Health Canada Santé Canada

List of Recognized Standards for Medical Devices

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Canada

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Table of Contents

Changes to the List of Recognized Standards

Standards Added

ISO 5840-1:2015 Cardiovascular implants - Cardiovascular implants - Cardiac valve prostheses - Part 1: General requirements
ISO 5840-2:2015 Cardiovascular implants - Cardiac valve prostheses - Part 2: Cardiovascular implants - Surgically implanted heart valve substitutes
ISO 14708-6:2010 Implants for surgery - Active implantable medical devices - Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators)
ISO 14708-7:2013 Implants for surgery - Active implantable medical devices - Part 7: Particular requirements for cochlear implant systems
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 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
ASTM F1829-17 Standard Test Method for Static Evaluation of Anatomic Glenoid Locking Mechanism in Shear

ASTM F1875-98 (R2014) Standard Practice for Fretting Corrosion Testing of Modular Implant Interfaces: Hip Femoral Head-Bore and Cone Taper Interface
ASTM F2582-14 Standard Test Method for Impingement of Acetabular Prostheses
ASTM F2665-09 (R2014) Standard Specification for Total Ankle Replacement Prosthesis
ISO 14160:2011 Sterilization of health care products - Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives -- Requirements for characterization, development, validation and routine control of a sterilization
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
Standards Updated
ISO 7198:2016 Cardiovascular implants and extracorporeal systems - Vascular prostheses - Tubular vascular grafts and vascular patches
ISO 14708-1:2014 Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety, marking and for information to be provided by the manufacturer.
ISO 14708-3:2017 Active implantable medical devices -- Part 3: Implantable neurostimulators
IEC 62304:2015 Medical device software - Software life cycle processes
ISO 22442-1:2015 Ed.2 Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management

ISO 22442-2:2015 Ed.2 Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling
ISO 11979-2:2014 Ophthalmic implants -- Intraocular lenses -- Part 2: Optical properties and test methods
IEC 60601-1-3:2013 Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-2-37:2015 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC 60601-2-44:2016 Medical electrical equipment - Part 2-44:Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography
IEC 60601-2-54:2015 Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
ISO 11135:2014 Sterilization of health care products – Ethylene oxide – Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 11137-2:2013 Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose
Standards Removed
ISO 5840:2005 Cardiovascular implants - Cardiac valve prostheses
CAN/CSA C22.2 NO 60601-1-2-08:2008 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

CAN/CSA C22.2 NO 60601-1-08:2008 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
CAN/CSA Z900.1-12 :2012 Cells tissues, and organs for transplantation: General requirements
CAN/CSA-ISO 14971-07:2007 Medical devices – Application of risk management to medical devices
IEC 61010-1:2001-Ed.2.0 Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements IEC 61010-1/Cor.1:2002 IEC 61010-1/Cor.2:2003
IEC 61010-2-101:2002-Ed.1.0 Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
CAN/CSA Z11135-1-09:2009 Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for 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 7199:2009 Cardiovascular implants and artificial organs – Blood-gas exchangers (oxygenators)
ISO 8359:1996 Oxygen Concentrators for medical use - Safety requirements ISO 8359:1996/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 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process ISO 10993-1:2009/Cor.1:2010
ISO 10993-2:2006 Biological evaluation of medical devices – Part 2: Animal welfare requirements
ISO 10993-3:2003 Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
ISO 10993-4:2002 Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood ISO 10993-4:2002/Amd.1:2006
ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
ISO 10993-6:2007 Biological evaluation of medical devices – Part 6: Tests for local effects after implantation
ISO 10993-7:2008 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals ISO 10993-7:2008/Cor.1:2009

