:2011 (Ed.3) | This Test Report Form applies to IEC 60601-2-19: 2009 (Second Edition) for use in conjunction with IEC 60601-1:2005 (Third Edition) |
| IEC/TRF 60601-2-20:2011 (Ed. 3) | This Test Report Form applies to IEC 60601-2-20: 2009 (Second Edition) for use in conjunction with IEC 60601-1:2005 (Third Edition) |
| IEC/TRF 60601-2-21:2011 (Ed. 3) | This Test Report Form applies to IEC 60601-2-21:2009 (Second Edition) for use in conjunction with IEC 60601-1:2005 (Third Edition) |
| IEC/TRF 60601-2-50:2011 (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) |

**(f) Lasers**

| | |
|---|---|
| IEC 60601-2-22:2007/ A1:2012 | 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 | Safety of laser products - Part 1: Equipment classification and requirements |
| IEC 60825-12:2004 | Safety of laser products - Part 12: Safety of free space optical communication systems used for transmission of information |
| IEC 60825-2:2004+ AMD1:2006+AMD2:2010 CSV | Safety of laser products - Part 2: Safety of optical fibre communication systems (OFCS) |
| IEC 60825-4:2006+ AMD1:2008+AMD2:2011 CSV | Safety of laser products - Part 4: Laser guards |

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|---|---|
| IEC TR 60825-13:2011 | Safety of laser products - Part 13: Measurements for classification of laser products |
| IEC TR 60825-14:2004 | Safety of laser products - Part 14: A user's guide |
| IEC TR 60825-17:2010 | 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 | Safety of laser products - Part 3: Guidance for laser displays and shows |
| IEC TR 60825-5:2003 | Safety of laser products - Part 5: Manufacturer's checklist for IEC 60825-1 |
| IEC TR 60825-8:2006 | Safety of laser products - Part 8: Guidelines for the safe use of laser beams on humans |
| ISO 11145:2006 | 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 11151-1:2000 | Lasers and laser-related equipment -- Standard optical components -- Part 1: Components for the UV, visible and near-infrared spectral ranges |

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| ISO 11151-2:2000 | 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 11551:2003 | Optics and optical instruments -- Lasers and laser-related equipment -- Test method for absorptance of optical laser components |
| ISO 11554:2006 | 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 11810-1:2005 | Lasers and laser-related equipment -- Test method and classification for the laser resistance of surgical drapes and/or patient protective covers -- Part 1: Primary ignition and penetration |
| ISO 11810-2:2007 | Lasers and laser-related equipment -- Test method and classification for the laser-resistance of surgical drapes and/or patient-protective covers -- Part 2: Secondary ignition |
| ISO 11990-1:2011 | Lasers and laser-related equipment -- Determination of laser resistance of tracheal tubes -- Part 1: Tracheal tube shaft |
| ISO 11990-2:2010 | Lasers and laser-related equipment -- Determination of laser resistance of tracheal tubes -- Part 2: Tracheal tube cuffs |

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|---|---|
| ISO 12005:2003 | Lasers and laser-related equipment -- Test methods for laser beam parameters – Polarization |
| ISO 13694:2000 | Optics and optical instruments -- 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 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 |

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| 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 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 |
| ISO/TS 17915:2013 | Optics and photonics -- Measurement method of semiconductor lasers for sensing |
| 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 |

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| 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 Z136.3-2011 | American National Standard for 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- 2009 | American National Standard for Safe Use of Lasers in Educational Institutions |
| ANSI Z136.6-2005 | American National Standard for Safe Use of Lasers Outdoors |
| ANSI Z136.8-2012 | American National Standard for Safe Use of Lasers in Research, Development, or Testing |

**(g) Lithotripsy equipment**

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| IEC 60601-2-36:1997 | Medical electrical equipment - Part 2-36: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy |

**(h) Magnetic resonance imaging (MRI) equipment**

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|---|---|
| IEC 60601-2-33:2013 (Ed.3.1) Consol with amd1 | Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis |

**(i) Microwave therapy equipment**

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|---|---|
| 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 60601-2-6: 2012 (Ed. 2.0) | Medical electrical equipment - Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment |
| IEC/TRF 60601-2-3:2014 (Ed.4) | This Test Report Form applies to: IEC 60601-2-3: 2012 (Third Edition) for use in conjunction with IEC 60601-1:2005 (Third Edition) |
| IEC/TRF 60601-2-6:2013 (Ed. 3) | This Test Report Form applies to: IEC 60601-2-6: 2012 (Second Edition) for use in conjunction with IEC 60601-1:2005 (Third Edition) + A1:2012 |

**(j) Nerve and muscle simulators**

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|---|---|
| IEC 60601-2-10:2012 | Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators |

**(k) Patient monitoring equipment**

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| IEC 60601-2-49:2011 | Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment |

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| IEC 80601-2-59:2008 | Medical electrical equipment -- Part 2-59: Particular requirements for basic safety and essential performance of screening thermographs for human febrile temperature screening |
| ISO/TR 13154:2009 | Medical electrical equipment -- Deployment, implementation and operational guidelines for identifying febrile humans using a screening thermograph |

**(l) Radiographic equipment (Brachytherapy)**

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

**(m) Radiographic equipment (Gamma Beam)**

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|---|---|
| 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 60601-2-11:2014 | This test report applies to IEC 60601-2-11:2013 (Third Edition) |

**(n) Radiographic equipment (X-Ray)**

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|---|---|
| IEC 60601-1-3:2008/ A1:2013 | Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment |
| IEC 60601-2-1:2014 (Ed.3.1) Consol with am1 | 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 |

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| IEC 60601-2-28:2010 (Ed. 2) | Medical electrical equipment. Part 2-28: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis |
| IEC 60601-2-32:2006 (Ed.2) | Medical electrical equipment. Part 2-32: Particular requirements for the safety of associated equipment of X-ray equipment |
| 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 60601-2-44:2009/ A1:2012 (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 60601-2-45:2011(Ed.3) | Medical electrical equipment - Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic sterotactic 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 60601-2-7:2007 (Ed.2) | Medical electrical equipment. Part 2-7: Particular requirements for the safety of high voltage generators of diagnostic X-ray generators |
| 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 |

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| IEC/ TRF 60601-2-54:2014 (Ed. 2) | This Test Report Form applies to: IEC 60601-2-54 (1st Edition): 2009 |
| IEC/TRF 60601-2-1:2014 (Ed.5) | This Test Report applies to: IEC 60601-2-1:2009 (First Edition) for use in conjunction with IEC 60601-1: 2005 (Third Edition) |
| IEC/TRF 60601-2-28:2010 (Ed.3) | This Test Report Form applies to IEC 60601-2-28:2010 (Second Edition) for use in conjunction with IEC 60601-1: 2005 (Third Edition) |
| IEC/TRF 60601-2-43:2011 (Ed. 2) | This Test Report Form applies to IEC 60601-2-43: 2010 (Second Edition): for use in conjunction with IEC 60601-1: 2005 (Third Edition) |
| IEC/TRF 60601-2-45:2012 (Ed.3) | This Test Report Form applies to IEC 60601-2-45: 2011 (Third Edition) for use with IEC 60601-1: 2005 (Third Edition) |
| IEC/TRF 60601-2-8:2013 (Ed.3) | This Test Report Form applies to IEC 60601-2-8: 2010 (Second Edition) for use with IEC 60601-1: 2005, CORR.1: 2006 + CORR.2: 2007 |
| 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 |

**(o) Radiotherapy stimulators**

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

**(p) Thermometers**

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|---|---|
| ISO 80601-2-56:2009 | Medical electrical equipment -- Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement |

**(q) Ultrasonic monitoring/therapy equipment**

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| 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 60601-2-5:2009 (Ed.3) | Medical electrical equipment - Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment |
| IEC/TRF 60601-2-37:2008 (Ed.5) | This Test Report Form applies to IEC 60601-2-37:2007 (Second Edition) for use in conjunction with IEC 60601-1:2005 (Third Edition) |
| IEC/TRF 60601-2-5:2013 (Ed.5) | This Test Report Form applies to IEC 60601-2-5: 2009 (Third Edition.) for use with IEC 60601 1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + A1:2012 |

