LIST OF RECOGNIZED STANDARDS FOR MEDICAL DEVICES

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ACKNOWLEDGEMENT

The Agency acknowledges the adoption of Health Canada's list of recognized standards for medical devices and the technical support of Health Canada in development of NAFDAC list of recognized standards for medical devices including in vitro diagnostics.

Changes to the list of recognized standards

Standards added

- ISO 12417-1:2015-Ed.1.0
  - Cardiovascular implants and extracorporeal systems - Vascular device-drug combination products - Part 1: General requirements
- IEC 60601-2-36:2014-Ed.2.0
  - Medical electrical equipment – Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy
- IEC 60601-2-62:2013-Ed.1.0
  - Medical electrical equipment - Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment
- ASTM D3577-19
  - Standard Specification for Rubber Surgical Gloves
- ASTM D3578-19
  - Standard Specification for Rubber Examination Gloves
- ASTM D5250-19
  - Standard Specification for Poly(vinyl chloride) Gloves for Medical Application
- ASTM D6319-19
  - Standard Specification for Nitrile Examination Gloves for Medical Application
- ASTM D6978-05 (R2019)
  - Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
- ISO 374-1:2016-Ed.1.0
  - Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks
  - ISO 374-1:2016-Ed.1.0/Amd.1:2018
- ISO 374-2:2019-Ed.1.0

    - Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration
- ISO 374-4:2019-Ed.1.0
    - Protective gloves against dangerous chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals
- ISO 374-5:2016-Ed.1.0
    - Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks
- ISO 11193-2:2006-Ed.1.0
    - Single-use medical examination gloves Part 2: Specification for gloves made from poly(vinyl chloride)
- CSA Z94.4.1:2021-Ed.1.0
    - Performance of filtering respirators
- ASTM F3091/F3091M-14 (R2021)
    - Standard specification for powder bed fusion of plastic materials
- ASTM F3335-20
    - Standard guide for assessing the removal of additive manufacturing residues in medical devices fabricated by powder bed fusion
- ISO 17327-1:2018-Ed.1.0
    - Non-active surgical implants - Implant coating - Part 1: General requirements
- ASTM F2924-14 (R2021)
    - Standard specification for additive manufacturing Titanium-6 Aluminum-4 Vanadium with powder bed fusion
- ASTM F3001-14 (R2021)
    - Standard specification for additive manufacturing Titanium-6 Aluminum-4 Vanadium ELI (extra low interstitial) with powder bed fusion
- ASTM F3213-17
    - Standard for additive manufacturing - finished part properties - standard specification for Cobalt-28 Chromium-6 Molybdenum via powder bed fusion
- ISO 7197:2006-Ed.3.0
    - Neurosurgical Implants - Sterile, Single-Use Hydrocephalus Shunts and Components
    - ISO 7197:2006-Ed.3.0/Corr1:2007
- ISO 10940:2009-Ed.2.0
    - Ophthalmic instruments - Fundus cameras
- ISO 15004-1:2020-Ed.2.0
    - Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments

- ASTM F1264-16 (E2016)
  - Standard specification and test methods for intramedullary fixation devices
- ASTM F1378-18 (E2019)
  - Standard specification for shoulder prostheses
- ASTM F2695-12 (R2020)
  - Standard specification for ultra-high molecular weight polyethylene powder blended with alpha-tocopherol (vitamin E) and fabricated forms for surgical implant applications
- IEC 60601-2-63:2021-Ed.1.2
  - Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment
- ISO 17664-1:2021-Ed.1.0
  - Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices
- ISO 17664-2:2021-Ed.1.0
  - Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices

Standards updated

- ISO 10993-3:2014-Ed.3.0
  - Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- ISO 10993-4:2017-Ed.3.0
  - Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
- ISO 10993-6:2016-Ed.3.0
  - Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
- ISO 10993-9:2019-Ed.3.0
  - Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products
- ISO 10993-11:2017-Ed.3.0
  - Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

- ISO 10993-15:2019-Ed.2.0
    - Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys
- ISO 14708-2:2019-Ed.3.0
    - Implants for surgery - Active implantable medical devices - Part 2: Cardiac pacemakers
- ISO 14708-5:2020-Ed.2.0
    - Implants for surgery - Active implantable medical devices - Part 5: Circulatory support devices
- ISO 14708-6:2019-Ed.2.0
    - Implants for surgery - Active implantable medical devices - Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators)
- ISO 27186:2020-Ed.2.0
    - Active implantable medical devices - Four-pole connector system for implantable cardiac rhythm management devices - Dimensional and test requirements
- ISO 5840-1:2021-Ed.2.0
    - Cardiovascular implants - Cardiovascular implants - Cardiac valve prostheses - Part 1: General requirements
- ISO 5840-2:2021-Ed.2.0
    - Cardiovascular implants - Cardiac valve prostheses - Part 2: Cardiovascular implants - Surgically implanted heart valve substitutes
- ISO 5840-3:2021-Ed.2.0
    - Cardiovascular implants - Cardiac valve prostheses - Part 3: Heart valve substitutes implanted by transcatheter techniques
- ISO 14117:2019-Ed.2.0
    - Active implantable medical devices - Electromagnetic compatibility - EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices
- ISO 25539-2:2020-Ed.3.0
    - Cardiovascular implants - Endovascular devices - Part 2: Vascular stents
- ISO 14971:2019-Ed.3.0
    - Medical devices - Application of risk management to medical devices
- ISO 11193-1:2020-Ed.3.0
    - Single-use medical examination gloves - Part 1: Specification for gloves made from rubber latex or rubber solution
- ISO 14155:2020-Ed.3.0

