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Guidance on Medical Device Establishment Licensing (MDEL)

GUI-0016

April 1, 2020

Canada

GUI-0016: Guidance on Medical Device Establishment Licensing (MDEL)

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This document does not constitute part of the *Food and Drugs Act* or its regulations, and in the event of any inconsistency or conflict between the Act or regulations and this document, the Act or the regulations take precedence. This document is an administrative document that is intended to facilitate compliance by the regulated party with the Act, the regulations, and the applicable administrative policies.

The following table shows the three types of icons used in this document, and the way they are intended to be used.

	**Important:** Key or cautionary information for people to know.
	**Information:** Supplementary information like quotes and legal references.
	**Tip:** Things for people to do or understand.

Table of contents

About this document

1. Purpose

This guidance document is intended for any person in the medical device industry and it provides guidance on regulatory requirements in relation to **Medical Device Establishment Licences (MDEL)**, including when and how to apply for an MDEL, and how to maintain an MDEL once issued.

This guidance document does not cover importing medical devices for personal use or for use on animals.

This guidance document explains:

- Medical devices establishment licensing regime under sections 44 to 51.1 of the Medical Devices Regulations to the *Food and Drugs Act*.
- Responsibilities of any person who imports or distributes medical devices in Canada.
- Health Canada's responsibilities.

2. Scope

This guidance document covers licensing requirements for medical device establishment licences (MDEL), including who requires an MDEL.

This guidance document describes how to:

- apply for an MDEL (see section 5 – Applying for an MDEL)
- submit an annual licence review before April 1 of each year (see section 6 – Submitting your Annual Licence Review application)
- make change(s) to your existing licence, for example, an amendment or section 48 notification (see section 7 – Updating or cancelling your MDEL)
- cancel your MDEL (see section 7)
- reinstate your licence after a suspension (see section 8 – Steps to take if your MDEL is suspended or cancelled by Health Canada)

The scope of this guidance document does not cover:

- **Drug Establishment Licence** (DEL). For more information about DELs, see the *Guidance on Drug Establishment Licences and Associated Fees (GUI-0002)*.
- **Medical Device Licence** (MDL). For information on how to obtain an MDL, see the *Guidance Document: How to Complete the Application for a New Medical Device Licence*.
- **Fees for the review of an MDEL application**. For more information related to MDEL fees, see the *Guidance document – Fees for the Review of Medical Device Establishment Licence Applications* and/or *How to Pay Your Establishment Licence Fees*.

3. Introduction

What is a medical device?

The term 'medical device' covers a wide range of products used in the treatment, mitigation, diagnosis or prevention of a disease or abnormal physical state. See Appendix A - Glossary for regulatory definitions of a 'device' and 'medical devices'.

Medical devices are categorized into four classes (I, II, III or IV) based on the level of potential risk related to their use. Class I medical devices present the lowest potential risk (for example, wheelchairs), while Class IV medical devices present the highest potential risk (for example, pacemakers).

Medical devices include a range of health products, including:

- bandages/adhesive strips (Class I)
- crutches and canes (Class I)
- toothbrushes – manual (Class I)

- toothbrushes – powered (Class II)
- hearing aids (Class II)
- hip implants (Class III)
- respirators (Class III)
- artificial hearts (Class IV)

Combination products

A combination product is a therapeutic product that combines a device component with any other therapeutic product components, which by themselves would be classified as a singular product.

In general, an establishment licence requirement for a combination product is associated with the classification of the product. For example:

- A combination product classified as a **drug** will be subject to the Drug Establishment Licence (DEL) requirements pursuant to Part C, Division 1A and other related sections of the Food and Drug Regulations and the *Food and Drugs Act*.
- A combination product classified as a **medical device** will be subject to the Medical Device Establishment Licence (MDEL) requirements under section 44 and other related sections of the Medical Devices Regulations and the *Food and Drugs Act*.

For more information on combination products, see *Policy on Drug/Medical Device Combination Products – Decisions* or contact us before you submit your application (see Appendix C - contact information).

Medical device delivering a drug or medical cannabis

A medical device that is manufactured, sold or represented for delivering a drug, including medical cannabis, to a patient through smoking (i.e., the combustion of the drug and subsequent inhalation of the resulting smoke) is considered to be a Class II medical device as per the Notice: Classification of Medical Devces used to Deliver Drugs by Smoking posted on Health Canada's website.

- Manufacturers of a Class II, III or IV medical device must hold a medical device licence (MDL) to import or distribute their own medical device in Canada.
- Importers and distributors must hold an active MDEL to import or distribute all classes of medical devices in Canada, including medical devices that deliver a drug or medical cannabis.

Do I need a licence?

Health Canada issues two different types of licences for medical devices:

- **Medical Device Licence (MDL)** – a licence issued to manufacturers authorizing them to import or sell their Class II, III or IV medical devices in Canada.

  For more information on how to obtain an MDL, see the *Guidance Document: How to Complete the Application for a New Medical Device Licence*.

- **Medical Device Establishment Licence (MDEL)** – a licence issued to Class I manufacturers as well as importers or distributors of all device classes to permit them to import or distribute a medical device in Canada.

To view active **MDEL** holders, see the Medical Devices Establishment Licence Listing.

For a list of all current **MDL** holders, see the Medical Devices Active Licences Listing (MDALL).

In general, any person who imports into, or sells a medical device for human use in Canada requires an MDEL (see exceptions). You must apply for and maintain your MDEL to ensure compliance with the *Food and Drugs Act* and its Medical Devices Regulations. To maintain your MDEL, you must do the following:

1. Submit an annual licence review application before April 1 of each year (see section 6).
2. Notify Health Canada within 15 calendar days, if there is a change to information under paragraphs 45(a) and (b) of the Medical Devices Regulations (see section 7).

Leasing a medical device is captured under the definition of "sell" (see section 2 of the *Food and Drugs Act*). If you lease or rent a medical device, you are subject to the requirements of the Medical Devices Regulations, including the requirement to hold an MDEL under section 44.

- **Importer** – a person in Canada, other than the manufacturer of a medical device, who is responsible for the medical device being brought into Canada for sale.

- **Distributor** – a person, other than a manufacturer, importer or retailer, who sells a medical device in Canada for resale or use, other than for personal use. A person outside of Canada selling medical devices into Canada is also considered a distributor.

- **Manufacturer** (as defined in section 1 of the Medical Devices Regulations) – a person who sells a medical device under their own name, or under a trademark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf.

For a complete list of definitions, see Appendix A - Glossary.

MDEL requirement based on activity type

The following table provides common examples/situations for when an MDEL is required under the *Food and Drugs Act* and its Medical Devices Regulations. See Establishment licence exemptions and Table 2: Licence requirements and exemptions below, for examples of when an MDEL may not be required.

