



List of Recognized Standards



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TABLE OF CONTENTS

Anaesthetic and Respiratory [1](#)

Biocompatibility [1](#)

Cardiovascular [3](#)

Contraceptive Devices [4](#)

Dental [4](#)

Electromedical [6](#)

General Hospital [8](#)

In Vitro devices [9](#)

Material Standard [9](#)

Ophthalmology [12](#)

Orthopaedics [13](#)

Radiology [15](#)

Sterilization [16](#)

Anaesthetic and Respiratory
CAN/CSA-Z168.5.1-97 (R2001) Anaesthesia Ventilators
ISO 11196:1995 Anaesthetic gas monitors
ISO 11196:1995/Cor 1:1997
CSA 11196-98 (R2003) Anaesthetic Gas Monitors
ISO 7199:1996 Cardiovascular implants and artificial organs -- Blood-gas exchangers (oxygenators)
ISO 9919:2005 Medical electrical equipment -- Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use
CSA Z9919-94 (R2004) Pulse Oximeters for Medical Use - Requirements
Biocompatibility
ISO 10993-10:2002 Biological evaluation of medical devices -- Part 10: Tests for irritation and delayed-type hypersensitivity
CSA 10993-10- 98 (R2003) Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Sensitization
ISO 10993-11:1993 Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity
CSA 10993.11- 98 (R2002) Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity

ISO 10993-13:1998 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 10993-16:1997 Biological evaluation of medical devices -- Part 16: Toxicokinetic study design for degradation products and leachables
ISO 10993-4:2002 Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood
CSA 10993.4- 97 (R2001) Biological Evaluation of Medical Devices - Part 4: Selection of Tests for Interactions With Blood
ISO 10993-5:1999 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
CSA 10993-5- 01 Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity
ISO 10993-6:1994 Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation
CSA 10993.6- 97 (R2001) Biological Evaluation of Medical Devices - Part 6: Tests for Local Effects After Implantation
ISO 10993-7:1995 Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals
CSA 10993.7- 98 (R2002) Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals
ISO 10993-9:1999 Biological evaluation of medical devices -- Part 9: Framework for identification and quantification of potential degradation products

ISO 10993-1:2003 Biological evaluation of medical devices -- Part 1: Evaluation and testing
CSA 10993-1- 01 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing
ISO 10993-2:1992 Biological evaluation of medical devices -- Part 2: Animal welfare requirements
CSA 10993.2- 97 (R2001) 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
CSA 10993.3- 97 (R2001) Biological Evaluation of Medical Devices - Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity
ISO 10993-12:2002 Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials
CSA 10993.12- 98 (R2002) Biological Evaluation of Medical Devices - Part 12: Sample Preparation and Reference Materials
ISO 10993-17:2002 Biological evaluation of medical devices -- Part 17: Establishment of allowable limits for leachable substances
Cardiovascular
ISO 11318:2002 Cardiac defibrillators -- Connector assembly DF-1 for implantable defibrillators -- Dimensions and test requirements
ISO 14708-1:2000 Implants for surgery -- Active implantable medical devices -- Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
ISO 5840:2005 Cardiovascular implants -- Cardiac valve prostheses

CSA 5840-98 (R2002) Cardiovascular Implants - Cardiac Valve Prostheses
ISO 5841-3:2000 Implants for surgery -- Cardiac pacemakers -- Part 3: Low-profile connectors (IS-1) for implantable pacemakers ISO 5841-3:2000/Cor 1:2003
CSA 5841-3-01 Implants for Surgery - Cardiac Pacemakers - Part 3: Low-Profile Connectors (IS-1) for Implantable Pacemakers
IEC 60601-2-25 - Ed. 1.0 : 1993-03-19 Medical electrical equipment - Part 2: Particular requirements for the safety of electrocardiographs IEC 60601-2-25-am1 - Ed. 1.0 : 1999-05-07
Contraceptive Devices
ISO 4074:2002 Natural latex rubber condoms -- Requirements and test methods
Dental
ISO 10271:2001 Dental metallic materials -- Corrosion test methods ISO 10271:2001/Cor 1:2005
ISO 4049:2000 Dentistry -- Polymer-based filling, restorative and luting materials
ISO 6871-1:1994 Dental base metal casting alloys -- Part 1: Cobalt-based alloys ISO 6871-1:1994/Cor 1:1998 ISO 6871-1:1994/Amd 1:2005

