Health Canada Santé Canada

Draft List of Recognized Standards for Medical Devices

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Canada

Health Canada is responsible for helping Canadians maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks.

Également disponible en français sous le titre:
Ébauche: Normes reconnues pour les instruments médicaux

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Foreword

Guidance documents are meant to provide assistance to industry and health care professionals on how to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent, and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document may be acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant programme area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy, or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable Guidance documents.

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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

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Standard Specification for Rubber Surgical Gloves

ASTM D3578-19

Standard Specification for Rubber Examination Gloves

ASTM D5250-19

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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

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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

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

ISO 10940:2009-Ed.2.0

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ISO 15004-1:2020-Ed.2.0

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ASTM F1264-16 (E2016)

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Standard specification for shoulder prostheses

ASTM F2695-12 (R2020)

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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 EP07:2020-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

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

Standards Removed

ISO 17664:2004-Ed.2.0

Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices

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

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

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

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

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

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)

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

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

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

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

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

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

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

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

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

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

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)

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

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

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

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

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

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 EP6-A:2003-Ed.1.0

Evaluation of the linearity of quantitative measurement procedures: A statistical approach; Approved guideline

CLSI EP06:2020-Ed.2.0

Evaluation of Linearity of Quantitative Measurement Procedures

CLSI EP7-A2:2005-Ed.2.0

Interference testing in clinical chemistry; Approved guideline

CLSI EP07:2020-Ed.3.0

Interference Testing in Clinical Chemistry

CLSI H15-A3:2000-Ed.3.0

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

721 CLSI I/LA18-A2:2001-Ed.2.0

722 Specifications for immunological testing for infectious diseases; Approved guideline

723 CLSI I/LA21-A2:2008-Ed.2.0

724 Clinical evaluation of immunoassays; Approved guideline

725 CLSI MM01-A3:2012-Ed.3.0

726 Molecular Methods for Clinical Genetics and Oncology Testing; Approved Guideline

727 CLSI MM06-A2:2010-Ed.2.0

728 Quantitative Molecular Methods for Infectious Diseases

729 CLSI MM12-A:2006-Ed.1.0

730 Diagnostic nucleic acid microarrays; Approved guideline

731 CLSI MM13-A:2005-Ed.1.0

732 Collection, transport, preparation, and storage of specimens for molecular methods;
733 Approved guideline.

734 **Note**: Except: Section 6.1.1

735 CLSI MM16-A:2006-Ed.1.0

736 Use of external RNA controls in gene expression assays; Approved guideline

737 CLSI MM17-A:2008-Ed.1.0

738 Verification and validation of multiplex nucleic acid assays; Approved guideline

739 CLSI POCT14-A:2004-Ed.1.0

740 Point-of-care monitoring of anticoagulation therapy; Approved guideline

741 IEC 61010-1:2010-Ed.3.0

742 Safety requirements for electrical equipment for measurement, control, and
743 laboratory use - Part 1: General requirements

744 IEC 61010-1:2010-Ed.3.0/Cor.1:2011

745 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)

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)

852 ASTM F1537-08

853 Standard specification for wrought cobalt-28 chromium-6 molybdenum alloy for
854 surgical implants (UNS R31537, UNS R31538, and UNS R31539)

855 ASTM F1580-12

856 Standard specification for titanium and titanium-6aluminum-4vanadium alloy
857 powders for coatings of surgical implants

858 ASTM F1586-08

859 Standard specification for wrought nitrogen strengthened 21chromium-10nickel-
860 3manganese-2.5molybdenum stainless steel bar for surgical implants (UNS S31675)

861 ASTM F1713-08

862 Standard specification for wrought titanium-13niobium-13zirconium alloy for
863 surgical implant applications (UNS R58130)

864 ASTM F2026-16

865 Standard specification for polyetheretherketone (PEEK) polymers for surgical
866 implant applications

867 ASTM F2565-06

868 Standard guide for extensively irradiation-crosslinked ultra-high molecular weight
869 polyethylene fabricated forms for surgical implant applications

870 ASTM F2695-12 (R2020)

871 Standard specification for ultra-high molecular weight polyethylene powder blended
872 with alpha-tocopherol (vitamin E) and fabricated forms for surgical implant
873 applications

874 ASTM F2924-14 (R2021)

875 Standard specification for additive manufacturing Titanium-6 Aluminum-4 Vanadium
876 with powder bed fusion

877 ASTM F3001-14 (R2021)

878 Standard specification for additive manufacturing Titanium-6 Aluminum-4 Vanadium
879 ELI (extra low interstitial) with powder bed fusion

880 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

908 Standard specification for cobalt-28chromium-6molybdenum alloy forgings for
909 surgical implants (UNS R31537, R31538, R31539)

910 ASTM F899-12

911 Standard specification for wrought stainless steel for surgical instruments

912 ASTM F90-09

913 Standard specification for wrought cobalt-20chromium-15tungsten-10nickel alloy
914 for surgical implant applications (UNS R30605)

915 ASTM F961-08

916 Standard specification for 35cobalt-35nickel-20chromium-10molybdenum alloy
917 forgings for surgical implants (UNS R30035)

918 ISO 3826-1:2003-Ed.1.0

919 Plastic collapsible containers for human blood and blood components - Part 1:
920 Conventional containers

921 ISO 5832-1:2007-Ed.4.0

922 Implants for Surgery - Metallic materials - Part 1: Wrought stainless steel

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

924 ISO 5832-2:1999-Ed.3.0

925 Implants for surgery - Metallic materials - Part 2: Unalloyed titanium

926 ISO 5832-3:1996-Ed.3.0

927 Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-
928 vanadium alloy

929 ISO 5832-4:1996-Ed.2.0

930 Implants for surgery - Metallic materials - Part 4: Cobalt-chromium-molybdenum
931 casting alloy

932 ISO 5832-5:2005-Ed.3.0

933 Implants for surgery - Metallic materials - Part 5: Wrought cobalt-chromium-
934 tungsten-nickel alloy

935 ISO 5832-6:1997-Ed.2.0

936 Implants for surgery - Metallic materials - Part 6: Wrought cobalt-nickel-chromium-
937 molybdenum alloy

938 ISO 5832-9:2007-Ed.2.0

939 Implants for surgery - Metallic materials - Part 9: Wrought high nitrogen stainless
940 steel

941 ISO 5832-11:1994-Ed.1.0

942 Implants for surgery - Metallic materials - Part 11: Wrought titanium 6-aluminium 7-
943 niobium alloy

944 ISO 5832-12:2007-Ed.2.0

945 Implants for surgery - Metallic materials - Part 12: Wrought cobalt-chromium-
946 molybdenum alloy

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

948 ISO 5834-2:2011-Ed.4.0

949 Implants for surgery - Ultra-high molecular weight polyethylene - Part 2: Moulded
950 forms

951 ISO 6474-1:2010-Ed.1.0

952 Implants for surgery - Ceramic materials - Part 1: Ceramic materials based on high
953 purity alumina

954 ISO 6474-2:2012-Ed.1.0

955 Implants for surgery - Ceramic materials - Part 2: Composite materials based on a
956 highpurity alumina matrix with zirconia reinforcement

957 ISO 7153-1:1991-Ed.2.0

958 Surgical instruments - Metallic materials - Part 1: Stainless steel

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

960 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

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

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

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

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

ASTM F1044-05:2005/(R 2017)

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

ASTM F1147-05:2005/(R 2017)

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

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

ASTM F1801-20

Standard practice for corrosion fatigue testing of metallic implant materials

ASTM F1829-17

Standard Test Method for Static Evaluation of Anatomic Glenoid Locking Mechanism in Shear

ASTM F1875-98

Standard Practice for Fretting Corrosion Testing of Modular Implant Interfaces: Hip Femoral Head-Bore and Cone Taper Interface

ASTM F1875-98:2014/(R 2014)

ASTM F2028-14

Standard Test Methods for Dynamic Evaluation of Glenoid Loosening or Disassociation

ASTM F2077-18

Test Methods for Intervertebral Body Fusion Devices

ASTM F2083-21

Standard specification for knee replacement prosthesis

ASTM F2267-04

Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device under Static Axial Compression

ASTM F2267-04:2004/(R 2018)

ASTM F2346-18

Standard test methods for static and dynamic characterization of spinal artificial discs

ASTM F2582-20

Standard Test Method for Impingement of Acetabular Prostheses

ASTM F2665-09

Standard Specification for Total Ankle Replacement Prosthesis

ASTM F2665-09:2014/(R 2014)

ASTM F2943-14

Standard Guide for Presentation of End User Labeling Information for Musculoskeletal Implants

ASTM F3140-17

Standard test method for cyclic fatigue testing of metal tibial tray components of unicondylar knee joint replacements

ASTM F543-17

Standard Specification and Test Methods for Metallic Medical Bone Screws

ASTM F746-04

Standard test method for pitting or crevice corrosion of metallic surgical implant materials

ASTM F746-04:2004/(R 2014)

ASTM F86-21

Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants

ASTM F897-19

Standard test method for measuring fretting corrosion of osteosynthesis plates and screws

ASTM F983-86

Standard practice for permanent marking of orthopaedic implant components

ASTM F983-86:1986/(R 2013)

ISO 5838-1:2013-Ed.3.0

Implants for surgery - Metallic skeletal pins and wires Part 1: General requirements

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

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

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

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

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

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

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

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

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1227 Sterilization of health care products - Biological indicators - Part 3: Biological
1228 indicators for moist heat sterilization processes

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1230 Packaging for terminally sterilized medical devices - Part 1: Requirements for
1231 materials, sterile barrier systems and packaging systems

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1233 Packaging for terminally sterilized medical devices - Part 2: Validation requirements
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1236 Sterilization of medical devices - Microbiological methods - Part 1: Determination of
1237 population of microorganisms on products

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1241 medical devices utilizing animal tissues and their derivatives - Requirements for
1242 characterization, development, validation and routine control of a sterilization
1243 process for medical devices

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1245 Sterilization of health care products - General requirements for characterization of a
1246 sterilizing agent and the development, validation and routine control of a
1247 sterilization process for medical devices

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1249 Processing of health care products - Information to be provided by the medical
1250 device manufacturer for the processing of medical devices - Part 1: Critical and semi-
1251 critical medical devices

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1253 Processing of health care products - Information to be provided by the medical
1254 device manufacturer for the processing of medical devices - Part 2: Non-critical
1255 medical devices

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1257 Sterilization of health care products - Moist heat Part 1: Requirements for the
1258 development, validation and routine control of a sterilization process for medical
1259 devices