Table 1: MDEL requirement based on activity type

MDEL: Medical device establishment licence

MDL: Medical device licence

Activity type	Description	Licence required
Importing	I am in Canada. I buy medical devices from a manufacturer and/or supplier (distributor) **outside** of Canada and sell them **in** Canada. The foreign manufacturer or distributor already has an MDEL.	MDEL
Importing	I am in Canada. I buy medical devices from a manufacturer and/or supplier (distributor) **outside** of Canada and sell them **in** Canada. The foreign manufacturer or distributor **may not** have an MDEL.	MDEL
Distributing	I am in Canada. I buy medical devices from a manufacturer and/or supplier (importer or distributor) **in** Canada and sell them **in** Canada.	MDEL

Activity type	Description	Licence required
Distributing	I am outside Canada. I sell medical devices **exclusively** to an MDEL holder in Canada. My name is **not** on the label.	No licence required
Distributing	I am outside Canada. I sell medical devices **exclusively** to healthcare facilities or retailers in Canada. My name is **not** on the label.	MDEL
Distributing	I am outside Canada. I sell medical devices to importers as well as healthcare facilities and/or retailers in Canada. My name is **not** on the label.	MDEL
Manufacturing	I am in or outside Canada. I sell **Class II, III or IV** medical devices in Canada that only have **my name** on the label as the manufacturer. I do not sell Class I medical devices in Canada.	MDL
Manufacturing	I am outside Canada. I sell **Class I** medical devices in Canada that only have **my name** on the label as the manufacturer. I do not sell Class II, III or IV medical devices in Canada. **I ship my devices directly to the Canadian retailer.**	MDEL
Manufacturing	I am outside Canada. I sell **Class I** medical devices in Canada that only have my name on the label as the manufacturer. I do not sell Class II, III or IV medical devices in Canada. **My client (importer/distributor) has an MDEL.**	No licence required

Activity type	Description	Licence required
Manufacturing	I manufacture medical devices in Canada. I sell **Class I** medical devices in Canada that only have my name on the label as the manufacturer. I do not sell Class II, III or IV medical devices in Canada. **My client (distributor) has an MDEL or I sell directly to the ultimate consumer.**	No licence required

Why do I need to get an MDEL?

An MDEL provides Health Canada assurance that medical devices sold or imported into Canada meet the safety requirements set out in the Medical Devices Regulations, and that procedures are in place to protect the public should a problem with a device be identified.

It also ensures that Health Canada is made aware of:

- Persons importing or distributing medical devices in Canada, including distributors located outside Canada, who are selling to Canadian facilities.
- Manufacturers of medical devices sold by MDEL holders, as well as the classification of those devices.
- Manufacturers of Class I medical devices who import or distribute their own devices.

Classification requirement

Your Medical Device Establishment Licence (MDEL) application **must** list the classes of medical devices for each manufacturer or supplier that you plan to import or distribute in Canada.

As an importer or a distributor of medical devices in Canada, it is your responsibility to contact the manufacturer for further information if you are uncertain of the classification of a medical device you intend to sell or import into Canada for human use.

If a medical device falls into multiple classes, the higher risk class will apply. For example, when a medical device is classified as both a Class III and Class IV, the final classification of the medical device will be Class IV.

Manufacturers are required to take reasonable measures to identify the risks inherent in a medical device and should be able to provide the classification for any of their medical devices being sold in Canada.

Links to guidance documents for medical device classification:

- Guidance for Industry – Keyword Index to Assist Manufacturers in Verifying the Class of Medical Devices
- *Guidance on the Risk-based Classification System for Non-In Vitro Diagnostic Devices (non-IVDDs)*
- *Guidance for the Risk-based Classification System for In Vitro Diagnostic Devices (IVDDs)*

It is the responsibility of the applicant to determine if they require an MDEL (for example, the medical device class and licensable activities you will be conducting). Fees for the examination of an MDEL application **cannot be refunded** once an application has been reviewed by Health Canada.

MDEL holders must demonstrate to Health Canada that they have met the regulatory requirements and have documented procedures in place, where applicable, related to the medical devices that they import or distribute (sell).

Manufacturers of Class II, III or IV medical devices only require a Medical Device Licence (MDL) to import or distribute **their own** medical devices in Canada.

It is your responsibility, as a regulated party, to understand your obligations under the *Food and Drugs Act* and its Medical Devices Regulations and to abide by them. Failure to comply with these obligations will lead to compliance and enforcement actions in accordance with the *Compliance and enforcement policy for health products (POL-0001)*.

Health Canada conducts inspections of MDEL licence holders to determine their compliance with the Medical Devices Regulations. Any party conducting a regulated activity can be inspected at any time. Guidance regarding the inspection process

can be found here: *How Health Canada inspects medical device establishments (GUI-0064)*.

Establishment licence exemptions

The following person are *exempt* from holding a Medical Device Establishment Licence (MDEL) under the Medical Devices Regulations to import into, or sell a medical device in Canada:

- Any person who imports a medical device for his/her own personal use.
- Retailers, including:
    - companies that sell medical devices to the end-user (ultimate consumer or end user) for their own personal use, or
    - manufacturers in Canada of Class I medical devices who sell their devices solely to ultimate consumers or end users.
- Health care facilities (as defined in section 1 of the Medical Devices Regulations) – means a facility that provides diagnostic or therapeutic services to patients. It includes a group of such facilities that report to one common management that has responsibility for the activities carried out in those facilities.
- Manufacturers of Class II, III or IV medical devices* that sell:
    - Medical devices for which they hold a valid medical device licence.
    - Medical devices subject to parts 2 and 3 of the Medical Devices Regulations.

  *(*To be exempt, the manufacturer cannot import or sell medical devices manufactured by other companies.)*
- Manufacturers of Class I medical devices* that import or distribute solely through a person that holds an establishment licence.

  *(*To be exempt, the manufacturer cannot import or sell medical devices manufactured by other companies.)*
- Dispensers (as defined in section 1 of the Medical Devices Regulations) – means a person who is a member of a professional governing body and who is entitled, by virtue of their membership in that body, to manufacture or adapt a medical device in accordance with a health care professional's written directions in order to meet the specific requirements of a patient.
- Anyone importing or selling devices only for use by animals (the label of the device must state that it is for use by animals).