ISO 6871-2:1994 Dental base metal casting alloys -- Part 2: Nickel-based alloys ISO 6871-2:1994/Amd 1:2005
ISO 6872:1995 Dental ceramic ISO 6872:1995/Amd 1:1997
ISO 6876:2001 Dental root canal sealing materials
ISO 7405:1997 Dentistry -- Preclinical evaluation of biocompatibility of medical devices used in dentistry -- Test methods for dental materials
ISO 8891:1998 Dental casting alloys with noble metal content of at least 25 % but less than 75 %
ISO 9693:1999 Metal-ceramic dental restorative systems ISO 9693:1999/Amd 1:2005
ISO 9917-2:1998 Dental water-based cements -- Part 2: Light-activated cements
ISO 3107:2004 Dentistry -- Zinc oxide/eugenol and zinc oxide/non-eugenol cements ISO 3107:2004/Cor 1:2006
ISO 6874:2005 Dentistry -- Polymer-based pit and fissure sealants
ISO 6877:2006 Dentistry -- Root-canal obturating points
ISO 9917-1:2003 Dentistry -- Water-based cements -- Part 1: Powder/liquid acid-base cements
ISO 24234:2004 Dentistry -- Mercury and alloys for dental amalgam

Electromedical
IEC 60601-1 - Ed. 3.0 : 2005-12-15 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-4 - Consol. Ed. 1.1 (incl. am1) : 2000-04-07 Medical electrical equipment - Part 1-4: General requirements for safety - Collateral Standard: Programmable electrical medical systems
IEC 60601-2-10 - Ed. 1.0 : 1987-12-30 Medical electrical equipment. Part 2: Particular requirements for the safety of nerve and muscle stimulators IEC 60601-2-10-am1 - Ed. 1.0 : 2001-09-26
IEC 60601-2-2 - Ed. 3.0 : 1998-09-23 Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment
IEC 60601-2-23 - Ed. 2.0 : 1999-12-10 Medical electrical equipment - Part 2-23: Particular requirements for the safety, including essential performance, of transcutaneous partial pressure monitoring equipment
IEC 60601-2-27 - Ed. 2.0 : 2005-08-29 Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment
IEC 60601-2-30 - Ed. 2.0 : 1999-12-22 Medical electrical equipment - Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment
IEC 60601-2-31 - Ed. 1.0 : 1994-10-12 Medical electrical equipment - Part 2: Particular requirements for the safety of external cardiac pacemakers with internal power source IEC 60601-2-31-am1 - Ed. 1.0 : 1998-01-30
IEC 60601-2-4 - Ed. 2.0 : 2002-08 Medical electrical equipment - Part 2-4: Particular requirements for the safety of cardiac defibrillators

IEC 60601-2-5 - Ed. 2.0 : 2000-07-13 Medical electrical equipment - Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment
ANSI/AAMI DF80:2003 Medical electrical equipment, Part 2: Particular requirements for the safety of cardiac defibrillators [including automated external defibrillators]
ANSI/AAMI PC69:2000 Active implantable medical devices - Electromagnetic compatibility - EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators
IEC 60529 - Consol. Ed. 2.1 (incl. am1) : 2001-02-27 Degrees of protection provided by enclosures (IP Code)
IEC 60601-1-8 Ed. 1.0 : 2003-08 Medical electrical equipment - Part 1-8: General requirements for safety - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems IEC 60601-1-8-Am1 Ed. 1.0 : 2006-03
IEC 60601-2-18 - Ed. 2.0 : 1996-08-07 Medical electrical equipment - Part 2: Particular requirements for the safety of endoscopic equipment IEC 60601-2-18-am1 - Ed. 2.0 : 2000-07-13
IEC 60601-2-24 - Ed. 1.0 : 1998-02-19 Medical electrical equipment - Part 2-24: Particular requirements for the safety of infusion pumps and controllers
IEC 60601-2-26 - Ed. 2.0 : 2002-11 Medical electrical equipment - Part 2-26: Particular requirements for the safety of electroencephalographs
IEC 60601-2-33 - Ed. 2.0 : 2002-05-22 Medical electrical equipment - Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis IEC 60601-2-33-am1 - Ed. 2.0 : 2005-08-30
IEC 60601-2-34 - Ed. 2.0 : 2000-10 Medical electrical equipment - Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment

IEC 60601-2-49 - Ed. 1.0 : 2001-07-24 Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment
IEC 60601-2-51 - Ed. 1.0 : 2003-02-27 Medical electrical equipment - Part 2-51: Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs
IEC 60601-2-47 - Ed. 1.0 : 2001-07-10 Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
General Hospital
ASTM F1585-00 Standard Guide for Integrity Testing of Porous Barrier Medical Packages
ASTM F1929-98(2004) Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
IEC 60601-2-38 - Ed. 1.0 : 1996-10-30 Medical electrical equipment - Part 2: Particular requirements for the safety of electrically operated hospital beds
IEC 60601-2-38-am1 - Ed. 1.0 : 1999-12-17
ISO 11193-1:2002 Single-use medical examination gloves -- Part 1: Specification for gloves made from rubber latex or rubber solution
ISO 11193-1:2002/Cor 1:2005
ISO 14971:2000 Medical devices -- Application of risk management to medical devices
ISO 14971:2000/Amd 1:2003
CAN/CSA-ISO 14971-01 Medical Devices - Application of Risk Management to Medical Devices
CAN/CSA-ISO 14971A-01 (2003)

<i>In Vitro</i> devices
CLSI EP05-A2 : 2004-08-20 Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second Edition
CLSI H15-A3 : 2000-12-01 Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard - Third Edition
CLSI H20-A : 1992-03-01 Reference Leukocyte Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard
CLSI EP12-A : 2002-08-20 User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline
IEC 61010-1: 2001-02-01 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements-Second Edition; Corrigendum 1:05/2002; Corrigendum 2:04/2003
IEC 61010-2-101: 2002-01-01 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use Part 2-101: Particular Requirements for in Vitro Diagnostic (IVD) Medical Equipment-First Edition
IEC 61326-1: 2005-12-01 Electrical equipment for measurement, control and laboratory use EMC requirements Part 1: General requirements-Edition 1.0
Material Standard
ASTM F1091-02 Standard Specification for Wrought Cobalt-20 Chromium-15 Tungsten-10 Nickel Alloy Surgical Fixation Wire (UNS R30605)
ASTM F1295-05 Standard Specification for Wrought Titanium-6 Aluminum-7 Niobium Alloy for Surgical Implant Applications (UNS R56700)

ASTM F1314-01 Standard Specification for Wrought Nitrogen Strengthened 22 Chromium - 13 Nickel - 5 Manganese - 2.5 Molybdenum Stainless Steel Alloy Bar and Wire for Surgical Implants (UNS S20910)
ASTM F1341-99 Standard Specification for Unalloyed Titanium Wire UNS R50250, UNS R50400, UNS R50550, UNS R50700, for Surgical Implant Applications
ASTM F1350-02 Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Surgical Fixation Wire (UNS S31673)
ASTM F1537-00 Standard Specification for Wrought Cobalt-28-Chromium-6-Molybdenum Alloy for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)
ASTM F1580-01 Standard Specification for Titanium and Titanium-6 Aluminum-4 Vanadium Alloy Powders for Coatings of Surgical Implants
ASTM F1586-02 Standard Specification for Wrought Nitrogen Strengthened 21 Chromium—10 Nickel—3 Manganese—2.5 Molybdenum Stainless Steel Bar for Surgical Implants (UNS S31675)
ASTM F562-02 Standard Specification for Wrought 35Cobalt-35Nickel-20Chromium-10Molybdenum Alloy for Surgical Implant Applications (UNS R30035)
ASTM F603-00 Standard Specification for High-Purity Dense Aluminum Oxide for Surgical Implant Application
ASTM F620-00 Standard Specification for Alpha Plus Beta Titanium Alloy Forgings for Surgical Implants
ASTM F621-02 Standard Specification for Stainless Steel Forgings for Surgical Implants
ASTM F67-00 Standard Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)