    - Clinical investigation of medical devices for human subjects - Good clinical practice
- CLSI EP06:2020-Ed.2.0
    - Evaluation of Linearity of Quantitative Measurement Procedures
- CLSI EP07:2018-Ed.3.0
    - Interference Testing in Clinical Chemistry
- ISO 22442-1:2020-Ed.3.0
    - Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management
- ISO 22442-2:2020-Ed.3.0
    - Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling
- IEC 60601-1-3:2021-Ed.2.2
    - Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
- IEC 60601-2-43:2019-Ed.2.2
    - Medical electrical equipment - Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures
- IEC 60601-2-54:2018-Ed.1.2
    - Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
- ASTM F2346-18
    - Standard test methods for static and dynamic characterization of spinal artificial discs
- ASTM F2582-20
    - Standard test method for dynamic impingement between femoral and acetabular hip components
- ASTM F2083-21
    - Standard specification for knee replacement prosthesis
- ASTM F1160-14 (R2017)(E2017)
    - Standard test method for shear and bending fatigue testing of calcium phosphate and metallic medical and composite calcium phosphate/metallic coatings
- ASTM F897-19
    - Standard test method for measuring fretting corrosion of osteosynthesis plates and screws
- ASTM F1801-20

    - Standard practice for corrosion fatigue testing of metallic implant materials
- ASTM F86-21
    - Standard practice for surface preparation and marking of metallic surgical implants
- ISO 11137-1:2006-Ed.1.0
    - Sterilization of health care products - Radiation - Part 1: Requirement for development, validation and routine control of a sterilization process for medical devices
    - ISO 11137-1:2006-Ed.1.0/Amd.1:2013
    - ISO 11137-1:2006-Ed.1.0/Amd.2:2018
- ISO 11137-3:2017-Ed.2.0
    - Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation and routine control
- ISO 11138-1:2017-Ed.3.0
    - Sterilization of health care products - Biological indicators - Part 1: General
- ISO 11138-2:2017-Ed.3.0
    - Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes
- ISO 11138-3:2017-Ed.3.0
    - Sterilization of health care products - Biological indicators - Part 3: Biological indicators for moist heat sterilization processes
- ISO 11607-1:2019-Ed.2.0
    - Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2:2019-Ed.2.0
    - Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
- ISO 11737-1:2018-Ed.3.0
    - Sterilization of medical devices - Microbiological methods - Part 1: Determination of population of microorganisms on products
    - ISO 11737-1:2018-Ed.3.0/Amd.1:2021

List of recognized standards

Anaesthetic and respiratory

- ASME PVHO-1:2007
  - Safety standard for pressure vessels for human occupancy
- ISO 5356-1:2015-Ed.4.0
  - Anaesthetic and Respiratory Equipment - Conical Connectors - Part 1: Cones and Sockets
- ISO 5356-2:2012-Ed.3.0
  - Anaesthetic and Respiratory Equipment - Conical Connectors - Part 2: Screw threaded weight bearing connectors
- ISO 5360:2012-Ed.3.0
  - Anaesthetic Vaporizers - Agent Specific Filling System
- ISO 7199:2016-Ed.3.0
  - Cardiovascular implants and artificial organs – Blood-gas exchangers (oxygenators)
- ISO 8359:1996-Ed.2.0
  - Oxygen Concentrators for medical use - Safety requirements ISO 8359:1996-Ed.2.0/Amd.1:2012
- ISO 80601-2-12:2011-Ed.1.0
  - Medical electrical equipment – Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
    ISO 80601-2-12:2011-Ed.1.0/Cor.1:2011
- ISO 80601-2-13:2011-Ed.1.0
  - Medical electrical equipment – Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation
    ISO 80601-2-13:2011-Ed.1.0/Amd.1:2015
- ISO 80601-2-55:2011-Ed.1.0
  - Medical electrical equipment – Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
- ISO 80601-2-61:2011-Ed.1.0
  - Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- ISO 80601-2-72:2015-Ed.1.0
  - Medical electrical equipment – Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients

Biocompatibility

- ASTM F981-04
    - Standard practice for assessment of compatibility of biomaterials for surgical implants with respect to effect of materials on muscle and bone
- ISO 10993-1:2018-Ed.5.0
    - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
    - **Note**: Devices subject to Clause 5.3.2 may require additional testing beyond that which is specified in Clause 5.3.2
- ISO 10993-2:2006-Ed.2.0
    - Biological evaluation of medical devices - Part 2: Animal welfare requirements

- ISO 10993-3:2014-Ed.3.0
    - Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- ISO 10993-4:2017-Ed.3.0
    - Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
- ISO 10993-5:2009-Ed.3.0
    - Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-6:2016-Ed.3.0
    - Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
- ISO 10993-7:2008-Ed.2.0
    - Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals

o ISO 10993-7:2008-Ed.2.0/Cor.1:2009

- ISO 10993-9:2019-Ed.3.0
    - Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products

- ISO 10993-10:2010-Ed.3.0
    - Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-11:2017-Ed.3.0
    - Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ISO 10993-12:2007-Ed.3.0
    - Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
- ISO 10993-13:2010-Ed.2.0
    - Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices
- ISO 10993-14:2001-Ed.1.0
    - Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics
- ISO 10993-15:2019-Ed.2.0
    - Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys
- ISO 10993-16:2010-Ed.2.0
    - Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables
- ISO 10993-17:2002-Ed.1.0
    - Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances
- ISO 10993-18:2005-Ed.1.0
    - Biological evaluation of medical devices - Part 18: Chemical characterization of materials

Cardiovascular

- ISO 5840-1:2021-Ed.2.0
    - Cardiovascular implants - Cardiovascular implants - Cardiac valve prostheses - Part 1:
      General requirements

- **Note**: For heart valve substitutes that are indicated for use in low risk surgical patients, durability testing may be required beyond 200 million cycles, especially where long term clinical durability evidence is not available for the indicated patient population.
- Transition period: Ed.1.0 will continue to be recognized until Dec. 31, 2022

- ISO 5840-2:2021-Ed.2.0
  - Cardiovascular implants - Cardiac valve prostheses - Part 2: Cardiovascular implants -

