Medical Device Regulatory Requirements for Canada

Updated: March 2006

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For general information on Canada, please visit the CIA World Factbook entry on that country at www.cia.gov/cia/publications/factbook/geos/ca.html.

Web links were current as of March 2006

Regulatory Update:
As of January 1, 2003, Canadian regulations require that medical devices be designed and manufactured under a registered quality management system (QMS) that meets the criteria of International Standards Organizations (ISO) standards 13488-03 for Class II devices and 13485-03 for Class III and IV devices. The Canadian Medical Devices Conformity Assessment System (CMDCAS) (within the Therapeutic Products Directorate (TPD), in partnership with the Standards Council of Canada (SCC) are tasked with executing regulatory policy in that country.

The SCC qualifies organizations to register the QMS of medical device manufacturers. Only SCC-accredited registration bodies are eligible to register manufacturers for export into Canada.

The currently-used editions of the ISO standards will expire on July 15, 2006 and will be replaced by CAN/CSA-ISO 13485-2003 on May 15, 2006. For more information, see the Transition to ISO 2003 Standards section below.

Regulatory Framework

Medical device regulations in Canada apply to the sale and advertising for sale of a medical device and their importation. These regulations also apply to *in vitro* diagnostic products. All medical devices in Canada must be deemed safe and effective, including software accompanying any medical device.

Medical Device Classification:
Medical devices in Canada are classified according to their risk to the human body. Risk classes are numbered I to IV, with IV representing the highest classification as determined by the 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 applies.

Classification is as follows:

- Class I: lowest risk devices such as wound care and non surgically-invasive devices such as mechanical barriers
- Class II: low risk devices including contact lenses and the majority of surgically-invasive devices
- Class III: medium risk devices such as hip implants, glucose monitors and surgically-invasive devices that are intended to be absorbed into the body, or that are intended to remain in the body for at least thirty consecutive days
- Class IV: high risk devices such as pacemakers and surgically-invasive devices that diagnose, control or correct a defect in the central cardiovascular system

Manufacturers are required to ensure that medical devices meet safety and effectiveness requirements and to maintain data establishing the same. 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.

Labeling

All labeling must be "legible, permanent, and prominent," and must contain the following minimum data:

- The name of the device
- The name of the manufacturer
- In the case of Class III or IV devices, the control number
- Dimensions of the device
- Sterility information, if appropriate
- Expiration date
- Directions for use, storage, and disposal

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 either English or French, but manufacturers providing labeling in one language must be prepared to provide it in the other. Required information on devices to be sold directly to the general public must be both in English and in French.

Distribution records

In the event that a withdrawal from the market of a particular medical device is deemed necessary, manufacturers, importers, and distributors of medical devices are required to maintain distribution records for each device. Retailers and health care facilities employing the device for their own use are exempt from this requirement. Distribution records are to be kept for at least two years from the shipment of the device or for its projected useful life.

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, importer or distributor regarding any incident (occurring within our outside of Canada) that is related to the failure of the device or the death or "serious deterioration of the state of health of a patient."

In the event that a recall is necessary, the manufacturer, importer, or distributor of the medical device must inform the Ministry of Health of the event, and provide the following information:

- The name of the device
- Contact information for the manufacturer, importer or distributor
- Reason for the recall
- Evaluation of risk
- Number of units manufactured, imported into, or sold in Canada
- The period during which the affected units were sold
- Proposed strategy for conducting the recall, and ultimately,
- The results of the recall and proposed actions to prevent a recurrence of the problem

Custom made devices
Custom made Class III or Class IV devices require authorization from the Ministry of Health for importation into Canada. 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.

Transition to ISO 2003 Standards
On July 15, 2003, ISO published standard ISO 13485-03 titled *Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes*, and was adopted in Canada as CAN/CSA—ISO 13485:2003. Health Canada initiated a three-year transition period from ISO 13485-98 and ISO 13488-98 to their respective 2003 versions beginning on this publication date and ending on July 16, 2006. Registration bodies approved to issue registrations to the 2003 standards are

- AMTAC Certification Services Limited
- BSI America
- DQS GmbH
- G-MED
- Intertek Testing Services
- Kema-Registered Quality, Inc.
- LGA InterCert Gmbh
- Lloyd's Register Quality Assurance, Inc.

- National Standards Authority of Ireland
- Quality Management Institute
- RWTUV Systems GmbH
- SGS International Certification Services Canada, Inc.
- TUV America, Inc.
- TUV Rheinland of North America
- Underwriters Laboratories, Inc.

These regulations do not apply to Class I medical devices, which are not required to satisfy any quality system standard.

A searchable index to determine risk classification of medical devices in Canada can be found at http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/md-im/keyword_motscles_e.pdf.

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, visit the Department of Commerce's Trade Information Center Website at www.tradeinfo.doc.gov . Click on "Country Information" followed by "NAFTA" and then "NAFTA Certificate of Origin."

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