



Health Canada

## Medical Devices Chapter 2: Canadian Requirements

### Chapter 2: Canadian Requirements

#### An Overview of the Quality System Requirements for the Sale of Medical Devices in Canada

Health Canada, under the authority of the *Food and Drugs Act*, regulates the sale of medical devices and drugs in Canada. On July 1, 1998, new Medical Devices Regulations ("the Regulations") came into force, replacing Regulations which had been in effect since 1975. These regulations are amended from time to time to reflect new policies or minor housekeeping changes. A consolidated version can be viewed on the following website:

<http://laws.justice.gc.ca/en/f-27/sor-98-282/129451.html>

The current Regulations are based on a risk assessment and risk management approach with a balance of pre-market review, quality systems and post-market surveillance.

One system classifies in vitro diagnostic devices. The second classifies all other medical devices and addresses the majority of devices available to Canadians. Both systems classify devices into one of four risk classes, Class I representing the lowest risk and Class IV the highest. The system for non-in vitro medical devices utilizes criteria such as invasiveness; length of invasiveness; body system exposed to the device; whether or not the device relies on a source of energy; whether the device diagnoses or is therapeutic; and whether or not the device delivers energy to the patient, in assigning a level of risk to a device. Special rules are included to classify, for example, devices incorporating animal tissues or devices that use recombinant DNA technology in their manufacture.

A set of safety and effectiveness requirements form the basis of the Regulations. These have been modeled on the "essential requirements" of the European Directives. For the majority of devices, demonstration of compliance with these requirements to Health Canada is assessed through a pre-market device licensing requirement; however, **all** devices are required to meet these safety and effectiveness requirements, as appropriate.

Before a Class II, III or IV medical device can be imported, sold or advertised for sale, a device licence must be obtained from Health Canada. Class I devices are exempt from device licensing requirements. Although manufacturers are responsible for classifying their devices, classification is subject to verification by Health Canada. The amount of information required to be submitted to obtain a device licence increases the higher the risk class of the device.

To monitor medical device distribution from the time of manufacture to use, importers and distributors are required to obtain an establishment licence. Manufacturers of Class I medical devices distributing directly to users are also required to obtain an establishment licence. Issuance of an establishment licence is contingent upon attestations from the applicant that recall, mandatory problem reporting and complaint handling procedures are in place, and that proper distribution records are maintained.

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# 1 Key Elements of the Medical Devices Regulations

## 1.1 Scope of Application

The Regulations apply to

- (a) the sale and advertising for sale of a medical device;
- (b) the importation of a medical device for sale or for use on patients.

In vitro diagnostic products that are drugs or that contain drugs are also covered under these Regulations, as if they were medical devices.

## 1.2 Medical Device and In Vitro Diagnostic Device Classification

Medical devices are classified into one of four classes (I, II, III or IV), based on how the device is represented for use by the manufacturer. Class I devices represent the lowest risk and Class IV devices represent the highest risk.

Schedule I, Part I of the Regulations sets out the rules for classifying medical devices other than in vitro diagnostic devices (IVDDs). These rules cover various combinations of the following criteria:

- whether or not the device is invasive (i.e., penetrating the body or in contact with intact skin);
- duration that the device is invasive (e.g., less than or greater than 30 days);
- method of achieving invasiveness (e.g., whether it is invasive through a body orifice or is surgically invasive);
- anatomy affected by the device (e.g., central nervous system);
- whether it is active or non-active (i.e., powered or non-powered); and
- special situations (e.g., devices utilizing animal tissue or contact lens solutions).

