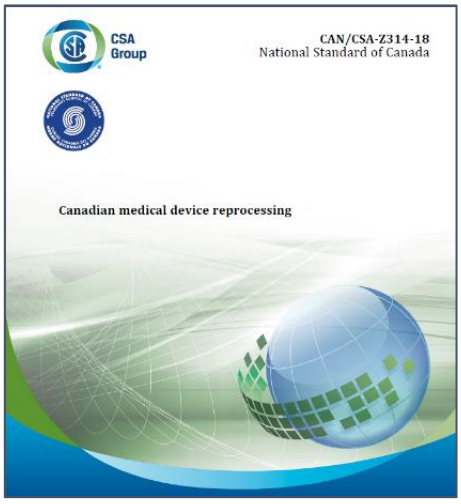
Z314-18 CANADIAN MEDICAL DEVICE REPROCESSING



Sector: **Health Care**

2018, Edition 1

Available for purchase at: http://shop.csa.ca/Medical Device Reprocessing

WHY IS THIS STANDARD NEEDED?

Medical devices are used in nearly every health care procedure. Patients and health care professionals expect these medical devices to be functionally and microbiologically safe. The safety of medical devices begins with the manufacturer and is supported and maintained by a system of National Standards and government regulations that includes medical device licensing, construction and performance standards, and incident reporting systems.

CSA Z314 – Canadian medical device reprocessing is designed to be a comprehensive document aligned to the medical device reprocessing workflow, no matter whether it occurs in a large acute care hospital or a dental office. It is intended to provide benefits to managers and staff of any health care setting where medical device reprocessing is performed and replaces the following CSA Standards:

- Z314.0 — *Medical device reprocessing — General requirements*
- Z314.3 — *Effective sterilization in health care settings by the steam process*
- Z314.8 — *Decontamination of reusable medical devices*
- Z314.10.1 — *Selection and use of gowns and drapes intended for use in health care facilities*
- Z314.10.2 — *Laundering, maintenance, and preparation of reusable gowns, drapes, and wrappers for health care settings and laundries*
- Z314.14 — *Selection and use of packaging (sterile barrier systems) in healthcare settings*
- Z314.15 — *Storage, transportation, and distribution of single use and reusable medical devices*
- Z314.22 — *Management of loaned, reusable medical devices*
- Z314.23 — *Chemical sterilization of reusable medical devices in health care settings*

STANDARD HIGHLIGHTS

- Guidance for setting up a medical device reprocessing QMS.
- Addresses personnel training, occupational health and safety, and infection prevention and control.
- Covers purchasing, loaned reusable medical devices and work areas and design.
- Establishes requirements for the medical device reprocessing workflow including:
    - Decontamination and sterilization methods
    - Sterile barrier systems, selection and use of gowns and drapes
    - Storage, transportation and distribution
    - Laundering, maintenance, and preparation of reusable gowns, drapes, and wrapper
- 21 annexes providing tools and additional guidance on topics in the Standard

RELATED STANDARDS

Effective medical device reprocessing can be achieved when this Standard is used in combination with the following related Standards:

CAN/CSA-C22.2 No. 60601 series on Medical electrical equipment
C282-15 Emergency electrical power supply for buildings
CAN/CSA-ISO 9000:16 Quality management systems — Fundamentals and vocabulary
CAN/CSA-ISO 9001:16 Quality management systems — Requirements
CAN/CSA-ISO 11138-1:17 Sterilization of health care products — Biological indicators — Part 1: General requirements
CAN/CSA-ISO 11140-1:16 Sterilization of health care products — Chemical indicators — Part 1: General requirements
CAN/CSA-ISO 14937:11 (R2016) 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
CAN/CSA-ISO 14971-07 (R2017) Medical devices — Application of risk management to medical devices
CAN/CSA-ISO 11607-1:16 Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
CAN/CSA-ISO 11607-2:16 Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes Emergency electrical power supply for buildings
CAN/CSA-ISO 9000:16 Quality management systems — Fundamentals and vocabulary
CAN/CSA-ISO 9001:16 Quality management systems — Requirements
CAN/CSA-ISO 11138-1:17 Sterilization of health care products — Biological indicators — Part 1: General requirements
CAN/CSA-ISO 11140-1:16 Sterilization of health care products — Chemical indicators — Part 1: General requirements
CAN/CSA-ISO 14937:11 (R2016) 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
CAN/CSA-ISO 14971-07 (R2017) Medical devices — Application of risk management to medical devices
CAN/CSA-ISO 11607-1:16 Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
CAN/CSA-ISO 11607-2:16 Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes
CAN/CSA-Z15883-2-09 (R2014) Washer-disinfectors — Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.
CAN/CSA-Z17664-06 (R2016) Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices

CONTACT INFORMATION

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