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# How Health Canada inspects medical device establishments



GUI-0064

Canada

## How Health Canada inspects medical device establishments (GUI-0064)

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### Disclaimer

This document does not constitute part of the *Food and Drugs Act* (the 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.

Ce document est aussi disponible en français.

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# About this document

## 1. Purpose

These guidelines describe how Health Canada inspects licensed medical device establishments (companies). They describe the inspection process and explain how inspectors assess compliance with the [Food and Drugs Act](#) (Act) and [Medical Devices Regulations](#) (Regulations).

These guidelines will help anyone with a medical device establishment licence understand and prepare for an inspection. They also ensure that inspections are carried out in a consistent manner no matter where or when they take place.

## 2. Scope

These guidelines apply to you if you have a medical device establishment licence (MDEL) and you are a:

- class I medical device manufacturer
- importer (Class I–IV medical devices)
- distributor (Class I–IV medical devices)



You are a distributor or an importer if you:

- rent or loan medical devices
- distribute devices for use as samples sell devices (regardless of number or amount) to health care facilities or providers who then sell the device to a patient (ultimate consumer or end-user)
- supply devices to a chain of retail outlets that are individually owned and operated (either independently or under a franchise agreement)

A distributor or importer is not the same as a retailer, who sells medical devices (or services using a device) only to the consumer. As a distributor or an importer, you must have an establishment licence to carry out your activities legally. (Retailers do not need a licence.)

You may also be inspected if you do **not** have an establishment licence but you are subject to the Act and Regulations. This includes:

- class I device manufacturer who imports or distributes their medical device through someone who has an establishment licence
- company or person subject to one of the following sections in the Regulations:
  - Part 2 – “Custom-made devices and medical devices to be imported or sold for special access”
  - Part 3 – “Medical devices for investigational testing involving human subjects”
- class II, III or IV manufacturer (including private-label manufacturer) who has a medical device licence



If you do not have a medical device establishment licence or need help in completing the application, see [\*Guidance on Medical Device Establishment Licensing and Medical Device Establishment Licence Fees \(GUI-0016\)\*](#).

# About inspections

## 3. How inspections work

Health Canada may inspect anyone who has a medical device establishment licence to ensure they comply with the *Food and Drugs Act* (Act) and the Medical Devices Regulations (Regulations). Those inspections support Health Canada's national compliance and enforcement program.

During the inspection, inspectors assess whether your establishment (company) complies with the parts of the Act and the Regulations that apply to you. Companies are manufacturers, importers, distributors, persons, partnerships and associations.

Following the inspection, inspectors rate companies as compliant or non-compliant with the Act and Regulations. The inspector bases the rating on the risk associated with the inspection's findings.



You can find information about the risk ratings in [Guidance on Risk Classification of Medical Device Observations \(GUI-0079\)](#).

### Focus of inspections

The activities you carry out under your medical device establishment licence (MDEL) are the focus of the inspection.

Health Canada inspectors will look at your procedures and processes to detect and respond to risks to safety and effectiveness. They will also look at the label and licence requirements that govern your actions to import, advertise and sell medical devices.

Separate inspections, called audits, assess your compliance with the quality management system standard (ISO 13485) needed to get a medical device licence. These audits are carried out by quality management system auditors working for registrars recognised by the Minister under the Canadian Medical Devices Conformity Assessment System (CMDCAS) or the Medical Device Single Audit Program (MDSAP). This type of inspection applies to you if you:

- design and/or manufacture class II, III or IV devices

- have a valid ISO 13485 quality management system certificate issued under CMDCAS or MDSAP

In spite of the audit of your quality management system, Health Canada inspectors may look to see that any Class II, III or IV device you import or sell:

- has a medical device licence
- is labelled and classified properly

## Health Canada’s authority to inspect

Under section 22(1) of the Act, Health Canada appoints inspectors to enforce the Act and ensure compliance. Section 23 of the Act also outlines the powers given to inspectors so they can perform their role.

While inspectors focus on establishment licence activities, section 23 gives them the power to examine and take action against anything that is not compliant with the Act and Regulations. Inspectors decide on the course of action to take based on the risk the deviation, deficiency or failure poses to health and safety.

## When inspections take place

Health Canada inspects licensed companies located inside and outside of Canada.

### Regular inspections

Health Canada conducts inspections based on risk and works continuously to refine this approach to planning inspections. For the most part, inspections are currently carried out on a repeated basis as follows:

- domestic manufacturers – every three years
- importers – every four years
- domestic distributors – every five years



An inspection carried out within the inspection cycle is a “regular inspection.” A regular inspection is the most common type of inspection Health Canada carries out. It assesses all the requirements of the Act and Regulations that apply to you. See Appendix B, [Checklist of regulations that apply to you](#), for what you will be assessed against.

## Special-case inspections

Health Canada also inspects companies outside of its inspection cycle. The decision to carry out a special-case inspection is based on risk factors such as:

- type of activity (manufacturer, importer, distributor)
- classification of devices (Class I, II, III or IV)
- compliance history
- year licensed
- company location (i.e. foreign or domestic)

There are five types of special-case inspections:

1. **New inspection** – The first inspection of a newly licensed company that is carried out in the same fiscal year (April to March) you get your establishment licence.
2. **Reassessment** – The inspection of a company that received a compliant rating during a regular inspection on the condition that it corrects deviations, deficiencies or failures. The inspector may decide to reassess at any time during or after the inspection. A reassessment usually takes place within 12 months of the regular inspection.
3. **Re-inspection** – The inspection of a company that received a non-compliant rating during a regular inspection. The re-inspection focuses on any deviations, deficiencies or failures to comply with regulatory requirements. A re-inspection usually takes place within 12 months of the regular inspection.
4. **Foreign site inspection** – The inspection of a company that is located outside of Canada and that has a medical device establishment licence.
5. **Targeted inspection** – The inspection of a company that Health Canada is concerned might not be complying with specific parts of the Act or Regulations. A targeted inspection looks at different criteria than what are used in a regular inspection.

## Amount of time inspections take

Inspections of companies in Canada are conducted on location. On-location inspections of small companies are generally completed in one day. Inspections of larger companies may take from two to five days.



Inspections will take a different form if you run a “virtual” or online company and do not rely on physical buildings to store your product.

