



## APPENDIX 1

### Canadian Standards Association Standards for Medical Devices and Equipment

#### Legend

*Example: ISO/TR 12001-FM:85 (R2019)*

F Indicates the standard is written in French.

TR Indicates the standard is a Technical Report

:85 Denotes the year of publication — in this case, 1985.

R The standard has been “reaffirmed”— no changes have been made to the standard since the date of publication.

#### Anesthesia, Respiratory and Critical Care

CSA Z168.5.6:96 (R2016)

Expired-Air Pulmonary Resuscitators

CSA Z305.0:13

Safety of personnel in perioperative environments

CSA Z305.8:03 (R2018)

Medical Supply Units

CSA Z305.12:06 (R2017)

Safe Storage, Handling, and Use of Portable Oxygen Systems in Residential Buildings and Health Care

CSA Z305.13:13 (R2018)

Plume scavenging in surgical, diagnostic, therapeutic, and aesthetic settings

CSA Z386:14 (R2019)

Safe use of lasers in health care

CSA Z387:19

Safe use of electrosurgical medical devices and systems in health care

CAN/CSA-ISO 5356-1:15

Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets

CAN/CSA-ISO 5356-2:18

Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors

CAN/CSA-Z5359:16

Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases, medical vacuum, medical support gases, and anaesthetic gas scavenging systems

CAN/CSA-Z5359A:16

Amendment 1:2019 to CAN/CSA-Z5359:16, Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases, medical vacuum, medical support gases, and anaesthetic gas scavenging systems

CAN/CSA-Z5360:16

Anaesthetic Vaporizers — Agent-Specific Filling Systems

CAN/CSA-Z5361:18

Anaesthetic and Respiratory Equipment — Tracheal Tubes and Connectors

CAN/CSA-ISO 5366:18

Anaesthetic and respiratory equipment — Tracheostomy tubes and connectors  
CAN/CSA-ISO 5367:19

Breathing tubes intended for use with anaesthetic apparatus and ventilators  
CSA Z7000:18

General requirements for quality management and safety in perioperative settings  
CSA-Z7396.1:17

Medical gas pipeline systems - Part 1: Pipelines for medical gases, medical vacuum, medical support gases, and anaesthetic gas scavenging systems  
CAN/CSA-Z8836:15

Suction Catheters for Use in the Respiratory Tract  
CAN/CSA-Z9170-1:11 (R2015)

Terminal units for medical gas pipeline systems - Part 1: Terminal units for use with compressed medical gases, vacuum, and anaesthetic gas scavenging systems  
CAN/CSA-Z9360-1:07 (R2017)

Anaesthetic and Respiratory Equipment - Heat and Moisture Exchangers (HMEs) for Humidifying Inspired Gases in Humans - Part 1: HMEs for Use with Minimum Tidal Volumes of 250 ml  
CAN/CSA-Z9360-2:07 (R2017)

Anaesthetic and Respiratory Equipment - Heat and Moisture Exchangers (HMEs) for Humidifying Inspired Gases in Humans - Part 2: HMEs for Use with Tracheostomized Patients Having Minimum Tidal Volumes of 250 ml  
CAN/CSA-Z10079-1:16

Medical Suction Equipment — Part 1: Electrically Powered Suction Equipment — Safety Requirements  
CAN/CSA- Z10079-1: 15/ AMD 1:2018

Medical Suction Equipment — Part 1: Electrically Powered Suction Equipment — Safety Requirements  
CAN/CSA-Z10079-2:14 (R2019)

Medical Suction Equipment — Part 2: Manually Powered Suction Equipment  
CAN/CSA-Z10079-3:14 (R2019)

Medical Suction Equipment — Part 3: Suction Equipment Powered from a Vacuum or Pressure Source  
CAN/CSA-Z10083:08 (R2013)

Oxygen concentrator supply systems for use with medical gas pipeline systems  
CAN/CSA-ISO-Z11195:19

Gas mixers for medical use - Stand-alone gas mixers  
CAN/CSA-Z10524 -1:12 (R2017)

Pressure Regulators and Pressure Regulators with Flow-Metering Devices for Medical Gas Systems  
CAN/CSA-Z10524-2:12 (R2017)

Pressure regulators for use with medical gases - Part 2: Manifold and line pressure regulators  
CAN/CSA-Z10524-3:12 (R2017)

Pressure regulators for use with medical gases - Part 3: Pressure regulators integrated with cylinder valves  
CAN/CSA-Z10524-4:12 (R2017)