Surgically implanted heart valve substitutes

  - Transition period: Ed.1.0 will continue to be recognized until Dec. 31, 2022
- ISO 5840-3:2021-Ed.2.0
  - Cardiovascular implants - Cardiac valve prostheses - Part 3: Heart valve substitutes implanted by transcatheter techniques
  - Transition period: Ed.1.0 will continue to be recognized until Dec. 31, 2022
- ISO 5841-3:2013-Ed.3.0
  - Implants for surgery - Cardiac pacemakers - Part 3: Low-profile connectors (IS-1) for implantable pacemakers
- ISO 7198:2016-Ed.2.0
  - Cardiovascular implants and extracorporeal systems - Vascular prostheses - Tubular vascular grafts and vascular patches
- ISO 10555-1:2013-Ed.2.0
  - Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements

o ISO 10555-1:2013-Ed.2.0/Amd.1:2017

- ISO 10555-3:2013-Ed.2.0
  - Intravascular catheters - Sterile and single-use catheters - Part 3: Central venous catheters
- ISO 10555-4:2013-Ed.2.0
  - Intravascular catheters - Sterile and single-use catheters - Part 4: Balloon dilatation catheters
- ISO 10555-5:2013-Ed.2.0

    - Intravascular catheters – Sterile and single-use catheters – Part 5: Over-needle peripheral catheters
- ISO 11318:2002-Ed.2.0
    - Cardiac defibrillators – Connector assembly DF-1 for implantable defibrillators – Dimensions and test requirements
- ISO 12417-1:2015-Ed.1.0
    - Cardiovascular implants and extracorporeal systems – Vascular device-drug combination products – Part 1: General requirements
- ISO 14117:2019-Ed.2.0
    - Active implantable medical devices – Electromagnetic compatibility – EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices
- ISO 14708-2:2019-Ed.3.0
    - Implants for surgery – Active implantable medical devices – Part 2: Cardiac pacemakers
- ISO 14708-5:2020-Ed.2.0
    - Implants for surgery – Active implantable medical devices – Part 5: Circulatory support devices
- ISO 14708-6:2019-Ed.2.0
    - Implants for surgery – Active implantable medical devices – Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators)
- ISO 25539-1:2017-Ed.2.0
    - Cardiovascular implants – Endovascular devices – Part 1: Endovascular prostheses
- ISO 25539-2:2020-Ed.3.0
    - Cardiovascular implants – Endovascular devices – Part 2: Vascular stents
- ISO 27186:2020-Ed.2.0
    - Active implantable medical devices – Four-pole connector system for implantable cardiac rhythm management devices – Dimensional and test requirements

Contraception

- ISO 4074:2002-Ed.1.0
    - Natural latex rubber condoms – Requirements and test methods

o ISO 4074:2002-Ed.1.0/Cor.1:2003

o ISO 4074:2002-Ed.1.0/Cor.2:2008

Dental

- ISO 3107:2011-Ed.4.0
    - Dentistry – Zinc oxide/eugenol and zinc oxide/non-eugenol cements
- ISO 4049:2019-Ed.5.0
    - Dentistry – Polymer-based restorative materials
- ISO 6872:2015-Ed.4.0
    - Dentistry – Ceramic materials

o ISO 6872:2015-Ed.4.0/Amd.1:2018

- ISO 6874:2015-Ed.3.0
    - Dentistry – Polymer-based pit and fissure sealants
- ISO 6876:2012-Ed.3.0
    - Dental root canal sealing materials
- ISO 6877:2006-Ed.2.0
    - Dentistry – Root-canal obturating points
- ISO 7405:2018-Ed.3.0
    - Dentistry – Evaluation of biocompatibility of medical devices used in dentistry
- ISO 9693-1:2012-Ed.1.0
    - Dentistry – Compatibility testing – Part 1: Metal-ceramic systems
- ISO 9917-1:2007-Ed.2.0
    - Dentistry – Water-based cements – Part 1: Powder/liquid acid-base cements
- ISO 9917-2:2017-Ed.3.0
    - Dentistry - Water-based cements – Part 2: Resin-modified cements
- ISO 10271:2011-Ed.2.0
    - Dental metallic materials – Corrosion test methods for metallic materials
- ISO 14801:2016-Ed.3.0

    - Dentistry — Implants — Dynamic loading test for endosseous dental implants
- ISO 22674:2016-Ed.2.0
    - Dentistry – Metallic materials for fixed and removable restorations and appliances
- ISO 22794:2007-Ed.1.0
    - Dentistry – Implantable materials for bone filling and augmentation in oral and maxillofacial surgery – Contents of a technical file
- ISO 22803:2004-Ed.1.0
    - Dentistry – Membrane materials for guided tissue regeneration in oral and maxillofacial surgery – Contents of a technical file
- ISO 24234:2015-Ed.2.0
    - Dentistry –Dental amalgam
- ISO/TS 11405:2015-Ed.3.0
    - Dental materials – Testing of adhesion to tooth structure
- ISO 13116:2014-Ed.1.0
    - Dentistry - Test Method for Determining Radio-Opacity of Materials
- ISO 29022:2013-Ed.1.0
    - Dentistry - Adhesion - Notched-edge shear bond strength test

Electromedical

- CAN/CSA C22.2 NO 60601-1:2014-Ed.3.0
    - Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60529:2001-Ed.2.1
    - Degrees of protection provided by enclosures (IP Code)

o IEC 60529:2001-Ed.2.1/Cor.1:2001

o IEC 60529:2001-Ed.2.1/Cor.2:2007

o IEC 60529:2001-Ed.2.1/Cor.3:2009

- IEC 60601-1:2005-Ed.3.0
    - Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

o IEC 60601-1:2005-Ed.3.0/Cor.1:2006

o IEC 60601-1:2005-Ed.3.0/Cor.2:2007

- IEC 60601-1:2012-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 disturbances – Requirements and tests
- 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 basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60601-1-10:2007-Ed 1.0
    - 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 -Ed 1.0
    - 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
- IEC 60601-2-1:2014-Ed.3.1
    - Medical electrical equipment - Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV
- IEC 60601-2-2:2009-Ed.5.0

- 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 60601-2-4:2010-Ed.3.0
  - Medical electrical equipment – Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators
- IEC 60601-2-5:2009-Ed.3.0
  - Medical electrical equipment – Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment
- ISO 14160:2020-Ed.3.0
  - 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
- IEC 60601-2-16:2008-Ed.3.0
  - Medical electrical equipment – Part 2-16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment

o IEC 60601-2-16:2008-Ed.3.0/Cor.1:2008

- IEC 60601-2-18:2009-Ed.3.0
  - Medical electrical equipment – Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- IEC 60601-2-22:2012-Ed.3.1
  - Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
- IEC 60601-2-23:2011-Ed.3.0
  - Medical electrical equipment – Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment
- IEC 60601-2-24:2012-Ed.2.0
  - Medical electrical equipment – Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers

- **Note**: Additional accuracy testing results for flow rates below 1 ml/h may be required depending on the pump's intended use

- IEC 60601-2-25:2011-Ed.2.0
  - Medical electrical equipment – Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
- IEC 60601-2-26:2012-Ed.3.0
  - Medical electrical equipment – Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
- IEC 60601-2-27:2011-Ed.3.0
  - Medical Electrical Equipment – Part 2-27: Particular Requirements for the Basic Safety and Essential Performance of Electrocardiographic Monitoring Equipment

o IEC 60601-2-27:2011-Ed.3.0/Cor.1:2012

- IEC 60601-2-31:2008-Ed.2.0
  - Medical electrical equipment – Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source

o IEC 60601-2-31:2008-Ed.2.0/Amd.1:2011

- IEC 60601-2-33:2010-Ed.3.0
  - Medical electrical equipment – Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis

o IEC 60601-2-33:2010-Ed.3.0/Cor.1:2012

- IEC 60601-2-34:2011-Ed.3.0
  - Medical electrical equipment – Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment
- IEC 60601-2-36:2014-Ed.2.0
  - Medical electrical equipment – Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy
- IEC 60601-2-47:2012-Ed.2.0

- Medical electrical equipment – Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems

- IEC 60601-2-49:2011-Ed.2.0
  - Medical electrical equipment – Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
- IEC 60601-2-50:2009-Ed.2.0
  - Medical electrical equipment – Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment

o IEC 60601-2-50:2009-Ed.2.0/Cor.1:2010

- IEC 60601-2-57:2011-Ed.1.0
  - Medical electrical equipment – Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use
- IEC 60601-2-62:2013-Ed.1.0
  - Medical electrical equipment - Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment
- IEC 60825-1:2014-Ed.3.0
  - Safety of laser products - Part 1: Equipment classification and requirements
- IEC 61000-3-2:2009-Ed.3.2
  - Electromagnetic compatibility (EMC) – Part 3-2: Limits – Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)

o IEC 61000-3-2:2009-Ed.3.2/Cor.1:2009

- IEC 61000-3-3:2008-Ed.2.0
  - Electromagnetic compatibility (EMC) – Part 3-3: Limits – Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤16A per phase and not subject to conditional connection
- IEC 61000-4-2:2008-Ed.2.0
  - Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement

techniques – Electrostatic discharge immunity test

- IEC 61000-4-3:2010-Ed.3.2
    - Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test
- IEC 61000-4-4:2012-Ed.3.0
    - Electromagnetic compatibility (EMC) – Part 4-4: Testing and measurement techniques – Electrical fast transient/burst immunity test
- IEC 61000-4-5:2005-Ed.2.0
    - Electromagnetic compatibility (EMC) – Part 4-5: Testing and measurement techniques –

Surge immunity test

o IEC 61000-4-5:2005-Ed.2.0/Cor.1:2009

- IEC 61000-4-6:2008-Ed.3.0
    - Electromagnetic compatibility (EMC) – Part 4-6: Testing and measurement techniques – Immunity to conducted disturbances, induced by radio-frequency fields
- IEC 61000-4-8:2009-Ed.2.0
    - Electromagnetic compatibility (EMC) – Part 4-8: Testing and measurement techniques – Power frequency magnetic field immunity test
- IEC 61000-4-11:2004-Ed.2.0
    - Electromagnetic compatibility (EMC) – Part 4-11: Testing and measurement techniques – Voltage dips, short interruptions and voltage variations immunity tests
- IEC 80601-2-30:2009-Ed.1.0
    - Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

o IEC 80601-2-30:2009-Ed.1.0/Cor.1:2010

- IEC CISPR 11:2010-Ed.5.1
    - Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement
- ISO 14708-1:2014-Ed.2.0

- Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety, marking and for information to be provided by the manufacturer.

General

- ASTM D4169-16
  - Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM F1140-13
  - Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages
- ASTM F1929-98
  - Standard test method for detecting seal leaks in porous medical packaging by dye penetration

o ASTM F1929-98:2004/(R 2004)

- ASTM F2096-11
  - Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
- ASTM F88-15
  - Standard Test Method for Seal Strength of Flexible Barrier Materials
- IEC 62304:2015-Ed.1.1
  - Medical device software - Software life cycle processes
- IEC 62366-1:2015-Ed.1.0
  - Medical devices -Part 1: Application of usability engineering to medical devices

o IEC 62366-1:2015-Ed.1.0/COR 1:2016

- ASTM D3577-19
  - Standard Specification for Rubber Surgical Gloves
- ASTM D3578-19
  - Standard Specification for Rubber Examination Gloves
- ASTM D5250-19
  - Standard Specification for Poly(vinyl chloride) Gloves for Medical Application
- ASTM D6319-19

- Standard Specification for Nitrile Examination Gloves for Medical Application
- ASTM D6978-05 (R2019)
  - Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
- ISO 374-1:2016-Ed.1.0
  - Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks

o ISO 374-1:2016-Ed.1.0/Amd.1:2018

- ISO 374-2:2019-Ed.1.0
  - Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration
- ISO 374-4:2019-Ed.1.0
  - Protective gloves against dangerous chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals
- ISO 374-5:2016-Ed.1.0
  - Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks
- ISO 10282:2002-Ed.2.0
  - Single-Use Sterile Surgical Rubber Gloves - Specification
- ISO 11193-1:2020-Ed.3.0
  - Single-use medical examination gloves - Part 1: Specification for gloves made from rubber latex or rubber solution
- ISO 11193-2:2006-Ed.1.0
  - Single-use medical examination gloves Part 2: Specification for gloves made from poly(vinyl chloride)
- ISO 11663:2009-Ed.1.0
  - Quality of dialysis fluid for haemodialysis and related therapies
- ISO 13959:2009-Ed.2.0
  - Water for haemodialysis and related therapies
- ISO 14155:2020-Ed.3.0
  - Clinical investigation of medical devices for human subjects - Good clinical practice
  - Transition period: Ed.2.0 with Cor.1:2011 will continue to be recognized until