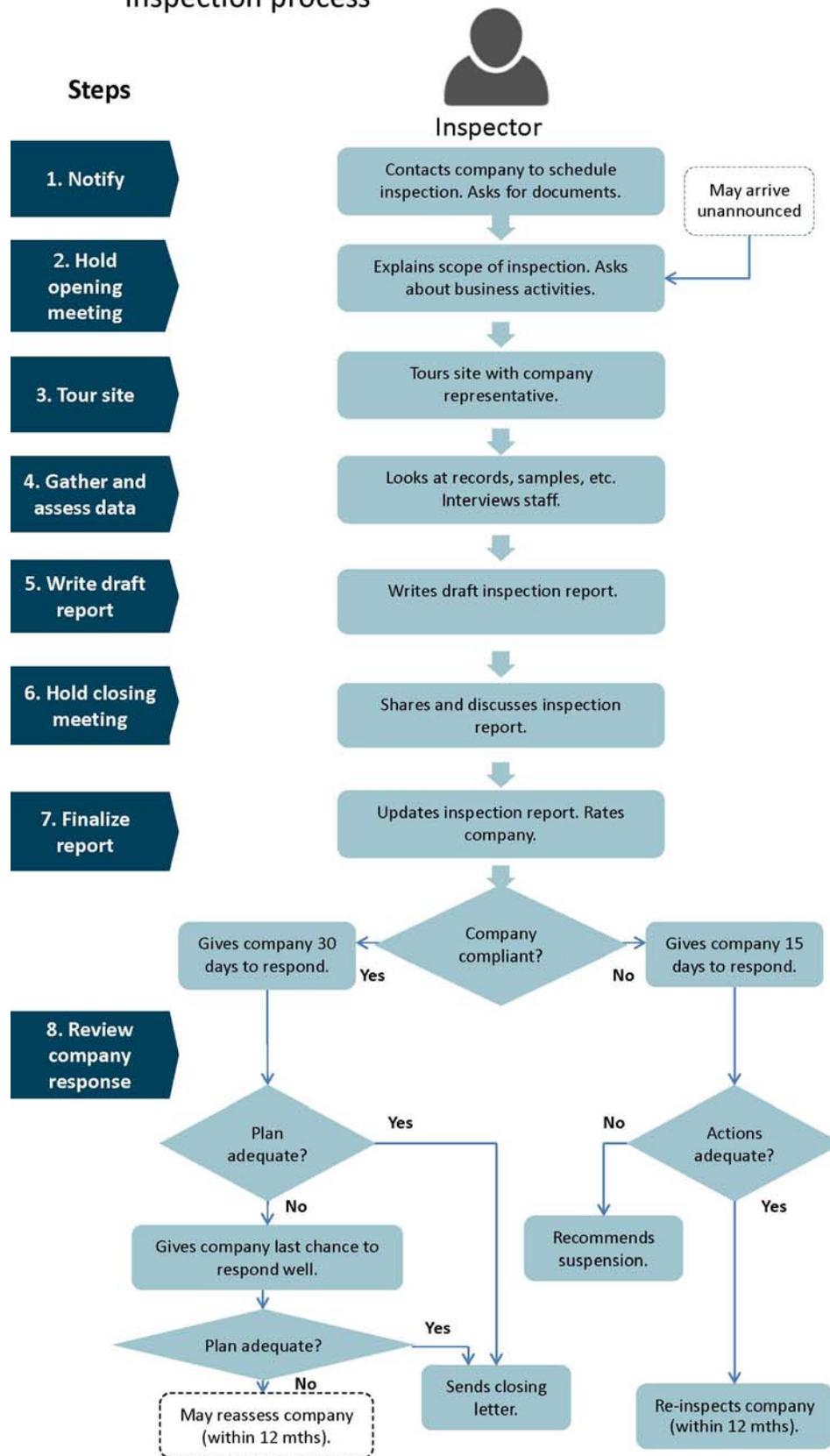
If you operate at more than one location, the inspector may also inspect the other sites where you carry out activities listed on your establishment licence application and store your procedures. This will add more time to your inspection since inspections are typically carried out by a single inspector. If needed, the lead inspector may ask other inspectors to join the inspection.

Inspections of companies outside of Canada may be inspected on or off site.

## 4. Inspection process

Inspections comprise a series of steps that proceed in the same sequence with all inspectors. The following diagram provides a visual depiction of the process.

# Inspection process



## Step 1: Notify company and schedule inspection

The inspector will contact you by telephone before the inspection to:

- Confirm information on your establishment licence (e.g. the activities of your company and the classes of devices offered for sale).
- Set a date and location for the inspection.



The inspector may choose to arrive without notice if it will result in a more accurate picture of your compliance. Likewise, the inspector may arrive unannounced if unable to reach you by phone.

The inspector may also ask you to provide:

- a copy of the most recent application you filled out for a medical device establishment licence
- a list of all medical devices you are currently selling
- the names of manufacturers for the devices you are selling
- copies of the procedures you said you have when applying for your licence (see Appendix C, [Checklist for inspections](#), for the procedures you will be expected to make available)

Once the inspection date has been determined, the inspector will confirm the details in writing.



When reviewing your procedures, the inspector will look to see that they:

- Define how to complete a task or tasks.
- Explain how to do the work, who should do it and under what circumstances.
- Identify who has been assigned any authority or responsibility and define what that authority or responsibility is.
- Identify the supplies, materials, documents and records needed to carry out the work.

## Step 2: Hold opening inspection meeting

The inspector will meet with you to:

- Describe the objectives of the Inspectorate's inspection program.
- Outline the scope of the inspection.
- Confirm company information such as contact person and contact information.
- Get an understanding of the nature of your company's activities.

## Step 3: Tour the site

The inspector will ask for a tour of your site to get an overview of the activities and devices available for sale. During the tour, the inspector may want to look at the following areas:

- shipping and receiving
- warehousing or storage
- manufacturing
- testing or quality control laboratory
- returns or servicing
- quarantine
- sales and marketing departments

The inspector may also interview staff in company areas.

## Step 4: Gather and assess data

The inspector will assess your compliance based on the interviews, tour and review of company procedures. The inspector will also collect and review samples of your company's records and medical devices. The review will take into account your company's product lines and the classification of your devices (i.e. Class I, II, III or IV). The number of samples looked at will depend on several factors:

- controls you have in place and their capability
- the degree of compliance you have shown in previous inspections
- number of devices offered for sale and whether they are available for review

Health Canada considers the data looked at (i.e. interviews, tour, samples) as “objective evidence” of your company’s compliance at a specific moment in time. This is because the evidence is based on facts the inspector:

- gets through observation, measurement, testing or other means
- can prove true

When looking at this evidence, the inspector will note a deviation, deficiency or failure to comply with the Regulations as an observation. Inspectors rate observations as:

- Risk 1 (high risk)
- Risk 2 (medium risk)
- Risk 3 (low risk)



For more information about the risk ratings, see [Guidance on Risk Classification of Medical Device Observations \(GUI-0079\)](#).