- Anyone importing or selling only medical devices subject to parts 2 and 3 of the Medical Devices Regulations, including:
    - custom-made devices
    - medical devices for special access
    - medical devices for investigational testing involving human subjects (clinical trials)

- **Exporters** of medical devices that are exempt under section 37 of the *Food and Drugs Act*:
    - Section 37 applies to medical devices that, although manufactured in Canada, are not intended to be sold for use in Canada.
    - Companies intending to invoke section 37 of the *Food and Drugs* Act related to medical devices must also meet the relevant requirements under the Medical Devices Regulations.
- **Warehouses** that only store medical devices:
    - To be exempt, warehouses must not buy, sell or consign medical devices.

See Table 2 below, for examples of MDEL/MDL requirements and exemptions based on activity type.

Table 2: Licence requirements and exemptions

The following table provides examples of licence requirement and exemption for an MDEL under the *Food and Drugs Act* and its Medical Devices Regulations.

MDEL: Medical device establishment licence

MDL: Medical device licence

Example	Exempt or not?
An establishment contracts a person to make a Class I medical device.	The contractor **does not need an MDEL.** The establishment whose name is on the label is the legally recognized manufacturer and **must hold an MDEL** (unless otherwise exempted).
An establishment contracts a person to make a Class II, III or IV	The contractor **does not need an MDEL**.

Example	Exempt or not?
medical device and ship to an address.	The establishment whose name is on the label is the legally recognized manufacturer and **must hold an MDL** as the private label manufacturer.
An establishment manufactures Class I, II, III or IV medical devices.	The establishment **must hold an MDL** for the Class II, III or IV medical devices they manufacture. They **must also hold an MDEL** to sell their own Class I medical devices (unless these are solely distributed through another MDEL holder).
An establishment imports medical devices into Canada to later export to other countries from Canada.	The establishment **must hold an MDEL** as an importer. The manufacturer must hold an MDL in respect of its Class II, III or IV medical devices prior to its importation.
An establishment sells medical devices to hospitals, other health care facilities, or healthcare professionals/first responders.	The establishment **must hold an MDEL**. The hospital is not the ultimate consumer.
A hospital imports medical devices for use on patients.	An **MDEL is not required**. Health care facilities (for example, hospitals) are exempt, but the Class I manufacturer or distributor from whom the hospital purchased the Class I medical device **must hold an MDEL**. Manufacturers of a Class II, III or IV medical device must hold an **MDL** to import or distribute their own medical device to the hospital in Canada.
A medical supply store rents or loans medical devices to **patients.**	The medical supply store **does not need an MDEL**.

Example	Exempt or not?
	Rent and loan is considered a sale. In this scenario the sales are to the ultimate consumer, so they are considered retail sales and are exempt.
A medical supply store is renting or loaning medical devices to **hospitals/healthcare professionals or first responders**, including for temporary or trial use.	The medical supply store **must have an MDEL**. Rent and loan is considered a sale. The hospital/professional is not the ultimate consumer.
An establishment distributes or imports used medical devices.	The establishment **must hold an MDEL**. It does not matter whether the devices are new or used.
An establishment supplies a dispenser with materials that the dispenser then uses to make medical devices.	The establishment **does not require an MDEL** if the materials are not medical devices themselves. For example, contact lens buttons/blanks and hearing aid circuits are not themselves medical devices.

Getting and managing your establishment licence

Sections 4 to 9 of this guidance document explain how to apply for and maintain a Medical Device Establishment Licence (MDEL). It outlines the requirements for each licensable activity related to an MDEL, including applying for, cancelling, re-instating, and keeping an MDEL up-to-date and valid.

4. Types of MDEL applications

Below is a description of the five types of MDEL applications.

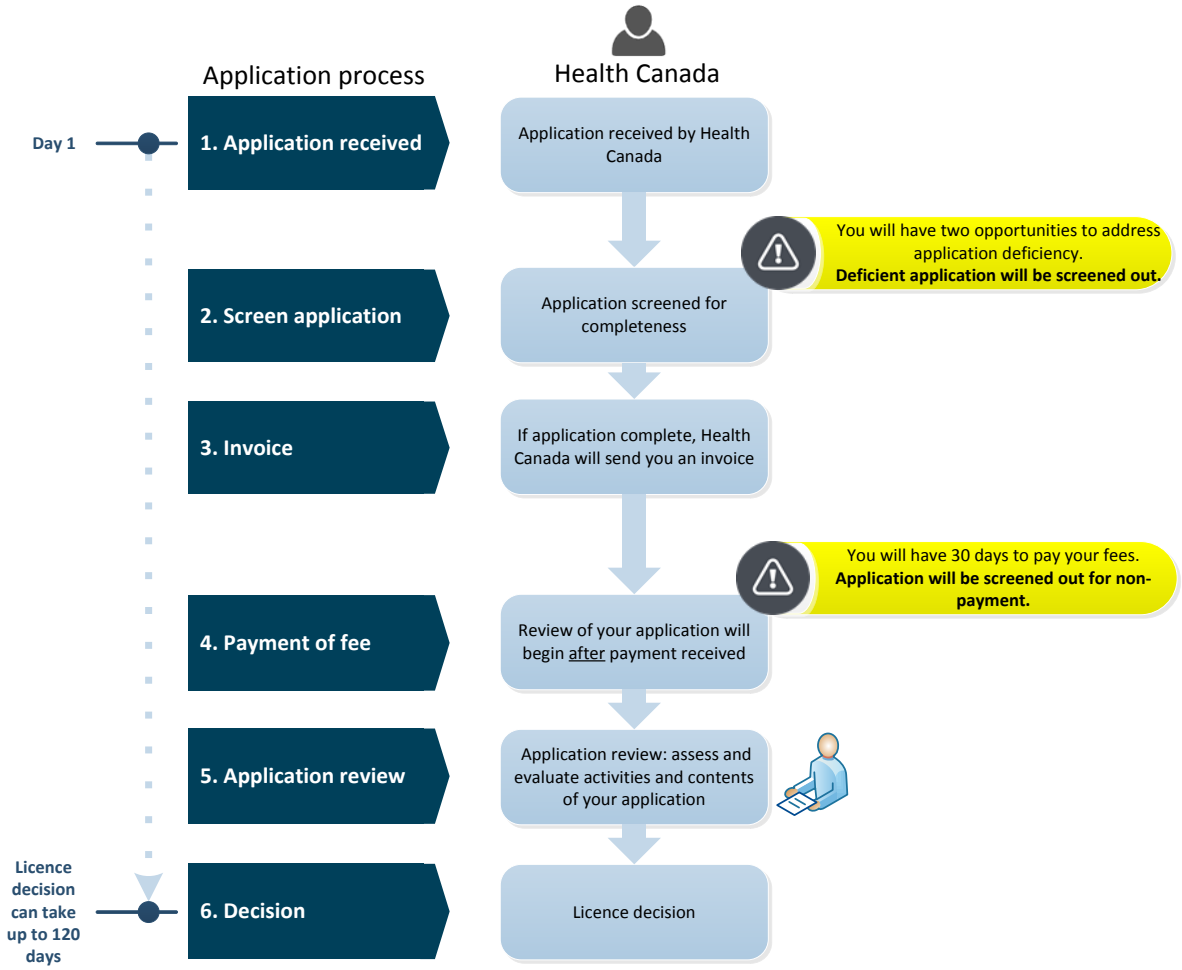
Table 3: MDEL application types and their respective requirements

