


Medical batteries

Some batteries used with medical devices that are imported or sold in Canada must be licensed

Here's what you need to know:

- Batteries specifically sold for use with medical devices are either class I or II medical devices.
- Manufacturers of Class I medical batteries may need a medical device establishment licence (MDEL).
- Manufacturers of Class II medical batteries must have a medical device licence (MDL).
- Importers and distributors of medical batteries must have an MDEL.
- Multipurpose batteries sold for both medical and non-medical use are **not** medical devices.

Medical batteries are medical devices and are regulated under the *Food and Drugs Act* and *Medical Devices Regulations*. The Act and Regulations govern the import, advertising and sale of medical devices in Canada.

Medical devices are classed into four groups (Class I, II, III and IV) based on the risk they pose to the health and safety of users, patients and other people. Class I devices present the lowest potential risk (e.g. powered wheelchairs). Class IV devices present the highest potential risk (e.g. pacemakers).

Manufacturers must get an MDL from Health Canada for all Class II medical batteries before they can be imported, advertised or sold in Canada. Before issuing a licence, Health Canada assesses the device for safety, effectiveness and compliance with the labelling and other requirements. To apply for an MDL, manufacturers must have a quality certificate issued under the Canadian Medical Devices Conformity Assessment System (CMDCAS). Information on CMDCAS can be found at: www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/index-eng.php.

Which batteries are considered medical devices?

Batteries are considered medical devices when they are designed, manufactured and labelled specifically for use with medical devices (e.g. a battery made exclusively for a defibrillator (AED)).

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When determining if a battery is a medical device, consider how it is used and marketed. Your battery is considered a medical device if the labelling represents it for use with medical devices only. For example, a battery labelled as a “hearing aid battery” is being marketed specifically for use with a medical device and is therefore considered a medical device.

Multipurpose batteries that are manufactured and labelled for general use—which may or may not include powering medical devices—are **not** considered medical devices. A battery that is used to power both your TV remote control and your electric toothbrush is not considered a medical device, since it has both medical and non-medical uses.

Which batteries must be licensed?

Batteries that only power Class I medical devices are classified as **Class I** medical devices. You do not need an MDL for Class I medical devices, but you may need a MDEL (see below).

Batteries used to power Class II, III or IV medical devices are classified as **Class II** medical devices. For example, a hearing aid is a Class II medical device, so a hearing aid battery is also a Class II medical device. If you manufacture a Class II medical battery, you must get an MDL from Health Canada. You cannot import or sell a Class II medical device unless the manufacturer has an MDL from Health Canada.

Who must have a medical device establishment licence (MDEL)?

If you manufacture **Class I** medical devices and plan on selling directly (without a distributor), you may need an MDEL. If you choose to sell through distributors, then they must get an MDEL. For a list of establishments with valid MDELs, see the Medical Devices Establishment Licence Listing (https://health-products.canada.ca/mdel-leim/index-eng.jsp).

If you import or distribute medical batteries, you need an MDEL (whether based in Canada or not).

To apply for an MDEL, complete the Medical Device Establishment Licence Application Form (FRM-0292) (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/form/frm-0292-eng.php).

How to meet requirements for medical device labels

If you manufacture medical devices, you must comply with the labeling requirement under the *Medical Devices Regulations*. See the Guidance document for labelling medical devices (http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/labl_etiq_dv10-eng.php) for more information.

Health Canada has more resources to help you:

- Guidance document for labelling medical devices
  www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/labl_etiq_dv10-eng.php
- Medical Devices Active Licence Listing
  www.hc-sc.gc.ca/dhp-mps/md-im/licen/mdlic-eng.php
- Medical device licence application forms
  www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/form/index-eng.php