Throughout the inspection, the inspector will keep you informed of deviations, deficiencies, or failures. If a deviation, deficiency or failure poses a high risk, the inspector will bring it to your attention at once.



You are encouraged to take action to correct any deviations, deficiencies or failures the inspector points out to you. If corrected before the closing meeting, the inspector will show that the issue has been resolved in the final inspection report.

The inspector will take corrective action or ask you to act immediately to address a high-risk observation. The inspector will make sure that any such actions comply with the [Guidance on Medical Device Compliance and Enforcement \(GUI-0073\)](#).

## Step 5: Write draft inspection report

The inspector will write the first draft of the inspection report based on the evidence of your company’s compliance. The inspection report will include the risk ratings of any deviations, deficiencies or failures noted during the inspection. It will also include your company’s rating if the inspector found you compliant with the Regulations. A non-compliant rating will not appear on the draft report.



Health Canada will make sure that anything seen as non-compliant is well defined, clear and supported by the Regulations. See Appendix B, [Checklist of regulations that apply to you](#), for what you must comply with based on your activities (i.e. manufacturing, importing or distributing).

## Step 6: Hold closing meeting

The inspector will hold a closing meeting with you on site or by telephone or videoconference. At the closing meeting, the inspector will:

- Give you a copy of the draft inspection report based on the assessment of your data.
- Verify that you understand the observations and risk ratings.
- Tell you what records and documents are needed to meet the regulations.
- Discuss the steps and actions needed to correct any deviations, deficiencies or failures noted during the inspection.



Health Canada will post its initial findings on its website to honour its commitment to openness and transparency. You can see the results at [Medical device inspections](#).

If a rating of non-compliant is recommended for your company, the inspector will give you a form letter with the draft inspection report. The letter serves to notify you that Health Canada will:

- Review the inspector's draft inspection report.
- Send you a final inspection report in which your non-compliant rating will be confirmed or changed.

The letter will also ask you to start taking corrective actions immediately. You will be expected to explain the actions you will take to address observations rated as high risk (Risk 1). We encourage you to ask questions so that you fully understand the inspector's findings.

## Step 7: Finalize inspection report

After the closing meeting, the inspector will complete the inspection report and send it to you with a cover letter. The cover letter will explain any next steps you are expected to take and provide deadlines. It will also tell you how to let Health Canada know if you disagree with anything in the inspection report.

When finalizing the report, the inspector will update the summary of the inspection and note any deviations, deficiencies or failures you acted to correct.

The final report will also confirm whether your company was found compliant with the Regulations.



Health Canada will post an inspection report card on its website as part of its commitment to openness and transparency. The report card summarizes the findings of the inspection. You can see the inspection findings at [Medical device inspections](#).

You will be expected to respond to the final report within the following timeframe:

- **Compliant rating** – Respond within 30 calendar days.
- **Non-compliant rating** – Respond within 15 calendar days.



A condition of getting a medical device establishment licence is having written procedures in place for various activities. See [Sections 44–51: Establishment licence](#) in this guide for the licence requirements, including the mandatory procedures.

When you completed the application for the licence, you were asked to confirm that you had the required procedures in place. You must produce a missing procedure within 30 calendar days of the date on the final inspection report if:

- You ticked the box on your establishment licence application that says you have a specific procedure in place.
- The procedure was not available at the time of the inspection.

The response you send Health Canada will vary depending on whether you receive a compliant or non-compliant rating.

If your company receives a **compliant rating**, you are expected to respond with a corrective action plan that:

- Lists the steps and actions you will take (or have already taken) to correct the observations.
- Provides a timeline you will use to complete the corrective actions.
- Includes documents that support corrective actions you have taken or will take (if asked for by the inspector).

If your company receives a **non-compliant** rating, you are expected to respond by:

- Listing the steps and actions you have taken to eliminate observations rated as high (Risk 1) and medium (Risk 2) risks.
- Providing a corrective action plan with timelines for completing any actions to address observations rated as low (Risk 3) risk.
- Includes documents that support corrective actions you have taken or will take (if asked for by the inspector).



If your company receives a non-compliant rating, the Establishment Licensing, Billing and Invoicing Unit within Health Canada will send you a “proposal to suspend” letter. You will be given a chance to respond to the proposal to suspend your licence.

## Step 8: Review company response and action taken

The inspector will review your written response to the inspection report to ensure it is complete and the corrective and preventive actions effective.

- **Company with compliant rating:** If your corrective action plan is:
  - **Adequate** – The inspector will send you a letter formally closing the inspection.
  - **Inadequate** (or you do not respond) – You will be given one more chance to respond as needed.

If your response remains inadequate, the inspector may reassess your company. The reassessment is normally conducted within 12 months.

- **Company with non-compliant rating:** If the actions you took are:
  - **Adequate** – The inspector will schedule a re-inspection within 12 months to evaluate the actions you have taken.

- **Inadequate** – The inspector will recommend the Establishment Licensing, Billing and Invoicing Unit of Health Canada suspend your licence.

The inspector will notify the licensing unit whether your response is adequate or inadequate.



If you were asked to include documents that support your corrective action plan, the inspector will also review and assess those documents. If inadequate, you will be expected to resubmit new documents.

## 5. How Health Canada enforces compliance

In keeping with the [Compliance and Enforcement Policy \(POL-0001\)](#), Health Canada prefers you to volunteer to come into compliance through corrective actions. But if you are unwilling or unable, Health Canada will enforce compliance.

In deciding on what action to enforce, we will consider the following factors:

- risk to health
- your cooperation during and after the inspection, as well as your written response to the inspection
- your compliance history

If you are a domestic company, Health Canada can:

- Request a stop sale of your product.
- Request a recall of your product.
- Order a recall of your product.
- Detain your product imports.
- Take control of your non-compliant items (on-site administrative seizure).
- Suspend your licence.
- Recommend to the Department of Justice for prosecution.

If you are a company outside of Canada, Health Canada can:

- Request a stop sale of your product.
- Request a recall of your product.

- Suspend your licence.
- Recommend a refusal of entry of your product into Canada.

Any actions taken by inspectors will be consistent with [\*Guidance on Medical Device Compliance and Enforcement \(GUI-0073\)\*](#) and the *Compliance and Enforcement Policy*. Inspectors can take action at any time during the inspection.