Type	Requirements
1. New application	Required for new applicants. Also required if you are resuming the sale of medical devices after your previous licence was cancelled by Health Canada, or cancelled by you, as the licence holder. If your MDEL was cancelled because the licence was suspended for a period of more than 12 months, your establishment will need to submit documentation with the application to demonstrate that the situation(s) that gave rise to the suspension has been corrected. The documentation can include, but is not limited to, an adequate corrective and preventive action (CAPA) plan or a corrective action plan (CAP). To verify that the corrections have been implemented, your establishment will be inspected by Health Canada before a licence decision is issued.
2. Notification	Subsequent to the issuance of an MDEL, a notification to Health Canada is required **within 15 calendar days** should the following changes occur: • The name and address of the establishment. • The name, title and/or telephone number of the representative of the establishment to contact for any information concerning the application.
3. Cancellation	Required if you no longer conduct licensable activities under an MDEL. Health Canada has the authority to cancel your licence if: • You fail to submit an annual licence review application by April 1 of each calendar year, or

	• your MDEL has been suspended for a period of more than 12 months.
4. Amendment	If you require changes to information on your MDEL that is not captured under a notification. Examples include changing the activities or classes of medical devices, sites and/or list of manufacturers.
5. Reinstatement	Required if you want to resume selling, importing or manufacturing medical devices following the suspension of your MDEL by Health Canada. For your MDEL to be reinstated, your establishment will need to submit documentation with the application to demonstrate that the situation(s) that gave rise to the suspension has been corrected. The documentation can include, but is not limited to, an adequate corrective and preventive action (CAPA) plan or a corrective action plan (CAP). To verify the corrections your establishment will be inspected by Health Canada before a licence decision is issued.

5. Applying for an MDEL

Diagram 1. Medical Device Establishment Licence (MDEL) – application screening and review process



How to apply

Step 1. Complete the *Medical Device Establishment Licence application form (FRM-0292)*.

If you are submitting a new application, a notification, or a cancellation of an MDEL, you must follow all the applicable requirements under section 45 of the Medical Devices Regulations.

You must complete the *MDEL Application Form (FRM-0292)* even if you sell or import only one medical device, as quantity does not affect the application.

Include the following in your application:

1. Your establishments name and address.
2. The name, title and telephone number of the representative for your establishment.
3. A statement on whether you are importing or distributing medical devices, or both, or whether you are manufacturing Class I medical devices.
4. The names and addresses of the manufacturers for each medical device you will import or distribute.

The manufacturer is the establishment who is listed on the medical device label. It may not be the same establishment who you buy the medical device from. Check your labels before adding the manufacturer to your application.

5. The class (Class I, II, III or IV) of each medical device you will import or distribute.
6. An **attestation signed by a senior official** with respect to documented procedures that must be in place depending on the activities conducted at the establishment:

   Importers:

   - For importers of all classes of medical devices, an attestation stating that your establishment currently has written operating procedures for:
     - complaint handling, recalls, and maintenance of distribution records and
     - mandatory problem reporting.
   - For importers of Class II, III or IV medical devices, an attestation stating that your establishment currently has written operating procedures in place allowing the

medical devices to be properly handled, stored, delivered, installed, corrected and serviced, where applicable.

Distributors:

- For distributors of all classes of medical devices, an attestation stating that your establishment currently has written operating procedures for:
  - complaint handling, recalls, and maintenance of distribution records.
- For distributors of Class II, III or IV medical devices, an attestation stating that your establishment currently has written operating procedures in place allowing the medical devices to be properly handled, stored, delivered, installed, corrected and serviced, where applicable.

Manufacturers:

- For manufacturers of Class I medical devices that import or distribute their own medical devices, an attestation stating that your establishment currently has written operating procedures for:
  - complaint handling, recalls, and maintenance of distribution records and
  - mandatory problem reporting.

Written procedures will be verified during a regulatory inspection.

If the procedures that were attested to in the MDEL application are not available during an inspection, it will be considered a “false attestation”, which may lead to an MDEL suspension.

7. The site addresses of each building where the attested to documented procedures, under paragraphs 45(g) through 45(i) of the Medical Devices Regulations, are in place.
   - You must indicate at least one site in section 4 of MDEL application form (FRM-0292) where the documented procedures are stored.
   - If the site listed is not the same legal entity, then it is the responsibility of the licence holder to ensure that site(s) listed in section 4 of their MDEL application has the applicable procedures in place and that inspectors are able to verify compliance without impediment.

- Manufacturers of the medical devices that you import or distribute will not be accepted as a site.
- A site must be in the same country as the establishment.
- A P.O. Box is not considered an acceptable site address.

Detailed instructions for how to complete the *MDEL application form (FRM-0292)* are included with the form.

Step 2. Email the completed application form to the MDEL application email account at: hc.mdel.application.leim.sc@canada.ca.

If you submit your application to Health Canada via email, but have other items that need to be sent by mail, include a copy of the email as the cover page to the mailed information. Send to:

Medical Devices Compliance and Establishment Licensing Unit
Regulatory Operations and Enforcement Branch (ROEB)
Jeanne Mance Building – Address Locator 1903C
200 Eglantine Driveway – 3rd Floor
Ottawa, ON K1A 0K9

When will you hear from us?

Performance standard

The performance standard to issue a decision is **120 calendar days** from the day a complete application is received, for the following application types:

- New application
- Annual Licence Review (ALR) application

For more information on the performance standard, see the *Performance Standards for the Fees in Respect of Drugs and Medical Devices Order*.

After you submit your application to Health Canada

After an application is received by Health Canada, it will be screened for completeness. MDEL applications are screened to verify completeness against the following criteria:

- application file is not corrupt

- application file is not password protected (we do not accept password protected PDF documents)
- all relevant sections of the application form are complete and signed
- presence of all indicated documents/emails
- verification/confirmation of changes requested

If the application is deemed complete, Health Canada will notify you via email that your application has been accepted for further examination/review, and include an invoice for the applicable fees.

Payment is due within 30 calendar days from the date of invoice.