Dec. 31, 2022

- ISO 14971:2019-Ed.3.0
    - Medical devices - Application of risk management to medical devices
- ISO 22442-1:2020-Ed.3.0
    - Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management
- ISO 22442-2:2020-Ed.3.0
    - Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling
- ISO 22442-3:2007-Ed.1.0
    - 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 26722:2009-Ed.1.0
    - Water treatment equipment for haemodialysis applications and related therapies
- SAI AS 2869:2008-Ed.4.0
    - Tampons – Menstrual
- CSA Z94.4.1:2021-Ed.1.0
    - Performance of filtering respirators

In vitro diagnostic

- CLSI C46-A2:2009-Ed.2.0
    - Blood gas and pH analysis and related measurements; Approved guideline
- CLSI EP12-A2:2008-Ed.2.0
    - User protocol for evaluation of qualitative test performance; Approved guideline
- CLSI EP14-A3:2014-Ed.3.0
    - Evaluation of Commutability of Processed Samples; Approved guideline
- CLSI EP17-A2:2012-Ed.2.0
    - Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved guideline
- CLSI EP24-A2:2011-Ed.2.0
    - Assessment of the Diagnostic Accuracy of Laboratory Tests Using Receiver

Operating Characteristic Curves; Approved Guideline – Second Edition

- CLSI EP25-A:2009-Ed.1.0
  - Evaluation of stability of in vitro diagnostic reagents; Approved guideline
  - (**Note**: Except: Section 7.1.3)
- CLSI EP28-A3C:2010-Ed.3.0
  - Defining, establishing, and verifying reference intervals in the clinical laboratory; Approved guideline
- CLSI EP5-A3:2014-Ed.3.0
  - Evaluation of precision of quantitative measurement procedures; Approved guideline
- CLSI EP06:2020-Ed.2.0
  - Evaluation of Linearity of Quantitative Measurement Procedures CLSI EP07:2018-Ed.3.0
- o Interference Testing in Clinical Chemistry CLSI H15-A3:2000-Ed.3.0
- o Reference and selected procedures for the quantitative determination of hemoglobin in blood; Approved standard
- CLSI H20-A2:2007-Ed.2.0
  - Reference leukocyte (WBC) differential count (proportional) and evaluation of instrumental
- methods; Approved standard CLSI I/LA18-A2:2001-Ed.2.0
  - Specifications for immunological testing for infectious diseases; Approved guideline
- CLSI I/LA21-A2:2008-Ed.2.0
  - Clinical evaluation of immunoassays; Approved guideline CLSI MM01-A3:2012-Ed.3.0
- o Molecular Methods for Clinical Genetics and Oncology Testing; Approved Guideline CLSI MM06-A2:2010-Ed.2.0
- o Quantitative Molecular Methods for Infectious Diseases CLSI MM12-A:2006-Ed.1.0
- o Diagnostic nucleic acid microarrays; Approved guideline CLSI MM13-A:2005-Ed.1.0
- o Collection, transport, preparation, and storage of specimens for molecular methods; Approved guideline. **Note**: Except: Section 6.1.1

- CLSI MM16-A:2006-Ed.1.0
    - Use of external RNA controls in gene expression assays; Approved guideline
- CLSI MM17-A:2008-Ed.1.0
    - Verification and validation of multiplex nucleic acid assays; Approved guideline CLSI POCT14-A:2004-Ed.1.0
- o Point-of-care monitoring of anticoagulation therapy; Approved guideline IEC 61010-1:2010-Ed.3.0
- o Safety requirements for electrical equipment for measurement, control, and laboratory use

– Part 1: General requirements

- o IEC 61010-1:2010-Ed.3.0/Cor.1:2011
    - IEC 61010-1:2010-Ed.3.0/Cor.2:2013 French Only/Version Francaise
- IEC 61010-2-101:2015-Ed.2.0
    - Safety requirements for electrical equipment for measurement, control, and laboratory use

– Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment IEC 61326-1:2012-Ed.2.0

- Electrical equipment for measurement, control and laboratory use – EMC requirements Part
- 1: General requirements IEC 61326-2-6:2012-Ed.2.0
    - Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment
- ISO 15197:2013-Ed.2.0
    - In vitro diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus
- ISO 23640:2011-Ed.1.0
    - In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents

Manufacturing

- ASTM F3091/F3091M-14 (R2021)

    - Standard specification for powder bed fusion of plastic materials
- ASTM F3335-20
    - Standard guide for assessing the removal of additive manufacturing residues in medical devices fabricated by powder bed fusion
- ISO 13408-1:2008-Ed.2.0
    - Aseptic processing of health care products - Part 1 : General requirements
- ISO 13408-2:2003-Ed.1.0
    - Aseptic processing of health care products - Part 2 : Filtration
- ISO 13408-3:2006-Ed.1.0
    - Aseptic processing of health care products - Part 3 : Lyophilization
- ISO 13408-4:2005-Ed.1.0
    - Aseptic processing of health care products - Part 4 : Clean-in-place technologies
- ISO 13408-5:2006-Ed.1.0
    - Aseptic processing of health care products - Part 5 : Sterilization in place
- ISO 13408-6:2005-Ed.1.0
    - Aseptic processing of health care products - Part 6 : Isolator systems
- ISO 13408-7:2012-Ed.1.0
    - Aseptic processing of health care products - Part 7 : Alternative processes for medical devices and combination products
- ISO 14644-1:1999-Ed.1.0
    - Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness
- ISO 14644-2:2000-Ed.1.0
    - Cleanrooms and associated controlled environments - Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
- ISO 14644-3:2005-Ed.1.0
    - Cleanrooms and associated controlled environments - Part 3: Test methods
- ISO 14644-4:2001-Ed.1.0
    - Cleanrooms and associated controlled environments - Part 4: Design, Construction and Start Up
- ISO 14644-5:2004-Ed.1.0
    - Cleanrooms and associated controlled environments - Part 5: Operations