# How inspectors assess your compliance

## 6. Compliance with the *Food and Drugs Act*

If you manufacture, advertise or sell medical devices, certain sections of the *Food and Drug Act* apply to you. These sections are highlighted here to help you understand how inspectors assess your compliance with the Act. Inspectors look to see whether you are engaged in any activity the Act forbids. This is important since you are responsible for meeting the requirements of the Act.

### Part 1 – Food, drugs, cosmetics and devices

#### Section 3: Prohibited advertising

Sections 3(1) and 3(2) forbid you from advertising and selling medical devices to the general public if the devices treat, prevent or cure the diseases, disorders, and abnormal physical states listed in Schedule A of the Act.

#### Section 19: Prohibited sales of devices

Section 19 forbids you from selling any device that may injure the health of the buyer or user when used as directed or under customary or usual conditions. No company shall sell a device that poses a health hazard.

#### Section 20: Deception, etc., regarding devices

Section 20(1) forbids you from labelling, packaging, treating, processing, advertising or selling a device in a manner that:

- is false, misleading or deceptive
- creates a mistaken impression regarding its design, construction, performance, intended use, quantity, character, value, composition, merit or safety

When Health Canada issues a medical device or a medical device establishment licence, it does not mean we approve of the device or the company, only that we authorize you to import or sell the device in Canada. So, advertising medical devices with claims that the device or company is “approved by Health Canada” or with displays of the Health Canada logo are not permitted. Under section 20(1), advertisements with these claims are considered misleading since they create an incorrect or mistaken impression about the device’s merit or safety.

Section 20 (2) forbids you from labelling and packaging devices unless they meet the requirements of the Regulations.

### Section 21: Where standard prescribed for device

Section 21 forbids you from labelling, packaging, selling or advertising any article in such a way that it could be mistaken for a device—unless the article meets the prescribed standard for that device.

## 7. Compliance with the Medical Devices Regulations

This section explains what inspectors look for when they assess your compliance with the Medical Devices Regulations. It also directs you to more information that will help you understand and meet those requirements.

### Sections 6–7: Classification of medical devices

If you are a manufacturer, you are responsible for classifying a medical device based on the rules in Schedule 1 of the Regulations. Failure to classify a device correctly may mean that you do not comply with the device’s licensing requirements.



For information on Health Canada’s classification system, and help in classifying your device, see the following documents:

- [\*Guidance for the Risk Based Classification System of In Vitro Diagnostic Devices\*](#)
- [\*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 \(non-IVDDs\)\*](#)

If you need more help to classify your device, contact the Licensing Services Division of the Medical Devices Bureau at:

- **Email:** device\_licensing@hc-sc.gc.ca
- **Telephone:** 613-957-7285
- **Fax:** 613-957-6345

## Part 1 – General

### Section 9–20: Manufacturer’s obligations and Safety and effectiveness requirements

If you are a manufacturer, you are responsible for showing and maintaining evidence that you meet the safety and effectiveness requirements in sections 9 to 20 of the Regulations.

As a result, the inspector may look to see that you have:

- Designed and manufactured a medical device that is safe.
- Identified any risks the device may pose to health and safety.
- Made sure the device:
  - does not harm the health or safety of a patient
  - includes benefits that outweigh any possible hazards
  - suits its intended purpose
  - shall not be harmed by transportation or storage conditions
- Estimated the period of time the device will be useful to the average user, when applicable.
- Made sure the materials used to manufacture the device are compatible with other parts and with its surroundings during normal use
- Designed, manufactured and packaged the device so that it will reduce foreseeable hazards, including:
  - flammability
  - explosion
  - presence of contaminant (chemical or microbial)

- radiation
- hazards (electrical, mechanical or thermal)
- fluid leaking from or entering into a device
- Manufactured sterile devices under appropriately controlled conditions and validated the sterilization method.
- Ensured any device intended to be used with other devices is compatible with the other devices.
- Ensured any device with a measuring function is within tolerance limits for its intended purpose.
- Designed software to perform as intended and validated the software’s performance.



For help in using international standards to meet safety and effectiveness requirements, see [Guidance Document: Recognition and Use of Standards under the Medical Devices Regulations](#).

If concerned before or during an inspection, the inspector may ask you to show that your devices are safe and effective and perform as the manufacturer intended. You will need to provide records to support this request. Manufacturers, importers and distributors may be cited under section 19 of the *Food and Drugs Act* if there is a violation.



Section 19 of the [Food and Drugs Act](#) (the Act) prohibits any person from selling “...any device that, when used according to directions... may cause injury to the health of the purchaser or user thereof.”

If medical devices are not properly transported, stored or handled, their safety and effectiveness may be affected negatively. If you sell such medical devices, you may be in violation of the Act.

The inspector may issue observations to manufacturers under sections 10 to 20 of the *Regulations*. Two of the most common observations are as follows:

- Section 12 (effectiveness for intended use) – when you cannot back up claims made about a device.
- Section 14 (transport and storage) – for concerns about how you transport or store a device.

## Sections 21–23: Labelling requirements

When assessing compliance with sections 21 to 23, inspectors tend to focus on labels for Class I and II devices. This is because the Medical Devices Bureau does not normally review labels when issuing the medical device licence for Class II devices. The Bureau also does not issue a licence for Class I devices. An inspector may ask questions to find out what type of controls you have in place to help you comply with labelling requirements.



A label can be a legend, word or mark that is affixed to a medical device or its packaging. It can also be information such as manuals, package inserts, brochures and leaflets. If the device is sold to the general public in Canada, most information on the label must be in English and French.

The inspector will also collect and review labels. The review will take into account your company's product lines and device classes (i.e. Class I, II, III or IV). The number of labels the inspector looks at will depend on:

- your label controls and how effective they are
- your inspection history and how compliant you were with labelling and other requirements



You can find help for labelling your device in the following documents:

- [\*Guidance for the Labelling of In Vitro Diagnostic Devices\*](#)
- [\*Guidance Document: Guidance for the Labelling of Medical Devices, not including in vitro diagnostic devices, Appendices for Labelling of Soft Contact Lenses, Decorative Contact Lenses, and Menstrual Tampons\*](#)

## Section 24: Contraceptive devices – advertising

Inspectors will review advertisements of contraceptive devices for compliance. Under section 24(1), advertising for condoms sold to the general public can only claim to reduce the risk of transmitting sexually transmitted diseases. Condoms cannot claim to prevent the diseases.