If the fees that are due for an MDEL application are not paid in a timely manner, Health Canada has the authority to withhold services, approvals, rights and/or privileges. Should Health Canada use this authority to stop the review of an application, the period of time where services are withheld does not count toward Health Canada's 120 day service standard.

For more information about MDEL fees, see the *Guidance document – Fees for the Review of Medical Device Establishment Licence Applications* and *How to Pay Your Establishment Licence Fees*.

Pause-the-clock policy

Health Canada uses a "clock" to measure performance against the 120 calendar day service standard.

- The clock starts on the date when Health Canada receives your complete application.
- In cases where the application requirements listed in the *Food and Drugs Act* or its Medical Devices Regulations are not met, a deficiency notice is issued to the applicant and the clock is paused.
- When Health Canada receives a response to a deficiency notice, the clock will resume.

Health Canada will contact you by email during the licensing process if we have questions or need additional information.

A **deficiency** is when an application cannot be further processed by Health Canada because it does not meet regulatory requirements or the intent/scope of the application is not clear. The applicant is provided an opportunity to submit the missing or incomplete information in order to avoid receiving a negative decision within 30 business days.

In such circumstances, the application clock would be paused for up to 30 business days at a time. If no response is received after the first deficiency notice or if the response that is received is inadequate, a second notice will be issued providing an additional 30 business days to respond.

If no response is received after the second notice is issued to address the same deficiency, or if the received response is inadequate, the application will be rejected.

Checking your application status

You may request a status update by emailing hc.mdel.questions.leim.sc@canada.ca, if:

- You have not received a notice that your application has been accepted for further examination within 30 calendar days from the date that it was received by our office.
- It has been **120 calendar days** since you submitted your application and Health Canada has not notified you of our decision about your application.

Licensing decisions

If your application meets all the requirements of section 45 of the Medical Devices Regulations, Health Canada will issue a Medical Device Establishment Licence (MDEL).

Health Canada may **refuse to issue you an MDEL** if your MDEL application contains false or misleading statement(s).

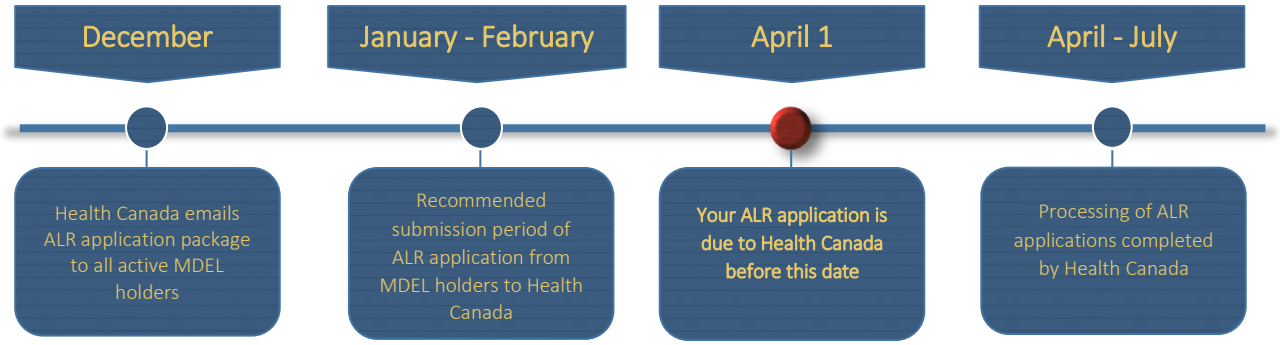
Health Canada will **refuse to issue you an MDEL** if the Minister or delegated authority has reasonable grounds to believe that issuing you an MDEL would constitute a risk to the health or safety of patients, users or other persons.

If Health Canada refuses to issue you an MDEL due to these reasons, as listed in section 47 of the Medical Devices Regulations, you will be notified in writing of the reasons for refusal and given an Opportunity to be Heard (OTBH).

6. Submitting your Annual Licence Review (ALR) application

Under the Medical Devices Regulations, all active MDEL holders **must** submit an application for annual licence review (ALR) **before April 1** of each year. The purpose of the ALR is to ensure continued compliance with regulatory requirements and to maintain up-to-date information. You must submit this application and pay the fee upon invoicing even if there are no changes to your licence.

Diagram 2. Annual Licence Review timeline



As a courtesy, Health Canada sends an ALR application package to all MDEL holders at the end of each calendar year. However, it is your responsibility to ensure a complete ALR application is received by Health Canada before April 1 of each year. If you do not receive your ALR package by mid-January, contact Health Canada. See Appendix C – Contact information for a list of contacts.

If you do not submit an application for ALR before April 1 of each year, Health Canada will cancel your MDEL.

You are **not** permitted to conduct any licensable activities with a cancelled MDEL. See paragraph 51.1(b) of the Medical Devices Regulations for details.

If an MDEL is cancelled and the establishment wishes to resume activities, you are required to apply for a **new** MDEL and meet the requirements set out in section 45 of the Medical Devices Regulations, as applicable.

After you submit an ALR application:

- Your ALR application review will be completed within 120 calendar days from the day the complete application is received by Health Canada.
- Your licence will continue to be valid as long as you submit your ALR application before April 1 of each year, and pay the fee within 30 calendar days from the date of invoice.
- You will receive a confirmation by email that your application has been entered in our system, and another confirmation when the application review process is complete.
- You will be contacted if the application is incomplete or if Health Canada has concerns.
- You will only receive a revised copy of your MDEL if, as a result of the ALR process, there is a change that affects the content of your MDEL.

7. Updating or cancelling your MDEL

Submitting a notification

Under section 48 of the Medical Devices Regulations, licence holders are required to notify Health Canada within 15 calendar days of a change in contact information, as described below.

You **must** submit a notification to Health Canada within 15 calendar days of:

- a change in the name or address of your establishment, or
- a change in the information of the establishment representative associated with your MDEL application (including name, title and telephone number).

Notify Health Canada by:

- submitting a revised FRM-0292 (follow the same steps described in How to apply) via email to hc.mdel.application.leim.sc@canada.ca.

There are no fees associated with making changes, notifications or amendments to your MDEL.

Submitting an amendment

You must inform Health Canada of any change affecting the information on your MDEL (for example, list of manufacturers, change in activity or class of device).

- **Mid-December to March 31** – submit your changes as part of your ALR application.
- **April 1 to mid-December** – submit your change(s) using FRM-0292.

Note: In the case of a change in contact information, you must notify Health Canada within 15 calendar days – see Submitting a notification.

For help with amending your MDEL information, contact the Medical Devices Compliance and Establishment Licensing Unit at hc.mdel.questions.leim.sc@canada.ca (see Appendix C for contact information).