ISO 10993-9:2009 Biological evaluation of medical devices – Part 9: Framework for identification and quantification of potential degradation products
ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
ISO 10993-11:2006 Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
ISO 10993-12:2007 Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
ISO 10993-13:2010 Biological evaluation of medical devices – Part 13: Identification and quantification of degradation products from polymeric medical devices
ISO 10993-14:2001 Biological evaluation of medical devices – Part 14: Identification and quantification of degradation products from ceramics
ISO 10993-15:2000 Biological evaluation of medical devices – Part 15: Identification and quantification of degradation products from metals and alloys
ISO 10993-16:2010 Biological evaluation of medical devices – Part 16: Toxicokinetic study design for degradation products and leachables
ISO 10993-17:2002 Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances
ISO 10993-18:2005 Biological evaluation of medical devices – Part 18: Chemical characterization of materials

Cardiovascular
ISO 5840-1:2015 Cardiovascular implants - Cardiovascular implants - Cardiac valve prostheses - Part 1: General requirements
ISO 5840-2:2015 Cardiovascular implants - Cardiac valve prostheses - Part 2: Cardiovascular implants - Surgically implanted heart valve substitutes
ISO 5840-3:2013 Cardiovascular implants — Cardiac valve prostheses — Part 3: Heart valve substitutes implanted by transcatheter techniques
ISO 5841-3:2013 Implants for surgery - Cardiac pacemakers - Part 3: Low-profile connectors (IS-1) for implantable pacemakers
ISO 7198:2016 Cardiovascular implants and extracorporeal systems - Vascular prostheses - Tubular vascular grafts and vascular patches
ISO 10555-1:2013 Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements
ISO 10555-3:2013 Intravascular catheters - Sterile and single-use catheters - Part 3: Central venous catheters
ISO 10555-4:2013 Intravascular catheters - Sterile and single-use catheters - Part 4: Balloon dilatation catheters
ISO 10555-5:2013 Intravascular catheters - Sterile and single-use catheters - Part 5: Over-needle peripheral catheters
ISO 11318:2002 Cardiac defibrillators – Connector assembly DF-1 for implantable defibrillators - Dimensions and test requirements

ISO 14117:2012-Ed.1.0 Active implantable medical devices - Electromagnetic compatibility - EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices
ISO 14708-2:2012 Implants for surgery – Active implantable medical devices – Part 2: Cardiac pacemakers
ISO 14708-5:2010 Implants for surgery – Active implantable medical devices – Part 5: Circulatory support devices
ISO 14708-6:2010 Implants for surgery - Active implantable medical devices - Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators)
ISO 25539-1:2003 Cardiovascular implants – Endovascular devices – Part 1: Endovascular prostheses ISO 25539-1:2003/Amd.1:2005
ISO 27186:2010 Active implantable medical devices – Four-pole connector system for implantable cardiac rhythm management devices – Dimensional and test requirements
Contraception
ISO 4074:2002 Natural latex rubber condoms – Requirements and test methods ISO 4074:2002/Cor.1:2003 ISO 4074:2002/Cor.2:2008
Dental
ISO 3107:2011 Dentistry – Zinc oxide/eugenol and zinc oxide/non-eugenol cements
ISO 4049:2009 Dentistry – Polymer-based restorative materials

ISO 6872:2008 Dentistry – Ceramic materials
ISO 6874:2005 Dentistry – Polymer-based pit and fissure sealants
ISO 6876:2012 Dental root canal sealing materials
ISO 6877:2006 Dentistry – Root-canal obturating points
ISO 7405:2008 Dentistry – Evaluation of biocompatibility of medical devices used in dentistry
ISO 9693:1999 Metal-ceramic dental restorative systems ISO 9693:1999/Amd.1:2005
ISO 9693-1:2012 Dentistry – Compatibility testing – Part 1: Metal-ceramic systems
ISO 9917-1:2007 Dentistry – Water-based cements – Part 1: Powder/liquid acid-base cements
ISO 9917-2:2010 Dentistry - Water-based cements – Part 2: Resin-modified cements
ISO 10271:2011 Dental metallic materials – Corrosion test methods for metallic materials
ISO 14801:2007 Dentistry — Implants — Dynamic fatigue test for endosseous dental implants
ISO 22674:2006 Dentistry – Metallic materials for fixed and removable restorations and appliances
ISO 22794:2007 Dentistry – Implantable materials for bone filling and augmentation in oral and maxillofacial surgery – Contents of a technical file