Pressure regulators for use with medical gases - Part 4: Low-pressure regulators  
CAN/CSA-Z10651-2:06

Lung Ventilators for Medical Use — Particular Requirements for Basic Safety and Essential Performance — Part 2: Home Care Ventilators for Ventilator-Dependent Patients CAN/CSA-Z10651-3:98 (R2018)

Lung Ventilators for Medical Use — Part 3: Particular Requirements for Emergency and Transport Ventilators

CAN/CSA-Z10651-4:08 (R2018)  
Lung ventilators - Part 4: Particular requirements for operator-powered resuscitators  
CAN/CSA-Z10651-5:08 (R2018)  
Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 5: Gas-powered emergency resuscitators  
CAN/CSA-Z10651-6:06 (R2015)  
Lung Ventilators for Medical Use — Particular Requirements for Basic Safety and Essential Performance — Part 6: Home-Care Ventilatory Support Devices  
CAN/CSA-ISO/TR-Z13154:19  
Medical electrical equipment - Deployment, implementation and operational guidelines for identifying febrile humans using a screening thermograph  
CAN/CSA-Z15002:12 (R2017)  
Flow-metering devices for connection to terminal units of medical gas pipeline systems  
CAN/CSA-Z17510:15  
Medical devices - Sleep apnoea breathing therapy - Masks and application accessories  
CAN/CSA-Z18777:08 (R2018)  
Transportable Liquid Oxygen Systems for Medical Use - Particular Requirements  
CAN/CSA- Z18778:08 (R2018)  
Respiratory Equipment - Infant Monitors - Particular Requirements  
CAN/CSA-Z18835:19  
Inhalational anaesthesia systems - Draw-over anaesthetic systems  
CAN/CSA-Z23328-1:04 (R2019)  
Breathing System Filters for Anaesthetic and Respiratory Use — Part 1: Salt Test Method to Assess Filtration Performance  
CAN/CSA-Z23328-2:03 (R2018)  
Breathing System Filters for Anaesthetic and Respiratory Use — Part 2: Non-Filtration Aspects  
CAN/CSA-Z23747:18  
Anaesthetic and respiratory equipment - Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans

### **Applications of Electricity in Health Care**

CAN/CSA-C22.2 NO. 60601-1:14 (R2018)  
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance  
CAN/CSA-C22.2 NO. 60601-1-2:16  
Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests  
CAN/CSA-C22.2 NO. 60601-1-3:09 (R2014)  
Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral standard: Radiation protection in diagnostic X-ray equipment  
CAN/CSA-C22.2 NO. 60601-1-6:11 (R2016)  
Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance - Collateral standard: usability  
CAN/CSA-C22.2 NO. 60601-1-8:08 (R2018)  
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  
CAN/CSA-C22.2 NO. 60601-1-9:15  
Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral standard: Requirements for environmentally conscious design  
CAN/CSA-C22.2 NO. 60601-1-10:09 (R2018)  
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  
CAN/CSA-C22.2 NO. 60601-1-11:15  
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  
CAN/CSA-C22.2 NO. 60601-1-12:15 (R2016)  
Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment  
CAN/CSA-C22.2 NO. 60601-2-1:11 (R2016)  
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  
CAN/CSA-C22.2 NO. 60601-2-2:19  
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  
CAN/CSA-C22.2 NO. 60601-2-3:14 (R2018)  
Medical electrical equipment - Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment  
CAN/CSA-C22.2 NO. 60601-2-4:12 (R2016)  
Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators  
CAN/CSA-C22.2 NO. 60601-2-5:11 (R2016)  
Medical electrical equipment - Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment  
CAN/CSA-C22.2 NO. 60601-2-6:14 (R2018)  
Medical electrical equipment - Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment  
CAN/CSA-C22.2 NO. 60601-2-8:12 (R2016)  
Medical electrical equipment - Part 2-8: Particular requirements for the basic safety and essential performance of therapeutic x-ray equipment operating in the range 10 kv to 1 mv  
CAN/CSA-C22.2 NO. 60601-2-10:14 (R2018)  
Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators  
CAN/CSA-C22.2 NO. 60601-2-11:15  
Medical electrical equipment - Part 2-11: Particular requirements for the basic safety and essential performance of gamma beam therapy equipment  
CAN/CSA-C22.2 NO. 60601-2-16:14 (R2019)  
Medical electrical equipment - Part 2-16: Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment  
CAN/CSA-C22.2 NO. 60601-2-17:15  
Medical electrical equipment - Part 2-17: Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment  
CAN/CSA-C22.2 NO. 60601-2-18:11 (R2016)  
Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment  
CAN/CSA-C22.2 NO. 60601-2-19:09 (R2018)  
Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators  
CAN/CSA-C22.2 NO. 60601-2-20:10 (R2019)  
Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators

CAN/CSA-C22.2 NO. 60601-2-21:10 (R2018)  
Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers

CAN/CSA-C22.2 NO. 60601-2-22:08 (R2018)  
Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

CAN/CSA-C22.2 NO. 60601-2-23:12 (R2016)  
Medical electrical equipment - Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous Partial pressure monitoring equipment

CAN/CSA-C22.2 NO. 60601-2-24:15  
Medical electrical equipment - Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers

CAN/CSA-C22.2 NO. 60601-2-25:12 (R2017)  
Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs

CAN/CSA-C22.2 NO. 60601-2-26:14 (R2018)  
Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs

CAN/CSA-C22.2 NO. 60601-2-27:11 (R2016)  
Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment

CAN/CSA-C22.2 NO. 60601-2-28:18  
Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis

CAN/CSA-C22.2 NO. 60601-2-29:10 (R2018)  
Medical electrical equipment - Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators

CAN/CSA-C22.2 NO. 60601-2-30:10 (R2015)  
Medical electrical equipment — Part 2-30: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source

CAN/CSA-C22.2 NO. 60601-2-31:09 (R2019)  
Medical electrical equipment - Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source

CAN/CSA-C22.2 NO. 60601-2-33:12 (R2016)  
Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis

CAN/CSA-C22.2 NO. 60601-2-34:12 (R2017)  
Medical electrical equipment - Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment

CAN/CSA-C22.2 NO. 60601-2-36:16  
Medical electrical equipment - Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy

CAN/CSA-C22.2 NO. 60601-2-37:08 (R2019)  
Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

CAN/CSA-C22.2 NO. 60601-2-39:09 (R2019)  
Medical electrical equipment - Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment

CAN/CSA-C22.2 NO. 60601-2-40:17  
Medical electrical equipment - Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment

CAN/CSA-C22.2 NO. 60601-2-41:11 (R2016)

Medical electrical equipment - Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis  
CAN/CSA-C22.2 NO. 60601-2-43:11 (R2016)

Medical electrical equipment - Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures  
CAN/CSA-C22.2 NO. 60601-2-44:10 (R2015)

Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of x-ray equipment for computed tomography  
CAN/CSA-C22.2 NO. 60601-2-45:11 (R2016)

Medical electrical equipment - Part 2-45: Particular requirements the basic safety and essential performance of mammographic x-ray equipment and mammographic stereotactic devices  
CAN/CSA-CSA C22.2 NO. 60601-2-46:18

Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables  
CAN/CSA-C22.2 NO. 60601-2-47:14 (R2018)

Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems  
CAN/CSA-C22.2 NO. 60601-2-49:11 (R2016)

Medical electrical equipment - Part 2-49: Particular requirements the basic safety and essential performance of multifunction patient monitoring equipment  
CAN/CSA-C22.2 NO. 60601-2-50:10 (R2018)

Medical electrical equipment – Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment  
CAN/CSA-C22.2 NO. 60601-2-52:11 (R2016)

Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds  
CAN/CSA-C22.2 NO. 60601-2-54:11 (R2016)

Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of x-ray equipment for radiography and radioscopy  
CAN/CSA-C22.2 NO. 60601-2-57:11 (R2016)

Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for the therapeutic, diagnostic, monitoring and cosmetic/aesthetic use  
CAN/CSA-C22.2 NO. 60601-2-62:15

Medical electrical equipment - Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment  
CAN/CSA-C22.2 NO. 60601-2-63:15

Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment  
CAN/CSA-C22.2 NO. 60601-2-64:15

Medical electrical equipment - Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment  
CAN/CSA-C22.2 NO. 60601-2-65:15

Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment  
CAN/CSA-C22.2 NO. 60601-2-66:15

Medical electrical equipment - Part 2-66: Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems  
CAN/CSA-C22.2 NO. 60601-2-68:15

Medical electrical equipment - Part 2-68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment

CAN/CSA-C22.2 NO. 80601-2-12:12 (R2017)  
Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators

CAN/CSA-C22.2 NO. 80601-2-13:15  
Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation

CAN/CSA-C22.2 NO. 80601-2-30-10 (R2015)  
Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

