COLLEGE OF ALBERTA DENTURISTS

College of Dental Technologists of Alberta

# Practice Guidance

## Medical Device Compliance

This guideline is provided with the collaboration of the College of Alberta Denturists and the College of Dental Technologists of Alberta.

### Purpose

With the continual expansion of the global market and the rise in digital sales and services, a diverse range of medical devices, including their materials and components, are now accessible.

While the College is not responsible for regulating medical devices, this guidance is intended to assist regulated members in navigating the use, sale, and licensure of medical devices in Canada.

In Canada, medical device licensure is managed by Health Canada. Regulated members should be aware of and must comply with Health Canada's regulations to ensure the safe and effective use of medical devices.

**The sale or use of prohibited medical devices or materials not licenced by Health Canada is in breach of the *Medical Devices Regulations* and may be considered an act of unprofessional conduct for regulated members.**

### Medical Devices and Types of Licenses

A medical device means any device within the meaning of the *Food and Drug Act*. Regulated members may encounter a variety of medical devices in their practice such as dentures, bridges, crowns, resins, denture coatings, filling materials, prosthodontic appliances, artificial teeth, denture repair kits, and materials used in the fabrication of dental appliances and devices.

Regulated members have a professional obligation to adhere to Health Canada regulations. Compliance can be achieved by ensuring that all medical devices, including materials used in the manufacture, repair, or alteration of dental appliances, devices and prosthetics, are approved by Health Canada and appropriately licenced.

**Classification of Medical Devices**

| Device Class | Examples | Risk | Requirements |
|---|---|---|---|
| Class I | Dental wax, articulating paper, cotton ball, cotton swabs, oral/tongue depressors, probes, | Lowest | Class I device manufacturers or importers must hold a Medical Device Establishment License (MDEL). Regulated members must:<br><br>a) Confirm that the company (establishment) importing or distributing the medical device has an MDEL. This can be verified using the Holders of an Active Medical Devices Establishment Licence Database. |
| Class II | Air-powered dental handpiece, dental operative units, orthodontic resin, dental burs, dentures, denture resins, resins for denture relining/repairing/rebasing | Low | Class II, III, and IV devices must have Health Canada's approval in the form of a Medical Device License. Regulated members must:<br><br>a) Verify that all medical devices and materials used are listed in the Health Canada database of approved products by searching the Medical Devices Active Licence Listing.<br>b) Confirm that the company (establishment) importing or distributing the medical device has an MDEL. This can be verified using the Holders of an Active Medical Devices Establishment Licence Database. |
| Class III | Dental acrylic materials, dental filling materials, teeth shade resin, tooth bonding resin | Moderate | |
| Class IV | Defibrillators | Highest | |

**Medical Device License (MDL) and Medical Device Establishment License (MDEL) Verification**

- Refer to Health Canada's guidance document to determine what class a device falls under: Keyword Index to Assist Manufacturers in Verifying the Class of Medical Devices.
- Verify that all medical devices and materials used are listed in the Health Canada database of approved products.

## Strategies for Navigating Regulatory Compliance

To ensure ongoing compliance with the Medical Devices Regulations, regulated members should consider the following:

- Maintain up-to-date records of all materials and devices used in dental prosthetics, including their Health Canada approval status.
- Regularly review Health Canada updates and notifications regarding changes to the approval status of medical devices and materials to ensure ongoing compliance with Health Canada regulations.
- Ensure all team members involved in the handling, manufacturing, or altering of dental prosthetics are educated and informed about the importance of using Health Canada-approved materials.
- Implement protocols to immediately address any discrepancies or issues related to non-approved devices or materials.
- Report any adverse events or incidents related to medical devices promptly to Health Canada as per the regulatory requirements.

For questions regarding Medical Device or Medical Device Establishment Licensing in Canada specific to an individual business, clinic, dental laboratory, or other practice setting, regulated members must contact Health Canada directly.

## References


Food and Drugs Act (R.S.C., 1985, c. F-27). (2023). https://laws-lois.justice.gc.ca/PDF/F-27.pdf

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Minister of Health. (2006, September 1). Guidance for Industry: Keyword index to assist manufacturers in verifying the class of medical devices. https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/hpfb-dgpsa/pdf/md-im/keyword_motscles2-eng.pdf