ISO 22803:2004 Dentistry – Membrane materials for guided tissue regeneration in oral and maxillofacial surgery – Contents of a technical file
ISO 24234:2004 Dentistry – Mercury and alloys for dental amalgam
ISO/TS 11405:2003 Dental materials – Testing of adhesion to tooth structure
Electromedical
CAN/CSA C22.2 NO 60601-1-14:2014 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 60601-1-2:2007-Ed.3.0 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
IEC 60601-1-2:2014-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 60601-2-2:2009-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 60601-2-10:2012-Ed.2.0 Medical electrical equipment – Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
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 60601-2-22:2007-Ed.3.0 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 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 60601-2-47:2012-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 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 Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety, marking and for information to be provided by the manufacturer.
ISO 14708-3:2017 Active implantable medical devices -- Part 3: Implantable neurostimulators

ISO 14708-7:2013 Implants for surgery - Active implantable medical devices - Part 7: Particular requirements for cochlear implant systems
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 (2004) Standard test method for detecting seal leaks in porous medical packaging by dye penetration
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 Medical device software - Software life cycle processes
IEC 62366:2014 - Ed. 1.1 Medical devices – Application of usability engineering to medical devices
ISO 10282:2002 Single-Use Sterile Surgical Rubber Gloves - Specification
ISO 11193-1:2008 Single-use medical examination gloves – Part 1: Specification for gloves made from rubber latex or rubber solution ISO 11193-1:2008/Amd.1:2012
ISO 11663:2009 Quality of dialysis fluid for haemodialysis and related therapies

ISO 13959:2009 Water for haemodialysis and related therapies
ISO 14155:2011 Clinical investigation of medical devices for human subjects – Good clinical practice ISO 14155:2011/Cor.1:2011
ISO 14708-3:2008 Implants for Surgery - Active implantable medical devices - Part 3: Implantable neurostimulators
ISO 14971:2007 Medical devices – Application of risk management to medical devices
ISO 22442-1:2015 Ed.2 Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management
ISO 22442-2:2015 Ed.2 Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling
ISO 22442-3:2007 Medical devices utilizing animal tissues and their derivatives – Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents
ISO 26722:2009 Water treatment equipment for haemodialysis applications and related therapies
SAI AS 2869:2008 Tampons – Menstrual
In Vitro Diagnostic
CLSI C46-A2:2009 Blood gas and pH analysis and related measurements; Approved guideline
CLSI EP12-A2:2008 User protocol for evaluation of qualitative test performance; Approved guideline

CLSI EP14-A3:2014 Evaluation of Commutability of Processed Samples; Approved guideline
CLSI EP17-A2:2012 Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved guideline
CLSI EP24-A2:2012 Assessment of the Diagnostic Accuracy of Laboratory Tests Using Receiver Operating Characteristic Curves; Approved Guideline – Second Edition
CLSI EP25-A:2009 Evaluation of stability of in vitro diagnostic reagents; Approved guideline (Except: Section 7.1.3)
CLSI EP28-A3C:2010 Defining, establishing, and verifying reference intervals in the clinical laboratory; Approved guideline
CLSI EP5-A3:2014 Evaluation of precision of quantitative measurement procedures; Approved guideline
CLSI EP6-A:2003 Evaluation of the linearity of quantitative measurement procedures: A statistical approach; Approved guideline
CLSI EP7-A2:2005 Interference testing in clinical chemistry; Approved guideline
CLSI H15-A3:2000 Reference and selected procedures for the quantitative determination of hemoglobin in blood; Approved standard
CLSI H20-A2:2007 Reference leukocyte (WBC) differential count (proportional) and evaluation of instrumental methods; Approved standard
CLSI I/LA18-A2:2001 Specifications for immunological testing for infectious diseases; Approved guideline

CLSI I/LA21-A2:2008 Clinical evaluation of immunoassays; Approved guideline
CLSI MM01-A3:2012 Molecular Methods for Clinical Genetics and Oncology Testing; Approved Guideline
CLSI MM06-A2:2010 Quantitative Molecular Methods for Infectious Diseases
CLSI MM12-A:2006 Diagnostic nucleic acid microarrays; Approved guideline
CLSI MM13-A:2006 Collection, transport, preparation, and storage of specimens for molecular methods; Approved guideline (Except: Section 6.1.1)
CLSI MM16-A:2006 Use of external RNA controls in gene expression assays; Approved guideline
CLSI MM17-A:2008 Verification and validation of multiplex nucleic acid assays; Approved guideline
CLSI POCT14-A:2004 Point-of-care monitoring of anticoagulation therapy; Approved guideline
IEC 61010-1:2010-Ed.3.0 Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements IEC 61010-1:2010-Ed.3.0/Cor.1:2011 IEC 61010-1:2010-Ed.3.0/Cor.2:2013 French Only/Seulement 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 In vitro diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus
ISO 23640:2011 In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents
Manufacturing
ISO 13408-1:2008 Aseptic processing of health care products - Part 1 : General requirements
ISO 13408-2:2003 Aseptic processing of health care products - Part 2 : Filtration
ISO 13408-3:2006 Aseptic processing of health care products - Part 3 : Lyophilization
ISO 13408-4:2005 Aseptic processing of health care products - Part 4 : Clean-in-place technologies
ISO 13408-5:2006 Aseptic processing of health care products - Part 5 : Sterilization in place
ISO 13408-6:2005 Aseptic processing of health care products - Part 6 : Isolator systems
ISO 13408-7:2012 Aseptic processing of health care products - Part 7 : Alternative processes for medical devices and combination products
ISO 14644-1:1999 Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness
ISO 14644-2:2000 Cleanrooms and associated controlled environments - Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1

ISO 14644-3:2005 Cleanrooms and associated controlled environments - Part 3: Test methods
ISO 14644-4:2001 Cleanrooms and associated controlled environments - Part 4: Design, Construction and Start Up
ISO 14644-5:2004 Cleanrooms and associated controlled environments - Part 5: Operations
ISO 14644-6:2007 Cleanrooms and associated controlled environments - Part 6: Vocabulary
ISO 14644-7:2004 Cleanrooms and associated controlled environments - Part 7: Separative devices (clean air hoods, glove boxes, isolators and mini-environments)
ISO 14644-8:2012 Cleanrooms and associated controlled environments - Part 8: Classification of air cleanliness by chemical concentration (ACC)
ISO 14644-9:2012 Cleanrooms and associated controlled environments - Part 9: Classification of surface cleanliness by particle concentration
ISO 14644-10:2013 Cleanrooms and associated controlled environments - Part 10: Classification of surface cleanliness by chemical concentration
ISO 14698-1:2003 Cleanrooms and associated controlled environments - Biocontamination control - Part 1: General principles and methods
ISO 14698-2:2003 Cleanrooms and associated controlled environments - Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data
Materials
ASTM F1088-04a (R2010) Standard specification for beta-tricalcium phosphate for surgical implantations

ASTM F1091-08 Standard specification for wrought cobalt-20chromium-15tungsten-10nickel alloy surgical fixation wire (UNS R30605)
ASTM F1108-04 (R2009) Standard specification for titanium-6aluminum-4vanadium alloy castings for surgical implants (UNS R56406)
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 F2565-06 Standard guide for extensively irradiation-crosslinked ultra-high molecular weight polyethylene fabricated forms for surgical implant applications
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 F648-07e1 Standard specification for ultra-high-molecular weight polyethylene powder and fabricated form for surgical implants
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 Plastic collapsible containers for human blood and blood components – Part 1: Conventional containers
ISO 5832-1:2007 Implants for Surgery – Metallic materials – Part 1: Wrought stainless steel ISO 5832-1:2007/Corr1:2008
ISO 5832-2:1999 Implants for surgery – Metallic materials – Part 2: Unalloyed titanium
ISO 5832-3:1996 Implants for surgery – Metallic materials – Part 3: Wrought titanium 6-aluminium 4-vanadium alloy
ISO 5832-4:1996 Implants for surgery – Metallic materials – Part 4: Cobalt-chromium-molybdenum casting alloy
ISO 5832-5:2005 Implants for surgery – Metallic materials – Part 5: Wrought cobalt-chromium-tungsten-nickel alloy

ISO 5832-6:1997 Implants for surgery – Metallic materials – Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy
ISO 5832-9:2007 Implants for surgery – Metallic materials – Part 9: Wrought high nitrogen stainless steel
ISO 5832-11:1994 Implants for surgery – Metallic materials – Part 11: Wrought titanium 6-aluminium 7-niobium alloy
ISO 5832-12:2007 Implants for surgery – Metallic materials – Part 12: Wrought cobalt-chromium-molybdenum alloy ISO 5832-12:2007/Cor.1:2008
ISO 5834-2:2011 Implants for surgery – Ultra-high molecular weight polyethylene – Part 2: Moulded forms
ISO 6474-1:2010 Implants for surgery – Ceramic materials – Part 1: Ceramic materials based on high purity alumina
ISO 6474-2:2012 Implants for surgery - Ceramic materials - Part 2: Composite materials based on a highpurity alumina matrix with zirconia reinforcement
ISO 7153-1:1991 Surgical instruments – Metallic materials – Part 1: Stainless steel ISO 7153-1:1991/Amd.1:1999
ISO 13402:1995 Surgical and dental hand instruments – Determination of resistance against autoclaving, corrosion and thermal exposure
ISO 13782:1996 Implants for surgery – Metallic materials – Unalloyed tantalum for surgical implant applications

Ophthalmology
ANSI Z80.7:2002 Ophthalmic optics – Intraocular lenses
ISO 11979-1:2006 Ophthalmic implants – Intraocular lenses – Part 1: Vocabulary
ISO 11979-2:2014 Ophthalmic implants -- Intraocular lenses -- Part 2: Optical properties and test methods
ISO 11979-3:2006 Ophthalmic implants – Intraocular lenses – Part 3: Mechanical properties and test methods
ISO 11979-5:2006 Ophthalmic implants – Intraocular lenses – Part 5: Biocompatibility
ISO 11979-6:2007 Ophthalmic implants – Intraocular lenses – Part 6: Shelf-life and transport stability
ISO 11979-7:2006 Ophthalmic implants – Intraocular lenses – Part 7: Clinical investigations ISO 11979-7:2006/Amd.1:2012
ISO 11979-8:2006 Ophthalmic implants – Intraocular lenses – Part 8: Fundamental requirements ISO 11979-8:2006/Amd.1:2011
ISO 11980:2009 Ophthalmic optics – Contact lenses and contact lens care products – Guidance for clinical investigations
ISO 15004-2:2007 Ophthalmic instruments – Fundamental requirements and test methods – Part 2: Light hazard protection
ISO 18369-1:2006 Ophthalmic optics – Contact lenses – Part 1: Vocabulary, classification system and recommendations for labelling specifications ISO 18369-1:2006/Amd.1:2009

ISO 18369-2:2006 Ophthalmic optics – Contact lenses – Part 2: Tolerances
ISO 18369-3:2006 Ophthalmic optics – Contact lenses – Part 3: Measurement methods
ISO 18369-4:2006 Ophthalmic optics – Contact lenses – Part 4: Physicochemical properties of contact lens materials
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 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 F1160-14 Standard test method for shear and bending fatigue testing of calcium phosphate and metallic medical and composite calcium phosphate/metallic coatings
ASTM F1377-13 Standard specification for cobalt-28chromium-6molybdenum powder for coating of orthopedic Implants (UNS R30075)
ASTM F1609-08 (2014) Standard Specification for calcium phosphate coatings for implantable materials
ASTM F1717-14 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 F1801-97 (2004) 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 (R2014) Standard Practice for Fretting Corrosion Testing of Modular Implant Interfaces: Hip Femoral Head-Bore and Cone Taper Interface
ASTM F2028-14 Standard Test Methods for Dynamic Evaluation of Glenoid Loosening or Disassociation
ASTM F2077-11 Test Methods For Intervertebral Body Fusion Devices
ASTM F2267-04 (2011) Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression
ASTM F2582-14 Standard Test Method for Impingement of Acetabular Prostheses
ASTM F2665-09 (R2014) Standard Specification for Total Ankle Replacement Prosthesis
ASTM F2943-14 Standard Guide for Presentation of End User Labeling Information for Musculoskeletal Implants
ASTM F746-04 (2014) Standard test method for pitting or crevice corrosion of metallic surgical implant materials