- ISO 14644-6:2007-Ed.1.0
    - Cleanrooms and associated controlled environments - Part 6: Vocabulary
- ISO 14644-7:2004-Ed.1.0
    - Cleanrooms and associated controlled environments - Part 7: Separative devices (clean air hoods, glove boxes, isolators and mini-environments)
- ISO 14644-8:2013-Ed.2.0
    - Cleanrooms and associated controlled environments - Part 8: Classification of air cleanliness by chemical concentration (ACC)
- ISO 14644-9:2012-Ed.1.0
    - Cleanrooms and associated controlled environments - Part 9: Classification of surface cleanliness by particle concentration
- ISO 14644-10:2013-Ed.1.0
    - Cleanrooms and associated controlled environments - Part 10: Classification of surface cleanliness by chemical concentration
- ISO 14698-1:2003-Ed.1.0
    - Cleanrooms and associated controlled environments - Biocontamination control - Part 1: General principles and methods
- ISO 14698-2:2003-Ed.1.0
    - Cleanrooms and associated controlled environments - Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data

Materials

- ASTM F1088-04a
    - Standard specification for beta-tricalcium phosphate for surgical implantations
- ASTM F1088-04a:2010/(R 2010)ASTM F1091-08
    - Standard specification for wrought cobalt-20chromium-15tungsten-10nickel alloy surgical fixation wire (UNS R30605)
- ASTM F1108-04
    - Standard specification for titanium-6aluminum-4vanadium alloy castings for surgical implants (UNS R56406)

o ASTM F1108-04:2009/(R 2009)

- ASTM F1295-05
    - Standard specification for wrought titanium-6 aluminum-7 niobium alloy for

surgical implant applications (UNS R56700)

- ASTM F1314-07
  - Standard specification for wrought nitrogen strengthened 22chromium-13nickel- 5manganese-2.5molybdenum stainless steel alloy bar and wire for surgical implants (UNS S20910)
- ASTM F1350-08
  - Standard specification for wrought 18chromium-14nickel-2.5molybdenum stainless steel surgical fixation wire (UNS S31673)
- ASTM F136-12
  - Standard specification for wrought titanium-6aluminum-4vanadium ELI (Extra Low Interstitial) alloy for surgical implant applications (UNS R56401)
- ASTM F138-08
  - Standard specification for wrought 18chromium-14nickel-2.5molybdenum stainless steel bar and wire for surgical implants (UNS S31673)
- ASTM F139-08
  - Standard specification for wrought 18chromium-14nickel-2.5molybdenum stainless steel sheet and strip for surgical implants (UNS S31673)
- ASTM F1472-08
  - Standard specification for wrought titanium-6aluminum-4vanadium alloy for surgical implant applications (UNS R56400)
- ASTM F1537-08
  - Standard specification for wrought cobalt-28 chromium-6 molybdenum alloy for surgical implants (UNS R31537, UNS R31538, and UNS R31539)
- ASTM F1580-12
  - Standard specification for titanium and titanium-6aluminum-4vanadium alloy powders for coatings of surgical implants
- ASTM F1586-08
  - Standard specification for wrought nitrogen strengthened 21chromium-10nickel- 3manganese-2.5molybdenum stainless steel bar for surgical implants (UNS S31675)
- ASTM F1713-08
  - Standard specification for wrought titanium-13niobium-13zirconium alloy for surgical implant applications (UNS R58130)

- ASTM F2026-16
    - Standard specification for polyetheretherketone (PEEK) polymers for surgical implant applications
- ASTM F2565-06
    - Standard guide for extensively irradiation-crosslinked ultra-high molecular weight polyethylene fabricated forms for surgical implant applications
- ASTM F2695-12 (R2020)
    - Standard specification for ultra-high molecular weight polyethylene powder blended with alpha-tocopherol (vitamin E) and fabricated forms for surgical implant applications
- ASTM F2924-14 (R2021)
    - Standard specification for additive manufacturing Titanium-6 Aluminum-4 Vanadium with powder bed fusion
- ASTM F3001-14 (R2021)
    - Standard specification for additive manufacturing Titanium-6 Aluminum-4 Vanadium ELI (extra low interstitial) with powder bed fusion
- ASTM F3213-17
    - Standard for additive manufacturing - finished part properties - standard specification for Cobalt-28 Chromium-6 Molybdenum via powder bed fusion
- ASTM F560-08
    - Standard specification for unalloyed tantalum for surgical implant applications (UNS R05200, UNS R05400)
- ASTM F562-07
    - Standard specification for wrought 35cobalt-35nickel-20chromium-10molybdenum alloy for surgical implant applications (UNS R30035)
- ASTM F620-06
    - Standard specification for alpha plus beta titanium alloy forgings for surgical implants
- ASTM F621-08
    - Standard specification for stainless steel forgings for surgical implants
- ASTM F648-07
    - Standard specification for ultra-high-molecular weight polyethylene powder and fabricated form for surgical implants

- ASTM F648-07:2007/(e 2007)ASTM F67-06
    - Standard specification for unalloyed titanium for surgical implant applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)
- ASTM F688-05
    - Standard specification for wrought cobalt-35 nickel-20 chromium-10 molybdenum alloy plate, sheet, and foil for surgical implants (UNS R30035)
- ASTM F75-12
    - Standard specification for cobalt-28chromium-6molybdenum alloy castings and casting alloy for surgical implants (UNS R30075)
- ASTM F799-11
    - Standard specification for cobalt-28chromium-6molybdenum alloy forgings for surgical implants (UNS R31537, R31538, R31539)
- ASTM F899-12
    - Standard specification for wrought stainless steel for surgical instruments
- ASTM F90-09
    - Standard specification for wrought cobalt-20chromium-15tungsten-10nickel alloy for surgical implant applications (UNS R30605)
- ASTM F961-08
    - Standard specification for 35cobalt-35nickel-20chromium-10molybdenum alloy forgings for surgical implants (UNS R30035)
- ISO 3826-1:2003-Ed.1.0
    - Plastic collapsible containers for human blood and blood components – Part 1: Conventional containers
- ISO 5832-1:2007-Ed.4.0
    - Implants for Surgery – Metallic materials – Part 1: Wrought stainless steel