Schedule I, Part II sets out rules for classifying In Vitro Diagnostic Devices (IVDD). These rules are based on the degree of risk associated with the use of an IVDD. All IVDDs are classified into one of four classes. An IVDD with the highest risk is classified as Class IV while an IVDD with the lowest risk is classified as Class I. Criteria used to determine the class of each IVDD include:

- its indication(s) for use (the specific disorder, condition, or risk factor for which the test is intended);
- its application (screening, patient-based testing/diagnosis, monitoring, etc.);
- the technical/scientific/medical expertise of the intended user (testing laboratories vs near-patient testing);
- the importance of the information to the diagnosis (sole determinant or one of several determinants), taking into consideration the natural history of the disease or disorder including presenting signs and symptoms which may guide a physician; and
- the impact of the result (including both true and false positives and negatives, genetic testing, home testing) to the individual and/or the public health.

The intent of the four different classes within this classification can be described as follows:

Class IV IVDDs are those that, through their use, present a high public health risk to the community in general. These include IVDDs used for donor screening or for the diagnosis of life-threatening diseases caused by transmissible pathogens such as HIV and hepatitis viruses. These are diseases that result in death or long-term disability, that are often untreatable or require major therapeutic interventions and where an accurate diagnosis is vital to mitigate the public health impact of the condition.

Class III IVDDs are those that, through their use, present either a moderate public health risk or a high individual risk. They present a moderate public health risk, to the community in general or in some cases to a more confined environment such as a hospital, as they are used to detect transmissible agents that cause diseases. These diseases, although often treatable, may result in death or long-term disability if not treated in a timely manner and where an accurate diagnosis offers an opportunity to mitigate the public health impact of the condition. Examples include sexually transmitted agents and infectious agents that cause nosocomial infections. Class III IVDDs that present a high individual risk are those where an erroneous result would put the patient in an imminent life-threatening situation (e.g. IVDDs used in cases of suspected meningitis or septicaemia) or would have a major negative impact on outcome (e.g. result in death or severe disability) as they are a critical, or even the sole, determinant (cancer screening, prenatal screening). They may also present a high individual risk because of the stress and anxiety resulting from the information and the nature of the possible follow-up measures (e.g. genetic testing).

Class II IVDDs are those that, through their use, present either a low public health risk or a moderate individual risk. These present a low community risk because they detect infectious agents that are not easily propagated in a population or because they cause self-limiting diseases. They present a moderate individual risk as they are not the sole determinant or, if they are, it is not likely that an erroneous result will cause death or severe disability, have a major negative impact on outcome or put the individual in immediate danger.

Class I IVDDs are those that, through their use, present a minimal risk such as general in vitro diagnostic laboratory equipment, microbiology and cell culture media and general diagnostic reagents.

Before classifying a device, a manufacturer must first determine if the product meets the definition of a "device" as it is defined in the *Food and Drugs Act*. If it is determined that the definition applies, the manufacturer must then determine whether or not the definition of "medical device" in the Regulations applies. It is important to note that the definition in the Regulations excludes devices for use on animals, and if this is the case for the product in question, the Regulations would not apply.

The classification process can be complex and is dependent upon the interpretation of each rule as applied to a given device. The manufacturer is responsible for conducting a self-assessment of the device to determine its class. Where a medical device can be classified into more than one class, the highest class applies. Guidance is available to assist manufacturers in classifying their devices. The "Keyword Index" was prepared by Health Canada prior to the implementation of the new Regulations. Although helpful, caution must be exercised in using this guidance as a number of inaccuracies can be found in the classification of devices within the document. The document contains a disclaimer to the effect that it is not the authoritative source, and that if in doubt, manufacturers should contact Health Canada for a definitive classification. This guidance and guidance for the interpretation of the classification rules for medical devices can be found on the Health Canada website at:

[http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/index_e.html)

Further guidance may be obtained by viewing the list of Canadian licensed medical devices on the following website:

[www.mdall.ca](http://www.mdall.ca)

The classification rules for devices other than IVDDs are close to, but not identical with, the European classification rules. If one applied the classification rules for each jurisdiction to the same group of medical devices, there is a strong likelihood that all but a few would result in equivalent classifications.

The EU has four classes of medical devices which generally correspond to Canada's four classes, as illustrated in the following table.

<b>Canadian Medical Devices Regulations</b>		<b>European Council Directive 93/42/EEC (MDD)</b>
Class IV	generally corresponds to	Class III
Class III	generally corresponds to	Class IIb
Class II	generally corresponds to	Class IIa
Class I	generally corresponds to	Class I

Appendix 1 of this guide provides a sample listing of medical devices for each European device class. Using the above comparison table, one can see how these devices would be classified under the Canadian Classification Rules for Medical Devices. This list is based solely on the author's interpretation of the intended use of these devices and may not necessarily reflect Health Canada's determination of device class.

A manufacturer would be wise to confirm the class of a particular device with Health Canada before proceeding with the implementation of the quality system. This is particularly important when determining the quality system requirements for a particular device class.

### **1.3 General Requirements**

The following general requirements apply to all medical devices, except those that are custom-made, imported or sold for special access, or used for investigational testing on human subjects. These general requirements are set out in Part I of the Regulations. Requirements for devices that are custom-made or imported or sold for special access are set out in Part II. Requirements for devices used for investigational testing on human subjects are set out in Part III.

#### **1.3.1 Safety and Effectiveness Requirements**

Manufacturers must ensure that the medical device meets specific safety and effectiveness requirements as set out in Sections 10 to 20 of the Regulations. These requirements apply to all medical devices, except those that are custom-made; imported or sold for special access; or used for investigational testing on human subjects. The manufacturer must maintain records to demonstrate that these requirements are being met.

The safety and effectiveness requirements call for measures to ensure that the health or safety of patients, users or others is not adversely affected. They deal with

- the design and manufacture of the device;
- the degree of acceptable risks weighed against the benefits;
- the performance of the device;
- protection against deterioration of the device's characteristics and performance;
- protection of the device's characteristics and performance during transportation and storage;
- compatibility of materials used in the device's manufacture;
- minimizing the risk from reasonably foreseeable hazards (flammability; explosions; contamination; chemicals; microbial residue; radiation; electrical, mechanical or thermal hazards; and fluid leakages);
- appropriately controlled sterilization processes;
- compatibility with all other parts of the system with which it interacts;
- accurate and consistent measuring capability, where a measuring function is involved;
- validation of software, where software is involved; and
- labelling.

These safety and effectiveness requirements closely correspond to the essential requirements of the European MDD (ref: Annex I of the MDD). However, the MDD spells out the essential requirements in much greater detail. Similar to the European approach and the references in the MDD to the use of harmonized standards for complying with the essential requirements, Health Canada has developed a policy on the use of recognized standards in establishing the safety and effectiveness of medical devices. This policy can be found on the Health Canada website at the following address:

[http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/index_e.html)

### **1.3.2 Medical Device Licence**

Manufacturers must hold a licence for Class II, III and IV medical devices imported, sold or advertised for sale in Canada. Applications for a device licence must be submitted to Health Canada and must contain detailed information as set out in the Medical Device Licence section of the Regulations. This information must include specific quality system requirements as identified in that section. These requirements are described in Section 2 of this chapter.

Health Canada, upon satisfying itself that the device meets the safety and effectiveness requirements described above, will issue a device licence, which is subject to annual renewal. This annual renewal will require manufacturers to verify device information on file with Health Canada. Failure to renew a device licence will result in its cancellation by Health Canada.

### **1.3.3 Establishment Licence**

Any person who imports or sells a medical device in Canada, and any manufacturer of a Class I device who does not import or distribute solely through a person who holds an establishment licence, must hold an establishment licence. Retailers, health care facilities, and manufacturers of Class II, III and IV devices are exempt from this requirement. Applications for an establishment licence must be submitted to Health Canada and must contain detailed information as set out in the Establishment Licence section of the Regulations. Health Canada, upon satisfying itself that the establishment meets the requirements described in that section, will issue an establishment licence, which is valid for one year. Health Canada can refuse to issue or can cancel an establishment licence. Further guidance on Establishment Licensing can be found on the Health Canada website at:

[http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/index_e.html)

### **1.3.4 Labelling Requirements**

Medical devices imported or sold in Canada must have labels containing specific information, related to these devices, that is easily understood by the user. Where the device is too small to permit this information to be placed on the label, the information must be contained in the directions for use.

Licences and licence applications must contain a street address. A postal code can be included as additional information, but not as a replacement for a street address. These requirements are set out in the Labeling Requirements section of the Regulations. This section also sets out language requirements related to labels and directions for use. It is important to note that the address on the device licence must match the address on the quality system certificate. For example, you cannot have a street address on the licence and only a postal code on the quality system certificate. Both require a street address, although it is permissible for one to have a postal code in addition to the street address, and the other not to include a postal code. Further guidance on Labeling Requirements can be found on the Health Canada website at:

[http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/index_e.html)

### **1.3.5 Distribution Records**

A manufacturer, importer or distributor of a medical device must maintain distribution records of each device. This requirement does not apply to retailers or health care facilities in respect of devices used within that facility. The Distribution Records section of the Regulations sets out the information to be contained in these records, as well as additional requirements for implants. Records must be retained for the projected life of the device, as defined by the manufacturer, but not less than two years after the device was dispatched from the manufacturer. Record retention times are the same as those for the EU and US.

### **1.3.6 Mandatory Problem Reporting**

The manufacturers and the importers of devices must make preliminary and final reports to Health Canada concerning any incident involving their device that

(a) is related to the failure or deterioration of the device or inadequacies in the labelling or directions for use; and

(b) has led to a death or serious deterioration in the health of a patient, user or other person; or could have led to a death or serious deterioration in the health of a patient, user or other person.

The Mandatory Problem Reporting section of the Regulations sets out the types of incidents to be reported, time frames for reporting and content for the preliminary and final reports, including actions taken to prevent the incident from recurring.

These mandatory reporting requirements are harmonized with the European vigilance reporting requirements described in Section 6.1 of Chapter 1 of this guide.

Further guidance on the Mandatory Problem Reporting requirements of the Regulations can be found on the Health Canada website at:

[http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/index_e.html)

### **1.3.7 Recall**

A manufacturer, importer or distributor of a medical device must make provisions for carrying out the following:

(a) an effective and timely investigation of reported problems relating to the performance or safety of the device, including any customer complaints; and

(b) an effective and timely recall of the device.

Before undertaking the recall of a device, both the manufacturer and the importer must provide Health Canada with the detailed information set out in the Recall section of the Regulations. After such a recall, the manufacturer and the importer must report to Health Canada the results of the recall and the action taken to prevent a recurrence of the problem. The manufacturer and the importer must maintain records related to the recall. Further guidance on the recall requirements of the Regulations can be found on the Health Canada website at:

[http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/index_e.html)

### **1.3.8 Implant Registration**

The Implant Registration section of the Regulations sets out specific requirements of the manufacturer pertaining to the registration of implants and the use of implant registration cards to facilitate the provision of advisory information to patients. Devices subject to these requirements are listed in Schedule II of the Canadian Medical Devices Regulations. Health Canada may authorize methods of implant registration other than implant cards.

## **1.4 Custom-Made Devices and Medical Devices to be Imported or Sold for Special Access**

To import or sell Class III or IV custom-made devices or devices for special access, particular requirements must be met in relation to authorization, additional information, labelling, distribution records, reporting of incidents, and advertising. These requirements are covered in Part II of the Regulations. Special access is defined in the Regulations as "access to a medical device for emergency use or if conventional therapies have failed, are unavailable or are unsuitable." Guidance on how to apply for authorization to obtain custom-made or special access devices can be found on the Health Canada website at:

[http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/index_e.html)

Quality system requirements, identified in the Medical Device Licence section, Part I of the Regulations, do not apply to these categories of medical devices.

## **1.5 Medical Devices for Investigational Testing**

A manufacturer or importer of a Class II, III or IV medical device may sell a device to a qualified investigator for the purpose of conducting investigational testing involving human beings if authorized by Health Canada and if the required records and documents are kept. For Class I devices, such authorization is not required if the required records and documents are kept. For all classes of these devices, particular requirements are set out in relation to record keeping,

authorization, additional information, labelling, advertising, and other matters. These requirements are covered in Part III of the Regulations. Guidance on how to apply for authorization to conduct investigational testing on human subjects can be found on the Health Canada website at:

[http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/index_e.html)

Quality system requirements, identified in the Medical Device Licence section, Part I of the Regulations, do not apply to this category of medical device.

## 1.6 Export Certificates

The exporter of a medical device must maintain, at their principal place of business in Canada, records that contain the completed export certificates and must submit these certificates to Health Canada inspectors for examination when asked to do so. Export certificates must be retained for not less than five years after the date of export.

Part IV of the Regulations sets out the requirements pertaining to export certificates.

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## 2 Quality System Requirements

The quality system and related requirements are set out in Sections 32(2), 32(3), 32(4), 32.1, 32.2, 32.3, 32.4, 32.5, and 43.1 of the Regulations.

Manufacturers of Class II, III and IV devices must demonstrate that their devices are manufactured in accordance with internationally recognized quality system standards for medical devices. Presently the Canadian adoption of ISO 13485:1996 and ISO 13488:1996 are required by the Regulations. As of March 15, 2006, the international standard for medical devices will be ISO 13485:2003 *Medical devices-Quality management systems — System requirements for regulatory purposes*. ISO 13485:2003 embodies all the principles of Good Manufacturing Practices (GMP) widely used in the manufacture of medical devices. It is a stand-alone standard, with the same format and much of the same requirements as ISO 9001:2000 *Quality management system—Requirements*.

Canada has adopted ISO 13485:2003 as a Canadian National Standard and labeled it CAN/CSA-ISO 13485:2003. For class II devices, the quality system must satisfy the requirements of CAN/CSA-ISO 13485:2003, excluding design. For class III and IV devices, the quality system must satisfy the requirements for CAN/CSA-ISO 13485:2003, including design. Manufacturers operating under CAN/CSA-ISO 13485-98 and CAN/CSA-ISO 13488-98 quality systems have until March 15, 2006 to switch over to the 2003 version.

It is recommended that the scope of the organization's quality system, as defined in its quality manual, address all appropriate sections of Part 1 *Canadian Medical Devices Regulations*.

During the third-party audit, the organizations must demonstrate how it has effectively implemented the above.

Demonstration of conformance with the quality system requirements will be required at the time an application is made for a medical device licence. Manufacturers will need to provide a copy of a quality system certificate, which has been issued to them by any third-party audit

organizations (registrars) accredited by the Standards Council of Canada (SCC) and recognized by them and Health Canada under the Canadian Medical Devices Conformity Assessment System (CMDCAS) scope. For annual licence renewals, copies of the quality system certificate will not be required to accompany the renewal application. However, where a quality system certificate has been revised or amended as a result of a third-party audit by a registrar, the manufacturer must submit a copy of the revised or amended certificate to Health Canada within 30 days of the date of issue.

To view the most current list of accredited registrars, visit the Health Canada website at:

[http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/index_e.html)

## **2.1 Policy on the Canadian Medical Devices Conformity Assessment System (CMDCAS)**

CMDCAS outlines Health Canada's policy on the processes leading to SCC's accreditation of registrars, and the registration of a medical device manufacturer's quality system by these accredited registrars. A Health Canada-SCC Management Committee is responsible for managing CMDCAS accreditation-related issues.

Health Canada will have full access to information related to an accreditation assessment, reassessment or surveillance audit of a registrar, and from a registrar's assessment, reassessment or surveillance audit of a manufacturer, and will treat this information in accordance with appropriate federal regulations and guidelines dealing with confidential or proprietary information.

The resolution of complaints and disputes surrounding a manufacturer's compliance with the regulatory requirements is the responsibility of Health Canada and will be resolved through a formal appeal process.

## **2.2 Registering the Quality System**

### **2.2.1 The Process**

To prove conformity with an ISO standard, organizations normally contract the services of registrars. Registrars conduct independent third-party audits of a company's quality system. If the company passes the audit, the registrar recommends that the quality system be registered to the appropriate ISO standard.

Registration is normally valid for three years. There are three audits associated with the registration process:

- 1) The documentation audit, during which auditors assess the organization's quality system documentation, including the organization's policies and procedures, against the ISO standard;
- 2) The initial on-site audit during which auditors assess the company's quality system against the ISO standard. They verify records, question selected staff members about work practices that affect product or service quality, and ensure that the organization's stated quality practices are indeed being followed. If the audit is successful, the registrar will recommend ISO registration; and

3) Surveillance audits, which are conducted once or twice per year to assess segments of the company's quality system to ensure continued compliance with the ISO standard. All segments of a company's quality system are typically audited over a three-year period. After the third year of registration, a comprehensive on-site audit is normally conducted and the surveillance audit process is repeated.

A registrar's audit may result in one of three situations:

1) The quality system conforms and the registrar will recommend ISO registration;

2) A major nonconformance is found and a recommendation for registration cannot be made. A major nonconformance means the absence, or total breakdown, of one of the ISO elements or a number of nonconformities throughout various elements, which the registrar considers would result in a breakdown of the quality system. A major nonconformance would also include the absence of any applicable section of Part 1 of the *Canadian Medical Devices Regulations*, which should be included in the scope of the quality system. While registrars do not audit against the *Canadian Medical Devices Regulations*, they are required to raise nonconformities against the relevant clause of ISO 13485. A number of clauses in ISO 13485:2003 stipulate that additional requirements must be met where national or regional regulations call for these. For example, an auditor may find that mandatory problem reporting does not satisfy the *Canadian Medical Devices Regulations*, and will issue a nonconformance clause 8.5.1 of ISO 13485:2003. That clause requires documented procedures to notify the regulatory authorities of adverse incidents that meet their reporting criteria. It is Health Canada's responsibility to inspect for compliance against specific sections of the regulations. Where a major nonconformity is found, the organization being audited would be told to submit a revised plan to seek registration. On the basis of that plan, a re-audit would be scheduled; or

3) A minor nonconformity or observation, where a weakness in the quality system is discovered by auditors that is not severe enough to lead to a complete quality system breakdown but should be addressed. Often, auditors will recommend registration on the condition that the minor nonconformity or observation be rectified before the first surveillance audit.

In Canada, registrars are accredited by the Standards Council of Canada. To become accredited, registrars must comply with strict Standards Council of Canada requirements.

### 2.2.2 Registration Cost

Estimating the cost of registration is difficult, as it is influenced by such factors as the size of the organization being audited, and the number and complexity of its products. However, the costs will likely be similar to those identified in Section 3.3.3 of Chapter 1 relating to the CE mark. It is reasonable to assume that a manufacturer in the size range of 30 employees, manufacturing a Class II, III or IV device would have to pay between \$25 000 and \$30 000 for a quality system registration. This estimate includes travel and related costs, as well as semi-annual or annual surveillance audits.

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## 3 Information Sources

General information on the Medical Devices Regulations can be obtained from Health Canada by contacting

Medical Devices Bureau  
Room 1605, Main Statistics Canada Building  
Postal Locator 0301H1  
Tunney's Pasture  
Ottawa ON  
K1A 0L2  
Tel.: 613-957-4786  
Fax: 613-957-7318  
Email: [don\\_boyer@hc-sc.gc.ca](mailto:don_boyer@hc-sc.gc.ca)  
[nancy\\_shadeed@hc-sc.gc.ca](mailto:nancy_shadeed@hc-sc.gc.ca)

An electronic version of the Regulations can be obtained from Health Canada's website  
[http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/index_e.html).