CAN/CSA-C22.2 NO. 80601-2-35:12 (R2016)  
Medical electrical equipment-Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use

CAN/CSA-C22.2 NO. 80601-2-55:14 (R2019)  
Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors

CAN/CSA-C22.2 NO. 80601-2-56:12 (R2016)  
Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement

CAN/CSA-C22.2 NO. 80601-2-58:15  
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

CAN/CSA-C22.2 NO. 80601-2-59-10 (R2015)  
Medical electrical equipment - Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening

CAN/CSA-C22.2 NO. 80601-2-60:14  
Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment

CAN/CSA- C22.2 NO. 80601-2-61:14 (R2019)  
Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

CAN/CSA-C22.2 NO. 80601-2-67:17  
Medical electrical equipment — Part 2-67: Particular requirements for basic safety and essential performance of oxygen conserving equipment

CAN/CSA-C22.2 NO. 80601-2-69:16  
Medical electrical equipment - Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment

CAN/CSA-C22.2 NO. 80601-2-70:17  
Medical electrical equipment — Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment

CAN/CSA-C22.2 NO. 80601-2-71:17  
Medical electrical equipment — Part 2-71: Particular requirements for the basic safety and essential performance of functional near-infrared spectroscopy (NIRS) equipment

CAN/CSA-C22.2 NO. 80601-2-72:17  
Medical electrical equipment — Part 2-72:  
Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator dependent patients

CAN/CSA- C22.2 NO. 80601-2-74:19  
Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment requirements

CAN/CSA-CEI/IEC 1258:98 (R2002)  
Guidelines for the Development and Use of Medical Electrical Equipment Educational Materials

## **Quality Management and General Aspects for Medical Devices**

CAN/CSA-ISO 13485:16

Medical devices - Quality management systems - Requirements for regulatory purposes

CAN/CSA-ISO/TR 14969-05 (R2015)

Medical devices - Quality management systems - Guidance on the application of ISO 13485:2003

CSA CEI/IEC 62304:14 (R2019)

Medical device software - Software life cycle processes - CSA CEI/IEC 62304A:14 (R2019)

Amendment 1:2018 to CSA CEI/IEC 62304:14 Medical device software - Software life cycle processes

CAN/CSA-IEC 62366-1:15

Medical devices — Part 1: Application of usability engineering to medical devices

PLUS 13485:06

The ISO 13485 Essentials - A Practical Handbook for Implementing the ISO 13485 Standard for Manufacturers of Medical Devices

PLUS 14971:07

The ISO 14971:2007 Essentials – A Practical Handbook for Implementing the ISO 14971

Standard for Medical Devices

CAN/CSA-ISO 14971-07 (R2017)

Medical Devices — Application of Risk Management to Medical Devices

## **Blood and Blood Components**

CSA-Z902:15

Blood and Blood Components

## **Child-Resistant Packaging**

CAN/CSA-Z76.1:16

Reclosable child-resistant

## **Extra Corporeal Circulation Technology**

CSA Z364.2.1-13 (R2018)

Monitoring systems for hemodialysis equipment

Z364.5-17

Safe installation and operation of hemodialysis and peritoneal dialysis in a home setting

Z364.6-17

Quality management for kidney dialysis providers

## **Health Care Facilities**

PLUS 317 (Pub 2000)

Guidelines for Elementary Assessments of Building Systems in Health Care Projects

CSA Z317.1:16

Special Requirements for Plumbing Installations in Health Care Facilities

CSA Z317.2:15

Special Requirements for Heating, Ventilation, and Air-Conditioning (HVAC) Systems in Health Care Facilities

CSA Z317.5:17

Illumination design in Health Care Facilities

CSA Z317.10:15

Handling of health care waste materials

CSA Z317.11:17

Area Measurement for Health Care Facilities



CSA Z317.13:17

Infection Control during Construction or Renovation, and maintenance of Health Care Facilities

CSA Z317.14:17

Wayfinding for health care facilities

CSA Z8000:18

Canadian health care facilities

CAN/CSA-Z8001:13 (R2018)

Commissioning of Health Care Facilities

CSA Z8002:19

Operation and maintenance of health care facilities

CAN/CSA-Z10535.1:15

Hoists for the transfer of disabled persons - Requirements and test methods

CSA Z10535.2:17

Lifts for the transfer of persons - Installation, use, and maintenance

### **Medical Device Reprocessing**

CAN/CSA-Z314:18

Canadian medical device reprocessing