o ISO 5832-1:2007-Ed.4.0/Corr1:2008

- ISO 5832-2:1999-Ed.3.0
    - Implants for surgery – Metallic materials – Part 2: Unalloyed titanium
- ISO 5832-3:1996-Ed.3.0
    - Implants for surgery – Metallic materials – Part 3: Wrought titanium 6-aluminium 4- vanadium alloy
- ISO 5832-4:1996-Ed.2.0
    - Implants for surgery – Metallic materials – Part 4: Cobalt-chromium-

molybdenum casting alloy

- ISO 5832-5:2005-Ed.3.0
    - Implants for surgery – Metallic materials – Part 5: Wrought cobalt-chromium-tungsten- nickel alloy
- ISO 5832-6:1997-Ed.2.0
    - Implants for surgery – Metallic materials – Part 6: Wrought cobalt-nickel-chromium- molybdenum alloy
- ISO 5832-9:2007-Ed.2.0
    - Implants for surgery – Metallic materials – Part 9: Wrought high nitrogen stainless steel
- ISO 5832-11:1994-Ed.1.0
    - Implants for surgery – Metallic materials – Part 11: Wrought titanium 6-aluminium 7- niobium alloy
- ISO 5832-12:2007-Ed.2.0
    - Implants for surgery – Metallic materials – Part 12: Wrought cobalt-chromium-molybdenum alloy

o ISO 5832-12:2007-Ed.2.0/Cor.1:2008

- ISO 5834-2:2011-Ed.4.0
    - Implants for surgery – Ultra-high molecular weight polyethylene – Part 2: Moulded forms
- ISO 6474-1:2010-Ed.1.0
    - Implants for surgery – Ceramic materials – Part 1: Ceramic materials based on high purity alumina
- ISO 6474-2:2012-Ed.1.0
    - Implants for surgery - Ceramic materials - Part 2: Composite materials based on a high purity alumina matrix with zirconia reinforcement
- ISO 7153-1:1991-Ed.2.0
    - Surgical instruments – Metallic materials – Part 1: Stainless steel

o ISO 7153-1:1991-Ed.2.0/Amd.1:1999

- ISO 13402:1995-Ed.1.0
    - Surgical and dental hand instruments – Determination of resistance against autoclaving, corrosion and thermal exposure

- ISO 13782:1996-Ed.1.0
    - Implants for surgery – Metallic materials – Unalloyed tantalum for surgical implant applications
- ISO 17327-1:2018-Ed.1.0
    - Non-active surgical implants - Implant coating - Part 1: General requirements

Neurology

- IEC 60601-2-10:2012-Ed.2.0
    - Medical electrical equipment – Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- ISO 7197:2006-Ed.3.0
    - Neurosurgical Implants - Sterile, Single-Use Hydrocephalus Shunts and Components

o ISO 7197:2006-Ed.3.0/Corr1:2007

- ISO 14708-3:2017-Ed.2.0
    - Implants for Surgery - Active implantable medical devices -- Part 3: Implantable neurostimulators
- ISO 14708-7:2013-Ed.1.0
    - Implants for surgery - Active implantable medical devices - Part 7: Particular requirements for cochlear implant systems

Ophthalmology

- ANSI Z80.7:2002
    - Ophthalmic optics – Intraocular lenses
- ISO 10940:2009-Ed.2.0
    - Ophthalmic instruments - Fundus cameras
- ISO 11979-1:2006-Ed.2.0
    - Ophthalmic implants – Intraocular lenses – Part 1: Vocabulary
- ISO 11979-2:2014-Ed.2.0
    - Ophthalmic implants -- Intraocular lenses -- Part 2: Optical properties and test methods
- ISO 11979-3:2006-Ed.2.0
    - Ophthalmic implants – Intraocular lenses – Part 3: Mechanical properties and

test methods

- ISO 11979-4:2008-Ed.2.0
    - Ophthalmic implants - Intraocular lenses - Part 4: Labelling and information

o ISO 11979-4:2008-Ed.2.0/Amd.1:2012

- ISO 11979-5:2006-Ed.2.0
    - Ophthalmic implants – Intraocular lenses – Part 5: Biocompatibility
- ISO 11979-6:2007-Ed.2.0
    - Ophthalmic implants – Intraocular lenses – Part 6: Shelf-life and transport stability
- ISO 11979-7:2006-Ed.2.0
    - Ophthalmic implants – Intraocular lenses – Part 7: Clinical investigations

o ISO 11979-7:2006-Ed.2.0/Amd.1:2012

ISO 11979-8:2017-Ed.3.0

- Ophthalmic implants – Intraocular lenses – Part 8: Fundamental requirements
- ISO 11979-10:2018-Ed.2.0
    - Ophthalmic implants - Intraocular lenses - Part 10: Clinical investigations of intraocular lenses for correction of ametropia in phakic eyes
- ISO TR 22979:2017-Ed.2.0
    - Ophthalmic implants - Intraocular lenses - Guidance on assessment of the need for clinical investigation of intraocular lens design modifications
- ISO 11980:2009-Ed.2.0
    - Ophthalmic optics – Contact lenses and contact lens care products – Guidance for clinical investigations
- ISO 15004-1:2020-Ed.2.0
    - Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments

- ISO 15004-2:2007-Ed.1.0
    - Ophthalmic instruments – Fundamental requirements and test methods – Part 2: Light hazard protection
- ISO 18369-1:2006-Ed.1.0

    - Ophthalmic optics – Contact lenses – Part 1: Vocabulary, classification system and recommendations for labelling specifications

o ISO 18369-1:2006-Ed.1.0/Amd.1:2009

- ISO 18369-2:2006-Ed.1.0
    - Ophthalmic optics – Contact lenses – Part 2: Tolerances
- ISO 18369-3:2006-Ed.1.0
    - Ophthalmic optics – Contact lenses – Part 3: Measurement methods
- ISO 18369-4:2006-Ed.1.0
    - Ophthalmic optics – Contact lenses – Part 4: Physicochemical properties of contact lens materials
- IEC 80601-2-58:2016-Ed.2.1
    - Medical electrical equipment - Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery

Orthopaedics

- ASTM F1044-05
    - Standard test method for shear testing of calcium phosphate coatings and metallic coatings

o ASTM F1044-05:2005/(R 2017)

o ASTM F1044-05:2005/(E 2018)

- ASTM F1089-10
    - Standard test method for corrosion of surgical instruments
- ASTM F1147-05
    - Standard test method for tension testing of calcium phosphate and metal coatings

o ASTM F1147-05:2005/(R 2017)

o ASTM F1147-05:2005/(E 2017)

- ASTM F1160-14 (R2017)(E2017)
    - Standard test method for shear and bending fatigue testing of calcium phosphate and metallic medical and composite calcium phosphate/metallic

coatings

- ASTM F1264-16 (E2016)
    - Standard specification and test methods for intramedullary fixation devices
- ASTM F1377-13
    - Standard specification for cobalt-28chromium-6molybdenum powder for coating of orthopedic Implants (UNS R30075)
- ASTM F1378-18 (E2019)
    - Standard specification for shoulder prostheses
- ASTM F1609-08
    - Standard Specification for calcium phosphate coatings for implantable materials

o ASTM F1609-08:2008/(R 2014)

- ASTM F1717-18
    - Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
- ASTM F1798-13
    - Standard Test Method for evaluating the static and fatigue properties of interconnection mechanisms and subassemblies used in spinal arthrodesis implants
- ASTM F1800-12
    - Standard Practice for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements
- ISO 5838-2:1991-Ed.1.0
    - Implants for surgery – Skeletal pins and wires – Part 2: Steinmann skeletal pins – Dimensions
- ISO 5838-3:1993-Ed.1.0
    - Implants for surgery – Skeletal pins and wires – Part 3: Kirschner skeletal wires
- ISO 7153-1:1991-Ed.2.0
    - Surgical instruments – Metallic materials – Part 1: Stainless steel

o ISO 7153-1:1991-Ed.2.0/Amd.1:1999

- ISO 7206-4:2010-Ed.3.0

- 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-Ed.2.0
  - 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 9583:1993-Ed.1.0
  - Implants for surgery – Non-destructive testing – Liquid penetrant inspection of metallic surgical implants
- ISO 14242-1:2014-Ed.3.0
  - 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

o ISO 14242-1:2014-Ed.3.0/Amd. 1: 2018

- ISO 14242-2:2016-Ed.2.0
  - Implants for Surgery - Wear of total hip-joint prostheses - Part 2: Methods of measurement
- ISO 14243-1:2009-Ed.2.0
  - 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 14243-2:2016-Ed.3.0
  - Implants for surgery - Wear of total knee-joint prostheses - Part 2: Methods of measurement
- ISO 14243-3:2014-Ed.2.0
  - 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 14630:2012-Ed.4.0
  - Non-active surgical implants - General requirements

Radiology

- AIUM/NEMA UD 2:2004
    - Acoustic output measurement standard for diagnostic ultrasound equipment

o AIUM/NEMA UD 2:2004/(R 2009)

- AIUM/NEMA UD 3:2004
    - Standard for real-time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment
- IEC 60601-1-3:2021-Ed.2.2
    - Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment
- IEC 60601-2-28: 2017-Ed.3.0
    - Medical electrical equipment – Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
- IEC 60601-2-37:2015-Ed.2.1
    - Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- IEC 60601-2-43:2019-Ed.2.2
    - Medical electrical equipment – Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures

o IEC 60601-2-43:2017-Ed.2.1/Amd.1:2017

- IEC 60601-2-44:2016-Ed.3.2
    - Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography
- IEC 60601-2-45:2015-Ed.3.1
    - Medical electrical equipment – Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment

and mammographic stereotactic devices

- IEC 60601-2-54:2018-Ed.1.2
    - Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
- IEC 60601-2-63:2021-Ed.1.2
    - Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment

Sterilization

- ASTM F1980-07
    - Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- CAN/CSA Z17665-1-09:2009-Ed.1.0
    - 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 11135:2014-Ed.2.0
    - Sterilization of health care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices

o ISO 11135:2014-Ed.2.0/Amd.1:2018

- ISO 11137-1:2006-Ed.1.0
    - Sterilization of health care products - Radiation - Part 1: Requirement for development, validation and routine control of a sterilization process for medical devices

o ISO 11137-1:2006-Ed.1.0/Amd.1:2013

o ISO 11137-1:2006-Ed.1.0/Amd.2:2018

- ISO 11137-2:2013-Ed.3.0
    - Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
- ISO 11137-3:2017-Ed.2.0

    - Sterilization of health care products – Radiation – Part 3: Guidance on dosimetric aspects
- ISO 11138-1:2017-Ed.3.0
    - Sterilization of health care products – Biological indicators – Part 1: General
- ISO 11138-2:2017-Ed.3.0
    - Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes
- ISO 11138-3:2017-Ed.3.0
    - Sterilization of health care products – Biological indicators – Part 3: Biological indicators for moist heat sterilization processes
- ISO 11607-1:2019-Ed.2.0
    - Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2:2019-Ed.2.0
    - Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
- ISO 11737-1:2018-Ed.3.0
    - Sterilization of medical devices – Microbiological methods – Part 1: Determination of population of microorganisms on products

o ISO 11737-1:2018-Ed.3.0/Amd.1:2021

- ISO 14160:2020-Ed.3.0
    - Sterilization of health care products – Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives – Requirements for characterization, development, validation and routine control of a sterilization process for medical devices
- ISO 14937:2009-Ed.2.0
    - 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 17664-1:2021-Ed.1.0
    - Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices – Part 1: Critical and semi-critical medical devices

- ISO 17664-2:2021-Ed.1.0
    - Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices
- ISO 17665-1:2006-Ed.1.0
    - Sterilization of health care products - Moist heat Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices