APPENDIX 1
Canadian Standards Association Standards for Medical Devices and Equipment

Legend
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 Z305.8:03 (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 Z386:20
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 (R2020)
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 (R2020)
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-Z8836:19
Suction Catheters for Use in the Respiratory Tract
CAN/CSA-Z9170-1:19
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 Respired 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 Respired 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
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-Z10524-1:19
Pressure Regulators and Pressure Regulators with Flow-Metering Devices for Medical Gas Systems
CAN/CSA-Z10524-2:19
Pressure regulators for use with medical gases - Part 2: Manifold and line pressure regulators
CAN/CSA-Z10524-3:19
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-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 (R2019)
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
CAN/CSA-Z26825:10 (R2020)
Anaesthetic and respiratory equipment - User-applied labels for syringes containing drugs used during anaesthesia - Colours, design and performance

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
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
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
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
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
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
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
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
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
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-CSA C22.2 NO. 60601-2-2
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
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
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
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
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
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
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 (R2019)
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
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
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
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
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
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
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
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
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
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
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
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
Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment

CAN/CSA-CSA C22.2 NO. 60601-2-28
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
Medical electrical equipment - Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators

CAN/CSA-C22.2 NO. 60601-2-31
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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

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

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

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

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

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

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

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

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

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

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

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

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

Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment requirements
CAN/CSA-C22.2 NO. 80601-2-79

Medical Electrical Equipment - Part 2-79: Particular Requirements For Basic Safety And Essential Performance Of Ventilatory Support Equipment For Ventilatory Impairment
ISO 80601-2-80

Medical Electrical Equipment - Part 2-80: Particular Requirements For Basic Safety And Essential Performance Of Ventilatory Support Equipment For Ventilatory Insufficiency
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
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 62304A:14 (R2019)
Medical device software - Software life cycle processes
Amendment 1:2018 to CSA CEI/IEC 62304:14 Medical device software - Software life cycle processes
CAN/CSA-IEC 62366-1:15 (R2020)
Medical devices — Part 1: Application of usability engineering to medical devices
CAN/CSA-ISO 14971-07 (R2017)
Medical Devices — Application of Risk Management to Medical Devices

**Blood and Blood Components**
CSA-Z902:20
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 Z317.2:19
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 Z317.10:21
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