ASTM F86-13 Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants
ASTM F897-02 (2013) Standard test method for measuring fretting corrosion of osteosynthesis plates and screws
ASTM F983-86 (2013) Standard practice for permanent marking of orthopaedic implant components
ISO 5838-1:2013 Implants for surgery - Metallic skeletal pins and wires Part 1: General requirements
ISO 5838-2:1991 Implants for surgery – Skeletal pins and wires – Part 2: Steinmann skeletal pins – Dimensions
ISO 5838-3:1993 Implants for surgery – Skeletal pins and wires – Part 3: Kirschner skeletal wires
ISO 7153-1:1991 Surgical instruments – Metallic materials – Part 1: Stainless steel ISO 7153-1:1991/Amd.1:1999
ISO 7206-4:2010 Implants for surgery partial and total hip joint prostheses – Part 4: Determination of endurance properties and performance of stemmed femoral components
ISO 7206-6:2013 Implants for surgery - Partial and total hip joint prostheses - Part 6: Endurance properties testing and performance requirements of neck region of stemmed femoral components
ISO 9583:1993 Implants for surgery – Non-destructive testing – Liquid penetrant inspection of metallic surgical implants
ISO 14242-1:2012 Implants for surgery — Wear of total hip-joint prostheses — Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test

ISO 14242-2:2000 Implants for Surgery - Wear of total hip-joint prostheses - Part 2: Methods of measurement
ISO 14243-1:2009 Implants for surgery - Wear of total knee-joint prostheses - Part 1: Loading and displacement parameters for wear-testing machines with load control and corresponding environmental conditions for test
ISO 14243-2:2009 Implants for surgery - Wear of total knee-joint prostheses - Part 2: Methods of measurement
ISO 14243-3:2004 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 Non-active surgical implants - General requirements
Radiology
AIUM/NEMA UD 2:2004 (R2009) Acoustic output measurement standard for diagnostic ultrasound equipment
AIUM/NEMA UD 3:2004 Standard for real-time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment
IEC 60601-1-3:2013 Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-2-28:2010-Ed.2.0 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 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

IEC 60601-2-43:2010-Ed.2.0 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 Medical electrical equipment - Part 2-44:Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography
IEC 60601-2-54:2015 Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
Sterilization
ASTM F1980-07 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
CAN/CSA Z17665-1-09:2009:2009 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 Sterilization of health care products – Ethylene oxide – Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 11137-1:2006 Sterilization of health care products – Radiation – Part 1: Requirement for development, validation and routine control of a sterilization process for medical devices
ISO 11137-2:2013 Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose
ISO 11137-3:2006 Sterilization of health care products – Radiation – Part 3: Guidance on dosimetric aspects
ISO 11138-1:2006 Sterilization of health care products – Biological indicators – Part 1: General
ISO 11138-2:2006 Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes

ISO 11138-3:2006 Sterilization of health care products – Biological indicators – Part 3: Biological indicators for moist heat sterilization processes
ISO 11607-1:2006 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2:2006 Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
ISO 11737-1:2006 Sterilization of medical devices – Microbiological methods – Part 1: Determination of population of microorganisms on products ISO 11737-1:2006/Cor.1:2007
ISO 14160:2011 Sterilization of health care products - Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives -- Requirements for characterization, development, validation and routine control of a sterilization
ISO 14937:2009 Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
ISO 17664:2004 Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices
ISO 17665-1:2006 Sterilization of health care products – Moist heat Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices