

## Medical Device Regulatory Requirements for Canada

Updated: June, 2011

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For general information on Canada, please refer to the U.S. and Foreign Commercial Service's country commercial guide, *Doing Business in Canada: 2011 Country Commercial Guide for U.S. Companies*, please visit [http://www.buyusainfo.net/docs/x\\_615709.pdf](http://www.buyusainfo.net/docs/x_615709.pdf) or visit the CIA World Factbook at <https://www.cia.gov/library/publications/the-world-factbook/geos/ca.html>.

Web links are current as of June, 2011

### Regulatory Framework

Health Canada is the Canadian agency that regulates medical devices pursuant to the Food and Drugs (R.S., 1985, c. F-27), and through the Medical Devices Regulations (SOR/98-282) which apply to the manufacturing, sale, advertising for sale, and importation of medical devices, including *in vitro* diagnostic devices. Manufacturers must ensure that their medical devices meet the safety and effectiveness requirements as defined in the Medical Devices Regulations (SOR/98-282, Section 9).

The Food and Drugs Act defines a medical device as: "any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in: the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in a human being; the restoration, correction or modification of a body function or the body structure of a human being; the diagnosis of pregnancy in a human being; or the care of a human being during pregnancy and at and after the birth of a child, including the care of the child. It also includes a contraceptive device but does not include a drug." The Food and Drugs Act is available at [http://www.hc-sc.gc.ca/fn-an/legislation/acts-lois/act-loi\\_reg-eng.php](http://www.hc-sc.gc.ca/fn-an/legislation/acts-lois/act-loi_reg-eng.php). The Medical Devices Regulations can be found at <http://www.hc-sc.gc.ca/dhp-mps/md-im/legislation/index-eng.php>.

### Quality Management Systems

Canadian regulations require that medical devices be manufactured, or designed and manufactured under a registered quality management system (QMS) that meets the criteria of the Canadian National Standard CAN/CSA ISO 13485:03 *Medical devices – Quality management systems – Requirements for regulatory purposes*. The Canadian national standard version is modeled after the International Organization for Standardization (ISO) standard ISO 13485:2003 *Medical devices – Quality management systems – Requirements for regulatory purposes*.

Third party auditing organizations are formally recognized by the Minister of Health under section 32.1 of the Medical Devices Regulations for the purpose of issuing QMS certificates to manufacturers of Class II, Class III or Class IV medical devices for regulatory purposes. (For more information on the risk assessment classification system, please see *Medical Device Classification* section below). Quality management system regulations do not apply to Class I medical devices.

The Therapeutic Products Directorate of Health Canada in partnership with Canada's national accreditation body, the Standards Council of Canada, recognizes third party auditing organizations in accordance with the Canadian Medical Devices Conformity Assessment System (CMDCAS)

Only Health Canada-recognized third parties (also called registrars) are eligible to certify manufacturers that intend to sell or advertise products for sale in Canada. The official list of Health Canada-recognized third parties (registrars) is maintained on the Health Canada website at [http://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). As of this writing, the list is as follows:

- BSI Group America, Inc.
- DQS GmbH
- Intertek Testing Services
- Kema Quality BV
- LGA InterCert GmbH
- Lloyd's Register Quality Assurance, Inc.
- National Standards Authority of Ireland
- Office of Manufacturing Quality, TGA
- RWTUV Systems GmbH
- SAI Global Certification Services Pty Ltd.
- SGS United Kingdom Ltd.
- TUV Rheinland of North America
- TUV SUD America, Inc.
- TUV USA, Inc.
- Underwriters Laboratories, Inc.

### **Medical Device Risk Classification**

Similar to the European Union, Health Canada applies a four-tier classification system to medical devices according to their risk to the human body, with Class I representing the lowest risk to the human body and Class IV representing the highest risk. Canada's Medical Devices Regulations (SOR/98-282, Schedule 1, Part 1) provide detailed classification rules for medical devices, which readers are strongly encouraged to review for purposes of classifying medical devices for export to the Canadian market. Medical device classifications are determined by the Canadian Risk-Based Classification System (RBCS), under the auspices of the Therapeutic Products Division (TPD) of Health Canada. If a medical device can be classified in more than one class, the higher class applies.

Manufacturers are required to ensure that medical devices meet safety and effectiveness requirements and to maintain data on these requirements. Manufacturers are likewise obligated to identify the risks inherent in the device, eliminate or reduce possible risk, and provide for appropriate protection from those risks.

On August 13, 2010, Health Canada issued “Guidance on Risk Classification of Medical Device Observations (GUI-0079),” which was implemented on October 1, 2010. This Guidance explains the Canadian Medical Device Inspection Program, the process by which inspectors assign a risk classification based on observations made during inspections of medical device manufacturers, importers and/or distributors. The Guidance is available at [http://www.hc-sc.gc.ca/dhp-mps/alt\\_formats/pdf/compli-conform/info-prod/md-im/gui-0079-eng.pdf](http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/compli-conform/info-prod/md-im/gui-0079-eng.pdf). Based on the inspector’s observations and the risk classification ultimately assigned, an Inspection Report is drafted, in which the inspector makes an overall recommendation for the continuation of the establishment’s license (rating of Compliant; C) or not (rating of Non-Compliant; NC).

According to a September 2010 letter from the Health Products and Food Branch Inspectorate, inquiries about this Guidance document can be submitted either by mail to the Manager, Medical Device Compliance Unit, HPFB Inspectorate, Graham Spry Building, A.L. #200D, 250 Lanark Avenue, Ottawa, Ontario, K1A 0K9, by fax at 613-954-0941, or by e-mail at MDCU-UCIM@hc-sc.gc.ca.

### **Labeling**

Under the Medical Devices Regulations (SOR/98-282, Sections 21-23), all labeling on medical devices imported into Canada must be “legible, permanent, and prominent,” and must contain the following minimum data:

- The name of the device
- The name and address of the manufacturer
- In the case of Class III or IV devices, the control number
- If the contents are not readily apparent, an indication of what the package contains
- The word "Sterile" if the manufacturer intends the device to be sold in a sterile condition
- The expiry date of the device
- Unless self-evident to the intended user, the medical conditions, purposes and uses for which the device is manufactured
- The directions for use and storage

If the device is to be sold to the general public, labeling information should be on the outside of the packaging (size permitting) and visible under the normal conditions of sale. Labeling must be in English and French and directions for use must be supplied in both official languages at the time of purchase.

### **Distribution and distribution records**

The selection of a national distributor with well-defined provincial and regional strategies and resources is essential in an increasingly competitive and changing Canadian market. The existence of service and technical support organizations inherent to the business of selling

medical devices, require established, reliable, and knowledgeable dealers willing to offer their service and loyalty, to ensure effective market penetration.

Under the Medical Devices Regulations, manufacturers, importers, and distributors of medical devices are required to maintain distribution records for each device sold in Canada (SOR/98-202, Sections 52-56). The Medical Device regulations require that the distribution records contain sufficient information to permit a complete and rapid withdrawal of the device from the market. The distribution records requirements do not apply to retailers and health care facilities that distribute medical devices for use within that facility. Distribution records are to be kept for at least two years from the shipment of the device or for its projected useful life, whichever period is longer.

### **Complaints, adverse incidents, and recalls**

Manufacturers, importers, and distributors are obliged to maintain records of reported problems related to the performance and safety of the device as well as actions taken in response to these incidents including recalls. A preliminary and final report to the Ministry of Health is required from the manufacturer and importer regarding any incident (occurring within or outside of Canada) regarding a device that is sold in Canada that is related to the failure of the device or the death or “serious deterioration of the state of health of a patient.” The preliminary report must contain the following information:

- The name of the device and its identifier number;
- Contact information for the manufacturer and/or importer;
- The date on which the incident came to the attention of the manufacturer or importer;
- Reason for the recall, including the consequences for the patient;
- The name, address and telephone number, if known, of the person who reported the incident to the manufacturer or importer;
- The identity of any other medical devices or accessories involved in the incident;
- The manufacturer’s or importer’s preliminary comments with respect to the incident;
- The course of action, including an investigation, that the manufacturer or importer proposes to follow in respect of the incident and a timetable for carrying out any proposed action and for submitting a final report; and
- A statement indicating whether a previous report has been made to the Minister with respect to the device and, if so, the date of the report (SOR/98-282, Section 60).

After the preliminary report is made to the Ministry of Health, a final report must be submitted in accordance with the timetable submitted in the preliminary report. The final report shall contain the following information:

- a description of the incident, including the number of persons who have experienced a serious deterioration in the state of their health or who have died;
- a detailed explanation of the cause of the incident and a justification for the actions taken in respect of the incident; and
- any actions taken as a result of the investigation, which may include (i) increased post-market surveillance of the device, (ii) corrective and preventive action

respecting the design and manufacture of the device, and (iii) recall of the device (SOR/98-282, Section 61).

In the event that a recall is necessary, the manufacturer and importer of the medical device must report to the Ministry of Health the results of the recall and the actions taken to prevent the recurrence of the problem (SOR/98-282, Section 63).

### **Custom-made devices**

Custom-made Class III or Class IV devices require authorization from the Ministry of Health for importation into Canada (SOR/98-202, Sections 69-78). To import or sell Class III or IV custom-made devices or devices for special access, the importer must meet particular requirements for authorization, additional information, labeling, distribution records, reporting of incidents, and advertising. Upon submission of required information, the Ministry of Health may determine that the benefits that may be obtained by the use of the product outweigh risks associated with its use.

### **NAFTA Certificate of Origin**

Under the North American Free Trade Agreement (NAFTA), certain products, including most medical devices, that “originate” in Canada, Mexico, or the United States enjoy low or zero tariff rates when traded between these countries. In order to receive this preferential treatment, products that qualify must have a NAFTA Certificate of Origin. For information on NAFTA Rules of Origin and the Certificate of Origin, please click **here**

[[http://www.export.gov/logistics/eg\\_main\\_018131.asp](http://www.export.gov/logistics/eg_main_018131.asp). ]

## **Contacts**

### **U.S. Consulate General - Montreal, US Commercial Service**

315 Place d'Youville, Suite 500  
Montreal, Quebec H2Y 0A4  
Contact: Connie Irrera, Commercial Service  
Tel: 514 908-3662  
Fax: 514 398-0711

### **The American Chamber of Commerce in Canada**

<http://www.amchamcanada.ca/index.php?action=home>

### **Therapeutic Products Directorate Director General's Office & Associate Director General's Office**

Therapeutic Products Directorate  
Health Products and Food Branch  
Address Locator: 3106B  
Ottawa, Ontario K1A 0K9  
Telephone: 613-957-0368  
Fax: 613-952-7756

### **Therapeutic Products Directorate's Medical Devices Bureau**

Telephone: 613-957-1909  
Fax: 613-957-7318  
E-mail: [MDB\\_Enquiries@hc-sc.gc.ca](mailto:MDB_Enquiries@hc-sc.gc.ca)  
For: device evaluations, device licensing, device surveillance, special access programs, and quality systems

### **For revisions to the standard and clarification on regulatory quality systems issues**

Quality Systems Section  
Medical Devices Bureau  
Therapeutic Products Directorate  
150 Tunney's Pasture Driveway, Room 1605  
Statistics Canada Main Building  
Tunney's Pasture, Address Locator 0301H1  
Ottawa, Ontario K1A 0K9  
Phone: 613-952-8250  
Fax: 613-946-6563  
Email: [MDB\\_Enquiries@hc-sc.gc.ca](mailto:MDB_Enquiries@hc-sc.gc.ca)

### **Bids for government contracts**

Contracts Canada Information Centre  
Public Works and Government Services Canada  
Place du Portage, Phase III  
Tower C 3C1  
11 Laurier Street

Hull, Quebec  
Canada K1A 0S5  
Tel: 800-811-1148  
Fax: 819-956-6123  
URL: <http://contractscanada.gc.ca>  
MERX (The Government Electronic Tendering Service)  
[www.merx.com](http://www.merx.com)