Cancelling your licence

You must inform Health Canada if you choose to cancel your MDEL. Before you submit the application for a cancellation (using FRM-0292), you must ensure that all activities under the MDEL have ceased.

Only the contact person or senior official for the MDEL may submit a cancellation request to Health Canada.

Health Canada may inspect an establishment that had its MDEL cancelled, to verify that all licensable activities have ceased.

Health Canada will review the cancellation request and notify the contact person, via email, that the MDEL has been cancelled and is no longer active.

8. Steps to take if your MDEL is suspended or cancelled by Health Canada

An MDEL may be suspended or cancelled by Health Canada in accordance with the Medical Devices Regulations. Contact the Medical Devices Compliance and Establishment Licensing Unit (see Appendix C for contact information) should you have any question concerning the suspension or cancellation of your MDEL.

If your MDEL is suspended or cancelled, you must **immediately stop importing or selling medical devices**. If you fail to stop these activities, Health Canada may take compliance and enforcement actions, as outlined in the *Compliance and enforcement policy for health products (POL-0001)*.

Health Canada's guidance on *Medical Device Compliance and Enforcement (GUI-0073)* states that if a regulated party does not voluntarily respond to Health Canada requests, such as inspections, request for copies of procedures, etc., to comply with the Medical Devices Regulations, measures can be considered, including the suspension of an establishment licence.

Suspension of your MDEL by Health Canada

Health Canada may suspend an MDEL when it has reasonable grounds to believe that:

- You (as the MDEL holder) have contravened the Medical Devices Regulations or any provisions of the *Food and Drugs Act* related to medical devices.
- You (as the MDEL holder) have made a false or misleading statement when applying for your licence.
- Not suspending your MDEL would constitute a risk to the health or safety of patients, users or other persons.

In making a decision to suspend (under section 49 or 50 of the Medical Devices Regulations), Health Canada will consider the MDEL holder's compliance history and the risk to the health or safety of patients, users or other persons in allowing the licence to remain valid.

Before suspending your establishment licence under **section 49 of the Medical Devices Regulations**, Health Canada will send you a written notice explaining:

- the reason(s) for the suspension
- action(s)/corrective measure you failed to take within a prescribed timeline following an inspection
- the opportunity to be heard (OBTH) process

Alternatively, your establishment licence may be **suspended under section 50 of the Medical Devices Regulations,** without an opportunity to be heard, to prevent injury to the health or safety of patients, users or other persons. If your licence is suspended under section 50 of the Medical Devices Regulations, Health Canada will notify you in writing and outline:

- the reason(s) for the suspension
- instructions on how to be heard if you disagree with the suspension

Health Canada may inspect an establishment that had its MDEL suspended to verify that all licensable activities have ceased.

Reinstating a suspended MDEL

You may submit a reinstatement application if you want to resume selling, importing or manufacturing medical devices **after Health Canada suspends your MDEL**.

To reinstate an MDEL after suspension:

- Correct the problems that caused the suspension.

  To be reinstated, your establishment will need to submit documentation with the application to demonstrate that the situation(s) that gave rise to the suspension has been corrected. The documentation can include, but is not limited to, an adequate corrective and preventive action (CAPA) plan or a corrective action plan (CAP).

To verify the corrections, your establishment will be inspected by Health Canada before a licence decision is issued.

- Submit an MDEL application form (FRM-0292). Follow the same steps as described in Applying for a licence.

- Submit payment within 30 calendar days from the date of invoice.

If the MDEL fees have not been paid, Health Canada has the authority to withhold services, approvals, rights and/or privileges.

For more information about fees related to MDELs, see the *Guidance document – Fees for the Review of Medical Device Establishment Licence Applications* and *How to Pay Your Establishment Licence Fees*.

- Your MDEL will be reinstated:

  1. If your MDEL application meets all the requirements under section 45 of the Medical Devices Regulations.

  2. Health Canada has verified that you have corrected the problems that caused the suspension.

Once the suspended MDEL has been reinstated, you may resume licensable activities.

Cancellation of your MDEL by Health Canada

The Minister or delegated authority **must** cancel an MDEL when:

- Your licence has been suspended for a period of more than 12 months.
- You do not submit an annual licence review application before April 1 of each year.

Health Canada may inspect an establishment that had its MDEL cancelled, to verify that all licensable activities have ceased.

Applying for a licence after cancellation

Health Canada's authority to reinstate an MDEL is limited to suspended MDELs. If an MDEL is cancelled and the establishment wishes to resume activities, you are required to apply for a **new** MDEL and meet the requirements set out in section 45 of the Medical Devices Regulations, as applicable.

To apply for an MDEL after cancellation:

- If cancelled following a suspension, you must first correct the problems that caused the suspension and cancellation.

  Your establishment must submit documentation with the application to demonstrate that the situation that gave rise to the suspension and cancellation has been corrected. The documentation can include, but not limited to, an adequate corrective and preventive action (CAPA) plan or a corrective action plan (CAP).

To verify the corrections, your establishment will be inspected by Health Canada before a licence decision is issued.

- Submit an MDEL application form (FRM-0292). Follow the same steps described in Applying for a licence.

- Submit payment within 30 calendar days from the date of invoice.

  If the MDEL fees have not been paid, Health Canada has the authority to withhold services, approvals, rights and/or privileges.

  For more information about fees related to MDELs, see the *Guidance document – Fees for the Review of Medical Device Establishment Licence Applications* and *How to Pay Your Establishment Licence Fees*.

- You will be issued a **new** MDEL:

  1. If your MDEL application meets all the requirements under section 45 of the Medical Devices Regulations.

2. Health Canada has verified that you have corrected the problems that caused the suspension and cancellation.

Once a new MDEL number has been issued, you may resume licensable activities.

Disputes and the opportunity to be heard

To begin a dispute process, or to have the opportunity to be heard about a licence suspension and/or refusal, contact the Medical Devices Compliance and Establishment Licensing Unit (see Appendix C for contact information).

9. Additional regulatory requirements of an MDEL holder

This section outlines some of the key responsibilities of a Medical Device Establishment Licence (MDEL) holder.

Health Canada may inspect anyone who has an MDEL to ensure they comply with the *Food and Drugs Act* and its Medical Devices Regulations. For more information, see:
How Health Canada inspects medical device establishments (GUI-0064).

Maintaining records

Distribution records

The manufacturers, importers and distributors of a medical device must each maintain a distribution record for each device. You must also have a documented procedure in place for how you maintain your distribution records, as you attested to in your application for an MDEL.

Your distribution record must contain enough information to allow a complete and rapid withdrawal of any medical device from the market. Your procedures should specify the retention time for your distribution records and how they will be maintained.

Section 55 of the Medical Devices Regulations specifies that:

The manufacturer, importer and distributor shall retain the distribution record maintained in respect of a medical device for the longer of

(a) the projected useful life of the device, and
(b) two years after the date the device is shipped.

See sections 52–56 of the Medical Devices Regulations for more information on distribution record requirements, including minimum retention periods for distribution records and how to maintain records to allow for quick retrieval.

Complaint handling

Medical device manufacturers, importers and distributors must also maintain records of reported problems for all medical devices they have sold relating to the performance characteristics or safety of the device. These records must include all actions taken to respond to these problems. You must also have documented procedures for complaint handling and recalls. For more information on complaint handling, see the *Guidance on Investigation of Reported Medical Device Problems (GUI-0065)*.

Reporting problems

Importers and manufacturers of medical devices are required to provide a preliminary and final report to Health Canada about devices that they sold in Canada for which incidents that took place inside or outside Canada have been brought to their attention.

To avoid duplicate reporting, the manufacturer of the device may allow the importer to prepare and submit the preliminary and final reports on the manufacturer's behalf if the information that must be included is identical. The manufacturer must inform Health Canada, in writing, if such permission has been granted to the importer. However, a manufacturer may not prepare and submit a report on behalf of an importer.

For more information on what types of incidents must be reported and what to include in the report, see the *Guidance Document for Mandatory Problem Reporting for Medical Devices*.

Recalls

When recalling a medical device, the manufacturer and importer of that device must each send a report to Health Canada, on or before the recall, outlining the information specified in sections 64–65 of the Medical Devices Regulations.

As soon as possible after completing a recall, the manufacturer and importer must each report to Health Canada the results of the recall and the actions taken to prevent a recurrence of the problem. A manufacturer may allow the importer to submit the information and documents relating to the recall on its behalf by notifying Health Canada in writing if the information that must be submitted is identical for both of them.

For more information on recall requirements, see the *Recall Policy for health products (POL-0016)* and the *Guide to Recall of Medical Devices (GUI-0054)*.

Appendices

Appendix A – Glossary

Acronyms

ALR: Annual Licence Review

Act: *Food and Drugs Act*

DEL: Drug Establishment Licence

IVDDs: In Vitro Diagnostic Devices

MDEL: Medical Device Establishment Licence

MDL: Medical Device Licence

Non-IVDDs: Non-In Vitro Diagnostic Devices

OTBH: Opportunity to be Heard

ROEB: Regulatory Operations and Enforcement Branch

Terms

The following definitions explain how terms are used in this guidance document. If there is a conflict with a definition in the *Food and Drugs Act*, Medical Devices Regulations and/or the *Fees in Respect of Drugs and Medical Devices Order,* the definition in the legislation prevails.

Custom-made device (as defined in section 1 of the Medical Devices Regulations) - means a medical device, other than a mass-produced medical device, that

(a) is manufactured in accordance with a health care professional's written direction giving its design characteristics;

(b) differs from medical devices generally available for sale or from a dispenser; and

(c) is

(i) for the sole use of a particular patient of that professional, or

(ii) for use by that professional to meet special needs arising in the course of his or her practice. (instrument fait sur mesure)

Device (as defined in section 2 of the *Food and Drugs Act*) – Any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in:

(a) diagnosing, treating, mitigating or preventing a disease, disorder or abnormal physical state, or any of their symptoms, in human beings or animals,

(b) restoring, modifying or correcting the body structure of human beings or animals or the functioning of any part of the bodies of human beings or animals,

(c) diagnosing pregnancy in human beings or animals,

(d) caring for human beings or animals during pregnancy or at or after the birth of the offspring, including caring for the offspring, or

(e) preventing conception in human beings or animals;

however, it does not include such an instrument, apparatus, contrivance or article, or a component, part or accessory of any of them, that does any of the actions referred to in paragraphs (a) to (e) solely by pharmacological, immunological or metabolic means or solely by chemical means in or on the body of a human being or animal.

Dispenser (as defined in section 1 of the Medical Devices Regulations) – A person who is a member of a professional governing body and who is entitled, by virtue of their membership in that body, to manufacture or adapt a medical device in accordance with a health care professional's written directions in order to meet the specific requirements of a patient.

Distributor – A person, other than a manufacturer, an importer or a retailer, who sells a medical device in Canada for the purpose of resale or use, other than for personal use. A person outside of Canada selling medical devices into Canada is also considered to be a distributor.

Health care facility (as defined in section 1 of the Medical Devices Regulations) – A facility that provides diagnostic or therapeutic services to patients. It includes a group of such facilities that

report to one common management that has responsibility for the activities carried out in those facilities.

Health care provider – Any person who provides diagnostic or therapeutic services to individuals. This includes emergency first aid services by fire and ambulance departments.

Importer – A person in Canada, other than the manufacturer of a medical device, who is responsible for the medical device being brought into Canada for sale.

Inspection –Monitoring and assessment against the applicable requirements of the Act and its associated regulations. Inspections are routinely conducted based on risk to assess compliance.

Manufacturer (as defined in section 1 of the Medical Devices Regulations) – A person who sells a medical device under their own name, or under a trade-mark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labeling, packaging, refurbishing or modifying the device, or for assigning to it a purpose whether those tasks are performed by that person or on their behalf.

Medical device (as defined in section 1 of the Medical Devices Regulations) – A device within the meaning of the Act, but does not include any device that is intended for use in relation to animals.

New applicant – A "new" applicant is a person who has never applied for an MDEL before, including under another name (or previously cancelled MDEL).

Person (as defined in section 2 of the *Food and Drugs Act* and section 1 of the Medical Devices Regulations) – An individual or an *organization* as defined in section 2 of the *Criminal Code*. It includes a partnership and an association.

Procedure – A logically distinct set of activities designed to accomplish a specific task(s). It is concerned with how to achieve the task, rather than what is to be achieved. It defines the work that should be done, and explains how it should be done, who should do it, and under what circumstances. The procedure defines what authority and what responsibility has been allocated, which supplies and materials should be used, and which documents and records must be used to carry out the work.

Record – A document stating results achieved or providing evidence of activities performed.

Retailer – A person who sells a device, or a service using a device, solely to the ultimate consumer.

Many retailers may not be aware whether devices are being purchased by the ultimate consumer for their own use. Where a sale occurs to those who are identifiable as not being the ultimate consumer, the seller is considered to be a distributor, and not a retailer.

Sales agent – A person who is authorized or appointed by a manufacturer to sell or distribute their products as per the attested to procedures, without taking ownership of these products. The sales agent reports to the MDEL holder at one of the sites listed on the MDEL.