<p>ASTM F688-05 Standard Specification for Wrought Cobalt-35Nickel-20Chromium-10Molybdenum Alloy Plate, Sheet, and Foil for Surgical Implants (UNS R30035)</p>
<p>ASTM F745-00 Standard Specification for 18 Chromium-12.5 Nickel-2.5 Molybdenum Stainless Steel for Cast and Solution-Annealed Surgical Implant Applications</p>
<p>ASTM F75-01 Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)</p>
<p>ASTM F799-02 Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539)</p>
<p>ASTM F899-02 Standard Specification for Stainless Steel for Surgical Instruments</p>
<p>ASTM F90-01 Standard Specification for Wrought Cobalt-20 Chromium-15 Tungsten-10 Nickel Alloy for Surgical Implant Applications (UNS R30605)</p>
<p>ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion and thermal exposure</p>
<p>ISO 13782:1996 Implants for surgery -- Metallic materials -- Unalloyed tantalum for surgical implant applications</p>
<p>ISO 5832-11:1994 Implants for surgery -- Metallic materials -- Part 11: Wrought titanium 6-aluminium 7-niobium alloy</p>
<p>ISO 5832-12:1996 Implants for surgery -- Metallic materials -- Part 12: Wrought cobalt-chromium-molybdenum alloy</p>
<p>ISO 5832-3:1996 Implants for surgery -- Metallic materials -- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy</p>
<p>ISO 5832-4:1996 Implants for surgery -- Metallic materials -- Part 4: Cobalt-chromium-molybdenum casting alloy</p>

ISO 5832-5:1993 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 5832-9:1992 Implants for surgery -- Metallic materials -- Part 9: Wrought high nitrogen stainless steel
ISO 5834-2:1998 Implants for surgery -- Ultra-high molecular weight polyethylene -- Part 2: Moulded forms
ISO 6474:1994 Implants for surgery -- Ceramic materials based on high purity alumina
ISO 7153-1:1991 Surgical instruments -- Metallic materials -- Part 1: Stainless steel
ISO 7153-1:1991/Amd 1:1999
CAN/CSA-Z900.1-03: 2003-01-01 Cells, Tissues, and Organs for Transplantation and Assisted Reproduction: General Requirements
Ophthalmology
ISO 10338:1996 Optics and optical instruments -- Contact lenses -- Determination of curvature
ISO 10340:1995 Optics and optical instruments -- Contact lenses -- Method for determining the extractable substances
ISO 10344:1996 Optics and optical instruments -- Contact lenses -- Saline solution for contact lens testing
ISO 11979-2:1999 Ophthalmic implants -- Intraocular lenses -- Part 2: Optical properties and test methods
ISO 11979-2:1999/Cor 1:2003

ISO 11979-3:1999 Ophthalmic implants -- Intraocular lenses -- Part 3: Mechanical properties and test methods
ISO 11979-5:1999 Ophthalmic implants -- Intraocular lenses -- Part 5: Biocompatibility
ISO 11979-7:2006 Ophthalmic implants -- Intraocular lenses -- Part 7: Clinical Investigations
ISO 11980:1997 Ophthalmic optics -- Contact lenses and contact lens care products -- Guidance for clinical investigations
ISO 11980:1997/Cor 1:1998
ISO 9339-1:1996 Optics and optical instruments -- Contact lenses -- Determination of the thickness -- Part 1: Rigid contact lenses
ISO 9340:1996 Optics and optical instruments -- Contact lenses -- Determination of strains for rigid contact lenses
ISO 9341:1996 Optics and optical instruments -- Contact lenses -- Determination of inclusions and surface imperfections for rigid contact lenses
ISO 9913-1:1996 Optics and optical instruments -- Contact lenses -- Part 1: Determination of oxygen permeability and transmissibility with the FATT method
Orthopaedics
ASTM F1044-05 Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings
ASTM F1147-05 Standard Test Method for Tension Testing of Calcium Phosphate and Metal Coatings