## 4.12 Transfusion, infusion and injection equipment

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|---|---|
| IEC 60601-2-24:1998 | Medical electrical equipment Part 2-24: Particular requirements for the safety of infusion pumps and controllers |
| ISO 10985:2009 | Caps made of aluminium-plastics combinations for infusion bottles and injection vials -- Requirements and test methods |

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| ISO 1135-3:1986 | Transfusion equipment for medical use -- Part 3: Blood-taking set |
| ISO 1135-4:2012 | Transfusion equipment for medical use -- Part 4: Transfusion sets for single use |
| ISO 11418-1:2005 | Containers and accessories for pharmaceutical preparations -- Part 1: Drop-dispensing glass bottles |
| ISO 11418-2:2005 | Containers and accessories for pharmaceutical preparations -- Part 2: Screw-neck glass bottles for syrups |
| ISO 11418-3:2005 | Containers and accessories for pharmaceutical preparations -- Part 3: Screw-neck glass bottles (veral) for solid and liquid dosage forms |
| ISO 11418-5:1997 | Containers and accessories for pharmaceutical preparations -- Part 5: Dropper assemblies |
| ISO 11418-7:1998 | 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 devices for multiple use -- Requirements and test methods |
| ISO 15747:2010 | Plastic containers for intravenous injections |

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| 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 28620:2010 | Medical devices -- Non-electrically driven portable infusion devices |
| ISO 3826-1-:2013 | 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 6710:1995 | Single-use containers for venous blood specimen collection |
| ISO 8362-1:2009 | Injection containers and accessories -- Part 1: Injection vials made of glass tubing |
| ISO 8362-2:2008 | 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 |

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| ISO 8362-4:2011 | Injection containers and accessories -- Part 4: Injection vials made of moulded glass |
| ISO 8362-5:2008 | 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 8536-4:2010 | Infusion equipment for medical use -- Part 4: Infusion sets for single use, gravity feed |
| ISO 8536-4:2010/ Amd 1:2013 | Infusion equipment for medical use -- Part 4: Infusion sets for single use, gravity feed – *Amendment 1* |
| ISO 8536-5:2004 | Infusion equipment for medical use -- Part 5: Burette infusion sets for single use, gravity feed |
| ISO 8536-6:2009 | Infusion equipment for medical use -- Part 6: Freeze drying closures for infusion bottles |

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| ISO 8536-7:2009 | Infusion equipment for medical use -- Part 7: Caps made of aluminium-plastics combinations for infusion bottles |
| ISO 8536-8:2004 | Infusion equipment for medical use -- Part 8: Infusion equipment for use with pressure infusion apparatus |
| ISO 8536-9:2004 | Infusion equipment for medical use -- Part 9: Fluid lines for use with pressure infusion equipment |
| ISO 8536-10:2004 | Infusion equipment for medical use -- Part 10: Accessories for fluid lines for use with pressure infusion equipment |
| ISO 8536-11:2004 | Infusion equipment for medical use -- Part 11: Infusion filters for use with pressure infusion equipment |
| ISO 8536-12:2001 | Infusion equipment for medical use -- Part 12: Check valves |
| ISO 8536-12:2001/ 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 8871-2:2003 | Elastomeric parts for parenterals and for devices for pharmaceutical use -- Part 2: Identification and characterization |
| ISO 8871-2:2003 / Amd 1:2005 | Elastomeric parts for parenterals and for devices for pharmaceutical use -- Part 2: Identification and characterization – *Amendment 1* |

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|---|---|
| ISO 8871-3:2003 | Elastomeric parts for parenterals and for devices for pharmaceutical use -- Part 3: Determination of released-particle count |
| ISO 8871-4:2006 | Elastomeric parts for parenterals and for devices for pharmaceutical use -- Part 4: Biological requirements and test methods |
| ISO 8871-5:2005 | 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 (IVD) Medical Devices)

## 5.1 Glucose meters

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| ISO 15197:2013 | In vitro diagnostic test systems -- Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus |
| ISO/IEEE 11073-10417:2014 | Health informatics -- Personal health device communication -- Part 10417: Device specialization -- Glucose meter |