Sell (as defined in section 2 of the *Food and Drugs Act*) – Includes

> (a) offer for sale, expose for sale or have in possession for sale — or distribute to one or more persons, whether or not the distribution is made for consideration, and
>
> (b) lease, offer for lease, expose for lease or have in possession for lease.

Senior official – The senior official listed on a Medical Device Establishment Licence (MDEL) application is the person who has direct knowledge of the procedures in place, as confirmed by signing attestations in section 7 on the *MDEL application form* (FRM-0292).

Site(s) – Any additional building that is used by the MDEL holder (establishment) for keeping the procedures attested to in paragraphs 45(g) to (i) of the Medical Devices Regulations. A P.O. Box is not considered an acceptable site address. A site must be in the same country as the establishment.

Special access (as per Part 2, Medical Devices Regulations) – Access to a medical device for emergency use or if conventional therapies have failed, are unavailable or are unsuitable.

Supplier – Any person, other than the manufacturer, who distributes (sells) a medical device to an MDEL holder for the purpose of import or sale in Canada.

Ultimate consumer / end-user – The individual (also "end-user") who buys or receives a medical device for their own personal use (including within their household) or who receives treatment or is diagnosed with a device from a third party such as a health care facility or provider. Businesses that buy devices (e.g. first aid kits, disposable gloves) solely for use by their employees during work hours are also ultimate consumers, so long as their business does not offer health services to employees or other individuals.

Warehouse – A commercial warehouse would not require an establishment licence if they are only providing storage service and do not purchase, accept products on consignment, or enter into contracts for the sale of medical devices.

Appendix B – References

Laws

Criminal Code
https://laws-lois.justice.gc.ca/eng/acts/C-46/

Fees in Respect of Drugs and Medical Devices Order
https://laws-lois.justice.gc.ca/eng/regulations/SOR-2019-124/FullText.html

Financial Administration Act
laws-lois.justice.gc.ca/eng/acts/F-11/index.html

Food and Drugs Act
laws-lois.justice.gc.ca/eng/acts/F-27/index.html

Medical Devices Regulations
laws-lois.justice.gc.ca/eng/regulations/SOR-98-282/index.html

Application documents

Medical device establishment licence application: form and instructions (FRM-0292)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/forms/medical-device-establishment-licence-application-form-instructions-0292.html

Guidance

Compliance and enforcement policy for health products (POL-0001)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/policies-standards/compliance-enforcement-policy-0001.html

Fees in Respect of Human Drugs and Medical Devices
https://www.canada.ca/en/health-canada/services/drugs-health-products/funding-fees/fees-respect-human-drugs-medical-devices.html

Guidance document – Fees for the Review of Medical Device Establishment Licence Applications
https://www.canada.ca/en/health-canada/services/drugs-health-products/funding-fees/review-medical-device-establishment-licence.html

Guidance Document for Mandatory Problem Reporting for Medical Devices
https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/guidance-document-mandatory-problem-reporting-medical-devices-health-canada-2011.html

Guidance for the Risk-based Classification System for In Vitro Diagnostic Devices (IVDDs)
https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/guidance-document-guidance-risk-based-classification-system-vitro.html

Guidance on Drug Establishment Licences and Associated Fees (GUI-0002)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/directives-guidance-documents-policies/guidance-drug-establishment-licences-drug-establishment-licensing-fees-0002/document.html#s1

Guidance on Investigation of Reported Medical Device Problems (GUI-0065)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/problem-reporting/guidance-investigation-reported-medical-device-problems-0065.html

Guidance on the Risk-based Classification System for Non-In Vitro Diagnostic Devices (non-IVDDs)
https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/guidance-document-guidance-risk-based-classification-system-non-vitro-diagnostic.html

Guidance on Medical Device Compliance and Enforcement (GUI-0073)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/medical-devices/guidance-medical-device-compliance-enforcement-0073.html

How Health Canada inspects medical device establishments (GUI-0064)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/medical-devices/inspects-medical-device-establishments-0064.html

Guide to Recall of Medical Devices (GUI-0054)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/problem-reporting/medical-devices-recall-guide-0054.html

How to Pay Your Establishment Licence Fees
https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/cost-recovery/pay-fees/establishment-licences.html

Notice: Classification of Medical Devices used to Deliver Drugs by Smoking
https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/activities/announcements/notice-classification-devices-deliver-drugs-smoking.html

Performance Standards for the Fees in Respect of Drugs and Medical Devices Order
https://www.canada.ca/en/health-canada/services/publications/drugs-health-products/performance-fees-drugs-medical-devices.html

Policy on Drug/Medical Device Combination Products – Decisions
https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/policies/policy-drug-medical-device-combination-products-decisions.html

Recall Policy for health products (POL-0016)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/drugs/recall-policy-0016.html

Online listings

Keyword Index to Assist Manufacturers in Verifying the Class of Medical Devices
https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/guidance-industry-keyword-assist-manufacturers-class-medical-devices.html

Medical Devices Active Licence Listing (MDALL)
https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/licences/medical-devices-active-licence-listing.html

Medical Devices Establishment Licence Listing
https://health-products.canada.ca/mdel-leim/index-eng.jsp

Medical device inspections
http://www.healthycanadians.gc.ca/apps/md-im/index-en.htm

Appendix C – Contact information

Medical Device Establishment Licences (MDEL)

For questions about medical device establishment licences and the application process, contact the:

Medical Devices Compliance and Establishment Licensing Unit
Regulatory Operations and Enforcement Branch (ROEB), Health Canada
Jeanne Mance Building – Address Locator 1903C
200 Eglantine Driveway – 3rd Floor
Ottawa, ON K1A 0K9
Email: hc.mdel.questions.leim.sc@canada.ca
Telephone: 613-954-6790

For questions about invoicing and fees, contact the:

Cost Recovery Invoicing Unit
Regulatory Operations and Enforcement Branch (ROEB), Health Canada
Jeanne Mance Building – Address Locator 1904C
200 Eglantine Driveway – 4th Floor
Ottawa, ON K1A 0K9
Email: hc.criu-ufrc.sc@canada.ca
Fax: 613-957-4147

Medical Device Licences (MDL)

For questions about medical devices (including classification, labelling, clinical trials and obtaining a medical device licence), contact the:

Medical Devices Directorate
Health Products and Food Branch, Health Canada
Holland Cross, Tower A – Address Locator 3002
11 Holland Avenue – 2nd Floor
Ottawa, ON K1A 0K9
Email: hc.meddevices-instrumentsmed.sc@canada.ca
Fax: 613-957-6345
Teletypewriter: 1-800-465-7735 (Service Canada)