## Section 25: Class I medical devices

If you manufacture Class I medical devices, you must comply with the safety and effectiveness requirements in sections 10 to 20 of the Regulations. (For more information, see [Section 9–20: Manufacturer's obligations and Safety and effectiveness requirements](#) in this document.)

Health Canada's Medical Devices Bureau is responsible for enforcing safety and effectiveness requirements. Following a complaint by a consumer (or a report from an inspector), the Medical Devices Bureau may send you a letter directing you to take certain actions so that you meet those requirements. An inspector may then assess the actions you take to ensure they are carried out properly.

## Sections 26–27: Class II, III and IV medical devices

If you import or sell a Class II, III or IV device, you must have a medical device licence. Inspectors may ask questions to find out what type of controls you have in place to ensure that all Class II, III or IV devices imported, advertised or sold are properly licensed. This does not apply to any devices subject to parts 2 (custom-made and special access) and 3 (investigational testing) of the Regulations.

Inspectors will assess your compliance with device licensing requirements in the following ways:

- Confirm that medical device licences for products you import or sell (Section 26) are valid by:
  - making sure the devices are licensed
  - taking into account your product lines, device classes and kinds of licences (described in sections 28–31)
- Look at medical device catalogues for warning labels that explain that not all the devices in the catalogue may be licensed for sale in Canada, if that is the case (Section 27).
- Look at samples of advertising material from recent marketing promotions.
- Confirm that the advertised devices are licensed, based on evidence you provide.
- Verify that the claims made in the advertising material are valid by comparing them with the claims you made when applying for your licence.
- Review distribution and warehouse records if a licence has been suspended, cancelled, refused or amended.

For the most part, the number of samples the inspector looks at will depend on the controls you have in place to ensure you classify devices correctly. Sampling will also take into account:

- the complexity of your product lines
- how much and how complex is your advertising activity
- your company's compliance history

As well, the inspector will consider the factors that result in amendments to the device licence (e.g. a change in the device or manufacturer's name or to the device identifier).

## Sections 28–37: Device licence application and issuance

The Medical Devices Bureau is responsible for assessing applications for a medical device licence. As a result, applications for the licence are not normally included in an inspection.



For help in completing the medical device application, see the following guidance documents:

- [\*GD210: ISO 13485:2003 Quality Management System Audits Performed by Health Canada Recognized Registrars\*](#)
- [\*Guidance Document – How to Complete the Application for a New Medical Device Licence\*](#)
- [\*Guidance Document: How to Complete the Application for a New Medical Device Licence/Medical Device Licence Amendment for a Private Label Medical Device\*](#)
- [\*Guidance for Industry – Device Licence Applications for Ultrasound Diagnostic Systems and Transducers\*](#)
- [\*Guidance for the Interpretation of Sections 28 to 31: Licence Application Type\*](#)
- [\*Guidance for the Interpretation of Significant Change of a Medical Device\*](#)
- [\*List of registrars recognized by Health Canada under section 32.1 of the Medical Devices Regulations \(MDR\)\*](#)
- [\*Preparation of a Premarket Review Document for Class III and Class IV Device Licence Applications \(v.2\)\*](#)

## Section 36–37: Issuance and Lot of in vitro diagnostic devices

If a medical device licence has been issued with terms and conditions, or the terms and conditions have been amended, the inspector will look for evidence that you complied with these special conditions (section 36).

If a licence for an *in vitro* diagnostic device has been issued with terms and conditions, the inspector will look for evidence that you sent the required test results and protocols to Health Canada. The inspector will also confirm that when you sold the device you did not do anything for which you were not given permission.

## Sections 44–51: Establishment licence

The inspector will ask you to provide the application form you completed to get your establishment licence. The inspector will then verify that the following information in your application form is accurate:

- Manufacture, distribution and import activities
- name and address of manufacturers of devices you import or distribute
- documented procedures for:
  - distribution records
  - handling complaints
  - recalls
  - mandatory problem reporting (if you are an importer)
  - handling, storing, delivering, installing, correcting and servicing any Class II, III or IV device (for importers and distributors when applicable)



Find information on what to include in your procedures in Appendix D, [Checklist for procedures \(Class II, III or IV devices\)](#). This checklist can be helpful since the inspector may note deviations, deficiencies or failures related to your procedures (e.g. not following shipping procedures when packaging a temperature sensitive medical device).

The inspector will review your procedures to ensure you are using them and they are adequate. If you do not have procedures, or they are inadequate, your company will not be considered compliant with certain sections of the Regulations. For more information on how inspectors assess procedures, see the following sections in this document:

- [Sections 52–55: Distribution records](#)
- [Sections 57–58a: Complaint handling](#)
- [Section 58b: Complaint handling, and Sections 63–65: Recall](#)
- [Sections 59–61: Mandatory problem reporting](#)



You can also find information on sections 44 to 51 of the Regulations in [Guidance on Medical Device Establishment Licensing and Medical Device Establishment Licence Fees \(GUI-0016\)](#).

## Sections 52–55: Distribution records

Your distribution records should allow you to recall a medical device in an effective and timely way. The inspector will:

- Look for evidence that you have distribution records.
- Assess how well those records enable you to retrieve a list of your customers for a particular product.



Find information on the requirements for your distribution records in [Medical devices recall guide \(GUI-0054\)](#).

## Sections 57–58a: Complaint handling

The inspector will review your procedures to see that you are using them and that they meet the criteria in [Handling complaints about medical devices \(GUI-0065\)](#). The inspector will also review your records of reported problems to see whether:

- You are documenting reported problems and consumer complaints.
- Your records follow your procedures.
- You have taken actions to:
  - Correct and prevent problems from happening again.
  - Follow up with the manufacturer, as needed.



You can find information on how to set up an effective system for investigating and resolving problems in [Handling complaints about medical devices \(GUI-0065\)](#).

## Section 58b and Sections 63–65: Recall

The inspector will review your procedures to see that you are using them and that they meet the criteria in [Medical devices recall guide \(GUI-0054\)](#). The inspector will also review your recall records to see whether:

- You are documenting recalls.
- Your records follow your procedures.

- You have taken actions to:
  - Correct and prevent problems from happening again.
  - Follow up with the manufacturer, as needed.



You can find information on how a device should be recalled in the [Medical devices recall guide \(GUI-0054\)](#).

## Sections 59–61: Mandatory problem reporting

If you are a manufacturer or importer, the inspector will review your problem reports to see whether:

- The process for identifying and reporting problems is effective.
- The reports meet mandatory reporting criteria in the regulations.



Find information on what a problem report is, what incidents should be reported and what to include in the report in [Guidance Document for Mandatory Problem Reporting for Medical Devices](#).

## Sections 66–68: Implant registration

If you are a manufacturer, the inspector will review your implant registry to make sure it complies with sections 66 and 67. If you have been given permission to register implants with a different method, the inspector will review your records against the authorized method.

## Part 2 – Custom-made devices and medical devices to be imported or sold for special access

The inspector will identify and review custom-made or special access devices to make sure they comply with sections 69 and 70 and 75 to 78. The Medical Devices Bureau normally assesses compliance with sections 71 to 74.

If you are a health care professional and you want permission to sell or import a custom-made or special access device, see the [Medical Devices Special Access Programme](#) for how to go about it.

## Part 3 – Medical devices for investigational testing involving human subjects

The inspector will identify and review devices used for investigational testing (clinical trials) to make sure they comply with sections 79 to 81 and 86 to 88.

The Medical Devices Bureau normally assesses compliance with sections 82 to 85. These sections involve asking Health Canada to permit the sale or import of a device for investigational testing.

For information on how section 88, “Other requirements,” will be assessed, see the following sections in this document:

- [Sections 52–55: Distribution records](#)
- [Sections 57–58a: Complaint handling](#)
- [Section 58b: Complaint handling, and Sections 63–65: Recall](#)
- [Sections 59–61: Mandatory problem reporting](#)



For help in putting together the information needed to get permission to sell in vitro and other medical devices for investigational testing, see the following documents:

- [\*Preparation of an Application for Investigational Testing - In Vitro Diagnostic Devices\*](#)
- [\*Preparation of an Application for Investigational Testing – Medical Devices\*](#)

## Part 4 – Export certificates

If you are exporting a device that is exempt from the Regulations because it falls under section 37 of the *Food and Drugs Act*), the inspector will confirm the device meets the following conditions:

- The device is not manufactured for use in Canada.
- The device is not sold for use in Canada.
- The device label is clearly marked with the words “Export,” “Exportation” or “For Export.”

The inspector will also verify that you are keeping:

- an export certificate for each shipment and that the certificate meets the requirements of section 89(2) of the regulations
- export certificates for at least five years after the date of export (section 92 of the regulations)

# Appendices

## Appendix A – Glossary



These definitions explain how terms are used in this document. If there is a conflict with a definition in the *Food and Drugs Act* or Medical Devices Regulations, the definition in the Act or Regulations prevails.

**Company** – Any regulated party subject to the *Food and Drugs Act* and the Medical Devices Regulations, including manufacturers, importers, distributors, persons, partnerships and associations.

**Corrective action plan** – A statement of the steps and actions that will be taken to eliminate the observations identified during an inspection.

**Custom-made device** – 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. (Medical Devices Regulations)

**Dispenser** – 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. (Medical Devices Regulations)

**Distributor** – A person other than a manufacturer, importer or 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.

**Export certificate** – A certificate signed by the fabricator (the person who made the product) and a Commissioner for Taking Oaths which declares that:

- the device listed in the certificate is not manufactured or sold for use in Canada

- the package and contents of the device do not violate any known requirements of the importing country

**Health care facility** – 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. (Medical Devices Regulations)

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

**Investigational testing** – Also known as a clinical trial or study, investigational testing is a research study of one or more human subjects to assess the safety or performance of a medical device.

**Manufacturer** – 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. (Medical Devices Regulations)

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

**Procedure** – A logically distinct set of activities designed to accomplish a specific task. 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 it 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 to whom, which supplies and materials should be used and which documents and records must be used to carry out the work.

**Process** – A set of interrelated resources and activities that transform inputs into outputs. Resources may include management, services, personnel, finance, facilities, equipment, techniques and methods.

**Record** – A document that states the results achieved or provides evidence of activities performed. (ISO 9001:2008)

**Retailer** – Any company subject to the *Food and Drugs Act* and Medical Devices Regulations that sells a device, or services using the device, only to the ultimate consumer. (A company is a manufacturer, importer, distributor, person, partnership or association.)

**Site** – Any additional building within Canada that is used by a person or company with a medical device establishment licence (MDEL) for:

- conducting the activities listed on the MDEL application
- keeping the procedures that you attested to having

**Special Access Program** – Under the Act and Regulations, physicians and dentists can access medical devices for human use that do not have market authorization (permission to market the device for sale) in Canada. Health Canada decides whether to allow access to these devices based on the details of each case. If warranted, Health Canada will provide a Letter of Authorization to the health care provider. A copy of this letter must be sent with the shipment to allow timely entry of the drug or medical device into Canada.

**Ultimate consumer** – 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.

# Appendix B – Checklist of regulations that apply to you

Table 1 will help you find out which sections of the Medical Devices Regulations apply to you. The requirements will vary depending on whether you are:

- manufacturer of Class I, II, III or IV devices
- importer
- distributor

A “✓” for “yes” tells you the section of the Regulations you must comply with. Be sure to look at each activity you carry out to find out the requirements that apply to you.



If you manufacture Class I medical devices, check section 44(2)(d) of the Regulations to see if you need an establishment licence.

Table 1: Sections of Medical Devices Regulations that apply, by activity

Requirements	Section number	Manufacturer of Class I devices	Manufacturer of Class II, III or IV devices	Importer	Distributor
Part 1, General					
Safety and effectiveness	9–20	✓	✓		
Labelling	21–23	✓	✓	✓	✓
Contraceptive advertising	24		✓	✓	✓
Class I devices	25	✓			

Table 1: Sections of Medical Devices Regulations that apply, by activity

Requirements	Section number	Manufacturer of Class I devices	Manufacturer of Class II, III or IV devices	Importer	Distributor
Class II, III and IV devices					
Sale	26		✓	✓	✓
Advertising	27		✓	✓	✓
Licensing	28–32		✓		
Foreign manufacturers	33		Not in effect at this time.		
Licence amendment	34		✓		
Additional information and samples	35		✓		
Issuance	36		✓		
Lot of <i>in vitro</i> diagnostic devices	37		✓		
Refusal to issue	38		✓		
Additional information	39		✓		
Suspension	40–42		✓		
Obligation to inform	43		✓		

Table 1: Sections of Medical Devices Regulations that apply, by activity

Requirements	Section number	Manufacturer of Class I devices	Manufacturer of Class II, III or IV devices	Importer	Distributor
<b>Establishment licence</b>					
Establishment licensing	44	✓		✓	✓
Application	45	✓		✓	✓
Issuance	46	✓		✓	✓
Refusal	47	✓		✓	✓
Notification	48	✓		✓	✓
Suspension	49	✓		✓	✓
<b>Records</b>					
Distribution records	52–55	✓	✓	✓	✓
Complaint handling	57–58	✓	✓	✓	✓
Mandatory problem reporting	59–61	✓	✓	✓	
Recall	63–65	✓	✓	✓	
Implant registration	66–68		✓		

Table 1: Sections of Medical Devices Regulations that apply, by activity

Requirements	Section number	Manufacturer of Class I devices	Manufacturer of Class II, III or IV devices	Importer	Distributor
<b>Part 2 – Custom-made devices and medical devices to be imported or sold for special access</b>					
General	70	✓	✓	✓	✓
Authorization	71–72	✓	✓	✓	
Additional information	73	✓	✓	✓	
Labelling	75	✓	✓	✓	✓
Distribution records	76	✓	✓	✓	
Reporting incident	77	Reporting requirements apply to health care professionals.			
Implant registration	66–68		✓		
<b>Part 3 – Medical devices for investigational testing involving human subjects</b>					
General – sale or importation	80(1)	✓	✓	✓	✓
General – Class II, III and IV authorization	80(2)	✓	✓	✓	
General – Class I	80(3)	✓		✓	
Records	81	✓	✓	✓	✓

Table 1: Sections of Medical Devices Regulations that apply, by activity

Requirements	Section number	Manufacturer of Class I devices	Manufacturer of Class II, III or IV devices	Importer	Distributor
Authorization	82–83	✓		✓	✓
Additional information	84–85	✓	✓	✓	
Labelling	86	✓	✓	✓	✓
Advertising	87	✓	✓	✓	✓
Distribution record, complaint handling, mandatory problem reporting, recall and implant registration requirements	88	✓	✓	✓	✓
Part 4 – Export certificates					
Export certificates	89–92	✓	✓	✓	✓

# Appendix C – Checklist for inspections

Use the following checklist to help you prepare before, during and after a medical device establishment licence (MDEL) inspection.

Before the inspection:

**Have you gathered:**

- A copy of your most recent application for an MDEL?
- Written procedures for keeping distribution records and handling complaints and recalls?
- Written procedures for mandatory reporting of problems (if you are an importer)?
- Written procedures for how to handle, store, deliver, install and service the Class II to IV devices you import and distribute?
- A list of all medical devices you are currently selling?
- A list of all manufacturers for the devices you are selling?

**Have you checked and confirmed:**

- Documents (i.e. procedures, forms, records) are up to date and staff are using them?
- The classification of all medical devices that you sell is correct?
- Any devices that should be licensed are licensed?
- Labels on all devices are correct?
- Labels of any devices sold to the general public are written in French and English?
- Any advertisements of the devices are correct?

During the Inspection:

- Have you made sure staff is available to answer the inspector's questions as needed?

**Are you prepared to give the inspector:**

- Labels of selected medical devices?
- Advertising material for selected medical devices?
- Distribution records of selected medical devices?
- Records of complaints and the investigation and follow-up work you carried out?
- Recall and mandatory problem reports (if this applies)?

- Documents related to how you handle, store, deliver, install and service Class II to IV devices (if this applies)?
- Records of authorizations for investigational (clinical) testing on human subjects (if this applies)?
- Records of authorizations for importing devices for special access (if this applies)?

#### After the inspection:

- Have you scheduled a closing meeting with the inspector?
- Do you need to follow up with the inspector on questions you had during the inspection?
- Do you understand what you need to do to respond and correct the observations the inspector shared during the closing meeting?
- Have you written an action plan that outlines the actions and steps you will take to correct the inspector's observations?
- Does your action plan include a timeline for carrying out corrective actions?

#### Have you sent the inspector the action plan:

- Within 30 calendar days of the closing meeting (if you received a compliant rating)?
- Within 15 calendar days of the closing meeting (if you received a non-compliant rating)?
- Does your action plan include evidence of corrective actions you have already taken (e.g. revised procedures or labels, updated device licences)?
- Have you resolved and closed all observations listed in the inspector's final report?

# Appendix D – Checklist for procedures (Class II, III or IV devices)

Use this checklist for help with your procedures for Class II, III and IV devices. The checklist covers how to handle, store, deliver, install, correct and service the devices.

Procedures for storing, handling and delivering Class II, III or IV devices

**Keeping in mind the types of medical devices you deal with, do your procedures address:**

- How to protect devices from environmental conditions that may affect their safety or effectiveness?
- How to identify devices that need special storage or transport conditions (e.g. test kits containing reagents that must not be frozen)?
- How to store, handle and deliver medical devices that have special storage or transport conditions?
- How to rotate your stock of devices that has a limited shelf-life or expiry date (e.g. first in, first out)?
- How to handle or store devices to prevent damage, deterioration, mix-ups, contamination or other adverse effects?
- How to keep returned or recalled devices separate from other devices to prevent them from being shipped out by mistake?
- How to verify orders before they are shipped to avoid the wrong device from going out?

Procedures for installing Class II, III or IV devices

**If your device must be put together for use, do your procedures address:**

- How to train and certify employees to install, inspect and test devices that need it?
- How to make sure only properly trained and qualified employees install, inspect and test devices that need it?
- How to make sure that employees follow the manufacturer's instructions for installing, inspecting and testing devices that need it?
- How to make sure employees justify deviations from the manufacturer's instructions when installing, inspecting and testing devices that need it?
- How to make sure testing equipment will perform as needed when taking measurements?

How often testing equipment is calibrated?

## Procedures for servicing Class II, III or IV devices

**Keeping in mind the types of devices you deal with, do your maintenance and repair procedures address:**

- How to train and certify employees to service devices?
- How to make sure only properly trained and qualified employees service devices?
- How to make sure maintenance work (e.g. cleaning, lubrication, adjustment, inspection, part replacement, calibration and testing) is performed as instructed by the manufacturer?
- Whether there is a schedule for doing maintenance work?
- Whether the schedule for doing maintenance work meets or exceeds the timelines set by the manufacturer?
- Whether you keep a record of servicing work done?
- Whether your servicing records specify:
  - Name and location of the device
  - Installation date
  - Device identifier (model number)
  - Serial number or lot number (whichever applies)
  - Date of service work
  - Name of the staff person doing the servicing working
  - Service performed, including replacement part and any testing or inspection data
- How often servicing equipment is tested, calibrated and serviced?
- How to monitor repairs for trends that show premature or unexpected device failure or malfunction (especially where failure or malfunction may pose a risk to health)?
- How to investigate reports of unexpected failure or deterioration in device performance?
- When investigations should include inspections of the suspect device in other facilities to figure out the extent of the problem?
- When and how to inform the manufacturer of unexpected failure or deterioration in device performance?

- Whether to forbid staff from modifying the function, design or performance specifications of the device during repairs, unless given express permission by the manufacturer?
- How to get permission from the manufacturer to modify the function, design or performance specifications of the device during repairs?
- Whether to forbid staff from using parts or components that have not been permitted by the manufacturer (especially if they do not meet the specification of the original manufacturer's parts)?
- How to identify the parts or components that can be used for repairs of specific devices?
- Where to find the specifications of the original manufacturer's parts?

# Appendix E – References

## Laws

### *Food and Drugs Act*

<http://laws-lois.justice.gc.ca/eng/acts/f-27/>

### *Medical Devices Regulations*

<http://laws-lois.justice.gc.ca/eng/regulations/SOR-98-282/>

## Licence and other applications

### *Guidance on Medical Device Establishment Licensing and Medical Device Establishment Licence Fees (GUI-0016)*

[www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/directives/gui-0016-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/directives/gui-0016-eng.php)

### *Guidance Document – How to Complete the Application for a New Medical Device Licence*

[www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/md\\_gd\\_licapp\\_im\\_ld\\_demhom-eng.php](http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/md_gd_licapp_im_ld_demhom-eng.php)

### *Guidance Document: How to Complete the Application for a New Medical Device Licence/Medical Device Licence Amendment for a Private Label Medical Device*

[www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/applabel\\_demmarque\\_priv-eng.php](http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/applabel_demmarque_priv-eng.php)

### *Preparation of a Premarket Review Document for Class III and Class IV Device Licence Applications (v.2)*

[www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/prmkt2\\_precomm2-eng.php](http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/prmkt2_precomm2-eng.php)

### *Preparation of an Application for Investigational Testing – In Vitro Diagnostics Devices*

[www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/test\\_iv3-eng.php](http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/test_iv3-eng.php)

### *Preparation of an Application for Investigational Testing – Medical Devices*

[www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/md\\_gd\\_ita\\_im\\_ld\\_aee-eng.php](http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/md_gd_ita_im_ld_aee-eng.php)

## Guidance

### *Guidance for the Labelling of In Vitro Diagnostic Devices*

[www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/labl\\_etiq\\_ivd\\_div-eng.php](http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/labl_etiq_ivd_div-eng.php)

[Guidance for the Risk Based Classification System of In Vitro Diagnostic Devices](#)

[www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/ivd-rsk\\_idiv-rsq-eng.php](http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/ivd-rsk_idiv-rsq-eng.php)

[Guidance Document for Mandatory Problem Reporting for Medical Devices](#)

[www.hc-sc.gc.ca/dhp-mps/pubs/medeff/\\_guide/2011-devices-materiaux/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/_guide/2011-devices-materiaux/index-eng.php)

[Guidance Document: Guidance for the Labelling of Medical Devices, not including in vitro diagnostic devices, Appendices for Labelling of Soft Contact Lenses, Decorative Contact Lenses, and Menstrual Tampons](#)

[www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/labl\\_etiq\\_dv10-eng.php](http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/labl_etiq_dv10-eng.php)

[Guidance Document: Recognition and Use of Standards under the Medical Devices Regulations](#)

[www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/md\\_gd\\_standards\\_im\\_ld\\_normes-eng.php](http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/md_gd_standards_im_ld_normes-eng.php)

[Guidance Document: Schedule A and Section 3 to the Food and Drugs Act](#)

[www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/scha\\_guide\\_ld-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/scha_guide_ld-eng.php)

[Guidance for Industry – Device Licence Applications for Ultrasound Diagnostic Systems and Transducers](#)

[www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/ultrasound\\_ultrasons-eng.php](http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/ultrasound_ultrasons-eng.php)

[Guidance for Industry: Keyword Index to Assist Manufacturers in Verifying the Class of Medical Devices](#)

[www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/keyword\\_motscles2-eng.php](http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/keyword_motscles2-eng.php)

[Guidance for the Interpretation of Sections 28 to 31: Licence Application Type](#)

[www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/apptype\\_typedem-eng.php](http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/apptype_typedem-eng.php)

[Guidance for the Interpretation of Significant Change of a Medical Device](#)

[www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/signchnng\\_modimportante-eng.php](http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/signchnng_modimportante-eng.php)

[Handling complaints about medical devices \(GUI-0065\)](#)

[www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui-0065\\_md-im\\_problem\\_doc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui-0065_md-im_problem_doc-eng.php)

[Guidance on Medical Device Compliance and Enforcement \(GUI-0073\)](#)

[www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/gui-0073-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/gui-0073-eng.php)

[Guidance on the Risk-based Classification System for Non-In Vitro Diagnostic Devices \(non-IVDDs\)](#)

[www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/gd\\_rbc\\_non\\_ivdd\\_lg\\_scr\\_autres\\_idiv-eng.php](http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/gd_rbc_non_ivdd_lg_scr_autres_idiv-eng.php)

[Medical devices recall guide \(GUI-0054\)](#)

[www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui-0054\\_recall-retrait-doc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui-0054_recall-retrait-doc-eng.php)

[How risk is rated during inspections of medical device establishments \(GUI-0079\)](#)

[http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/md\\_insp\\_prog\\_prog\\_insp\\_mm-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/md_insp_prog_prog_insp_mm-eng.php)

## Other

[Compliance and Enforcement Policy \(POL-0001\)](#)

[www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/pol/pol\\_1\\_tc-tm-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/pol/pol_1_tc-tm-eng.php)

[GD210: ISO 13485:2003 Quality Management System Audits Performed by Health Canada Recognized Registrars](#)

[www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/cmdcas\\_scecim\\_audit13485\\_gd210-eng.php](http://www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/cmdcas_scecim_audit13485_gd210-eng.php)

[List of Registrars Recognized by Health Canada under section 32.1 of the Medical Devices Regulations \(MDR\)](#)

[www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/list\\_liste\\_regist-eng.php](http://www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/list_liste_regist-eng.php)

[Medical device inspections](#)

<http://healthycanadians.gc.ca/apps/md-im/index-en.html>

[The Medical Devices Special Access Programme](#)

[www.hc-sc.gc.ca/dhp-mps/acces/md-im/sapmdfs\\_pasimfd-eng.php](http://www.hc-sc.gc.ca/dhp-mps/acces/md-im/sapmdfs_pasimfd-eng.php)