



CANADIAN DENTAL ASSOCIATION
L'ASSOCIATION DENTAIRE CANADIENNE

Guidance Document Pertaining to Devices for Use in Dental Health Care

Based on
Medical Devices Regulations
Therapeutic Products Directorate
Health Canada

Prepared by the
Committee on Clinical and Scientific Affairs
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Introduction

The instruments, equipment, and materials used by dentists are considered to be medical devices by Health Canada and must comply with Canadian *Medical Devices Regulations* in order to be sold and used in Canada.

This Canadian Dental Association (CDA) document provides guidance to dentists concerning the purchase of dental instruments, equipment and materials and reporting of adverse incidents related to devices used in the practice of dentistry.

Rationale for Regulations

The purpose of the *Medical Devices Regulations (1998)* is to improve the safety, effectiveness and quality of medical devices sold in Canada and to bring Canada's regulations in line with those of our major trading partners. An important feature of the 1998 regulations was the establishment of device classes and requirements for manufacturers, importers and distributors to obtain appropriate authorization prior to the sale of medical devices in Canada.

Classes of Medical Devices

All medical devices are categorized into four classes. Class I represents the lowest risk class, and Class IV the highest (see Table 1 below).

Class I devices are those that make only non-invasive contact with the patient and do not transmit energy to the patient. Classes II, III and IV include devices of increasingly higher risk as determined by such factors as their degree of invasiveness, the hazards of energy transmission, and the potential consequences to the patient in case of device malfunction or failure.

Class	Risk	Licence required	Dental example	
I	Lowest	No ¹	Impression materials Prophylaxis cup	Toothbrush (manual)
II	Low	Yes	Bur Endodontic instruments Hand instruments	Orthodontic appliance Removable denture Toothbrush (power)
III	High	Yes	Endosseous implants Prosthetic materials	Restorative materials Crowns and bridges
IV	Highest	Yes	Bone void fillers containing animal tissue	

¹ Although these devices do not require a licence, the source establishment must hold an Establishment Licence from Health Canada.

Licensing Requirements

For the purposes of general marketing, all Class II, III, and IV medical devices sold in Canada must have a valid Medical Device Licence issued by the Therapeutic Products Directorate of Health Canada before they may be sold for use by dentists. Class I devices, because of their relatively low risk, do not require a device licence.

The Register of Licensed Medical Devices

The Therapeutic Products Directorate maintains a searchable list of all licensed medical devices on its website at: www.mdall.ca

This website has been enhanced to allow health care facilities and providers to search devices that have an active Medical Device Licence or were previously licensed at one time. To implement the expanded search capability to include previously licensed devices, a new window was designed to prompt for two search modes: Active Licence Search or Archived Licence Search. The Issue Date of the previous version of MDALL is replaced with the First Issue Date field to indicate when a product was initially authorized for sale. It is available at the Licence, Device and Device Identifier levels.

Health care facilities and providers contemplating the purchase of a Class II, III or IV device should use this list to verify that the manufacturer has a valid licence. As medical device licences can be suspended by Health Canada, cancelled during the annual renewal of licences by Health Canada, or discontinued by the manufacturer, it is important to conduct this verification each time the purchase of a medical device is considered.

Responsibilities of Manufacturers, Importers and Distributors

A manufacturer must obtain a licence before selling any Class II, III, or IV device in Canada. A distributor or importer of medical devices cannot legally sell an unlicensed device.

Additionally, importers and distributors of medical devices are required to obtain an Establishment Licence from Health Canada to ensure that proper distribution records are kept and that procedures are in place for handling complaints, reporting mandatory problems and recalling devices. Note that medical devices sold by foreign manufacturers directly to health care facilities are also required to have a valid Canadian Medical Device Licence.

Finally, dentists who import dental instruments, equipment and materials directly from a source establishment in the United States for use in their practices are not considered importers and do *not* require an Establishment Licence. However, the devices imported into Canada do need to have the appropriate medical device licence and, for Class I devices, the source establishment must have an Establishment Licence with Health Canada.

Responsibilities of Dental Laboratories

Dental laboratories fabricate oral appliances, dental restorations and prostheses as prescribed by dentists. All of these dental laboratory products are considered medical

devices. Removable dentures (partial and complete) and orthodontic appliances are Class II medical devices, whereas fixed restorations (bridges, crowns, inlays, onlays, veneers) and implant fixtures are Class III devices.

Fabricators of these devices must have a device licence for these products, unless the fabrication is conducted or supervised by a dental technologist who is a member of a self-regulating profession.

Dentists who import dental laboratory products directly from an offshore laboratory do not need an Establishment Licence, but the offshore laboratory or manufacturer that fabricated the appliance, restoration or prosthesis must have a Class II or III medical device licence.

Whether a dental laboratory product is fabricated in or outside Canada, fabricators are required to use materials licensed under Canada's *Medical Device Regulations*.

Safety and Effectiveness Requirements

Manufacturers of Class III and IV devices are required to provide Health Canada with evidence that their device is both safe and effective prior to its marketing. In addition, manufacturers must provide evidence that their quality systems meet the requirement of the ISO Standard 13485. Health Canada reviews this information prior to issuing a medical device licence authorizing the sale of the device in Canada.

It is extremely important that dentists follow manufacturer's instructions for use to ensure that the device will be used in a safe and effective manner, and to minimize risk of harm to either the user or patient.

Reporting of Adverse Incidents

Health Canada depends on health care professionals to report adverse incidents related to medical devices. Any serious or unexpected adverse incident related to medical devices should be reported to Health Canada at the following address:

Health Products and Food Branch Inspectorate
HEALTH CANADA
Address Locator: 2003D
Ottawa, Ontario K1A 0K9
Tel: The Inspectorate Hotline 1-800-267-9675

The **Medical Devices Problem Reporting Form** can be found at:

http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/rep_md_prob-rap_inc_im_tctm_e.html

Further Information

Further information on licensed devices or the licensing requirements of the *Medical Devices Regulations* may be obtained from:

Manager, Device Licensing Services Division
Medical Devices Bureau
Tel: 613-957-7285
Fax: 613-957-6345
Email: mdb_enquiries@hc-sc.gc.ca

Summary of Key Points for Dentists

- Class I devices do NOT require a device licence.
- Class II, III and IV devices sold in Canada must have a device licence.
- Health Canada's MDALL searchable online database (www.mdall.ca) is a reference tool to determine whether a device has a licence to be sold in Canada.
- Importers and distributors of devices are required to obtain an Establishment Licence from Health Canada.
- Canadian dentists have an ethical responsibility to use products that are for sale legally in Canada.
- Dentists should follow manufacturer's instructions to ensure that the device will be used in a safe and effective manner, and to minimize risk of harm to either the user or patient.
- Any serious or unexpected adverse incident related to devices should be reported to Health Canada.

Questions?

If you have questions concerning this guidance document, please contact Dr. Euan Swan, manager of dental programs, at eswan@cda-adc.ca.