ASTM F1160-05 Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings
ASTM F1377-04 Standard Specification for Cobalt-28Chromium-6Molybdenum Powder for Coating of Orthopedic Implants (UNS R30075)
ASTM F1612-95(2000) Standard Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components with Torsion
ASTM F1659-95 Standard Test Method for Bending and Shear Fatigue Testing of Calcium Phosphate Coatings on Solid Metallic Substrates
ASTM F1798-97(2003) Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants
ASTM F1801-97 (2004) Standard Practice for Corrosion Fatigue Testing of Metallic Implant Materials
ASTM F746-04 Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials
ASTM F86-04 Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants
ASTM F983-86(2005) Standard Practice for Permanent Marking of Orthopaedic Implant Components
ISO 14630:2005 Non-active surgical implants -- General requirements
ISO 5832-1:1997 Implants for surgery -- Metallic materials -- Part 1: Wrought stainless steel
ISO 5832-2:1999 Implants for surgery -- Metallic materials -- Part 2: Unalloyed titanium

ISO 5838-1:1995 Implants for surgery -- Skeletal pins and wires -- Part 1: Material and mechanical 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 7206-8:1995 Implants for surgery -- Partial and total hip joint prostheses -- Part 8: Endurance performance of stemmed femoral components with application of torsion
ISO 9583:1993 Implants for surgery -- Non-destructive testing -- Liquid penetrant inspection of metallic surgical implants
Radiology
AIUM/NEMA UD 2-2004, Revision 3 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
AIUM/NEMA UD 3-2004, Revision 2 Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
IEC 60601-2-37 - Consol. Ed. 1.1 (incl. am1) : 2004-10-14 Medical electrical equipment - Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment
IEC 60601-1-3 - Ed. 1.0 : 1994-07-14 Medical electrical equipment - Part 1: General requirements for safety - 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment

IEC 60601-2-28 - Ed. 1.0 : 1993-03-07 Medical electrical equipment - Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis
IEC 60601-2-32 - Ed. 1.0 : 1994-03-04 Medical electrical equipment - Part 2: Particular requirements for the safety of associated equipment of X-ray equipment
IEC 60601-2-43 - Ed. 1.0 : 2000-06-30 Medical electrical equipment - Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures
IEC 60601-2-44 - Consol. Ed. 2.1 (incl. am1) : 2002-11-15 Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography
IEC 60601-2-7 - Ed. 2.0 : 1998-02-26 Medical electrical equipment - Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators
Sterilization
ISO 11134:1994 Sterilization of health care products -- Requirements for validation and routine control -- Industrial moist heat sterilization
CSA 11134-98 (R2003) Sterilization of Health Care Products - Requirements for Validation and Routine Control - Industrial Moist Heat Sterilization
ISO 11135:1994 Medical devices -- Validation and routine control of ethylene oxide sterilization
ISO 11135:1994/Cor 1:1994
CSA 11135-98 (R2003) Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization

ISO 11137:1995 Sterilization of health care products -- Requirements for validation and routine control -- Radiation sterilization
CSA 11137-98 (R2003) Sterilization of Health Care Products - Requirements for Validation and Routine Control - Radiation Sterilization
ISO 11137:1995 Selection of items for dose setting ISO 11137:1995/Cor 1:1997 ISO 11137:1995/Amd 1:2001
ISO 11138-1:1994 Sterilization of health care products -- Biological indicators -- Part 1: General
ISO 11138-2:1994 Sterilization of health care products -- Biological indicators -- Part 2: Biological indicators for ethylene oxide sterilization
ISO 11138-3:1995 Sterilization of health care products -- Biological indicators -- Part 3: Biological indicators for moist heat sterilization
ISO 11737-1:1995 Sterilization of medical devices -- Microbiological methods -- Part 1: Estimation of population of microorganisms on products
ASTM F1980-02 Standard Guide for Accelerated Aging of Sterile Medical Device Packages