Canada

World Bank income group: High income

Legal

Legal framework: Yes

Authorizing legislation: Food and Drugs Act (R.S.C., 1985, c. F-27)
Medical Devices Regulations (SOR/98-282)

Guidelines: Guidance on the Risk-based Classification for Non-In Vitro Diagnostic Devices (non-IVDDs)

National Regulatory Authority

National Regulatory Authority present: Yes


Responsibilities of the NRA: N/A

Medical device definition

Medical device defined: Yes

Text: A device means an instrument, apparatus, contrivance or other similar article, or an in vitro reagent, including a component, part or accessory of any of them, that is manufactured, sold or represented for use in (a) diagnosing, treating, mitigating or preventing a disease, disorder or abnormal physical state, or any of their symptoms, in human beings or animals, (b) restoring, modifying or correcting the body structure of human beings or animals or the functioning of any part of the bodies of human beings or animals, (c) diagnosing pregnancy in human beings or animals, (d) caring for human beings or animals during pregnancy or at or after the birth of the offspring, including caring for the offspring, or (e) preventing conception in human beings or animals; however, it does not include such an instrument, apparatus, contrivance or article, or a component, part or accessory of any of them, that does any of the actions referred to in paragraphs (a) to (e) solely by pharmacological, immunological or metabolic means or solely by chemical means in or on the body of a human being or animal. Food and Drugs Act, R.S.C., 1985, c. F-27, 2.

In vitro diagnostic medical device (IVD) defined: Yes


Medical device classification

Classification: Yes

Categories: Class I, II, III, and IV. Medical Device Regulations, 6.

Classification rules: Yes

Classification rules details: Classification depends on the intended use of a medical device. Guidance on the Risk-based Classification for non-In Vitro Diagnostic Devices (Non-IVDs) Classification rules are detailed in Schedule 1 of Medical Device Regulations. id. 7.

Essential principles

Essential principles: Yes

Details: A manufacturer must ensure that a medical device meets safety and effectiveness requirements. Medical Devices Regulation, 9; see also id. 10-20 (detailing the safety and effectiveness requirements).

Conformity assessment

Conformity assessment bodies: Yes

Requirements and procedures for management systems certification bodies accreditation/ Medical devices manufacturers (CMDCAS)

Pre-marketing / procedure: YES - All medical devices other than lowest-risk Class I devices must be registered.

Reliance

Reliance: N/A

Details: N/A

Jurisdictions: N/A
Clinical investigation
Clinical investigation controls: Yes
Details: No person may import or sell a medical device for investigational testing, except,
- A manufacturer may sell a class II, III, or IV device to a qualified investigator if the manufacturer or importer holds an authorization and possesses necessary records
- A manufacturer or importer of a class I medical device if it possesses the necessary records
Medical Device Regulations, 80.
The Minister may issue an authorization to enable the sale of a medical device for clinical investigation when satisfied of the nature and risk of the investigation. Medical Device Regulations, 83.

Registration and listing
Registration of establishment: Yes
Details: No person may import or sell a medical device unless that person holds an establishment license. Medical Device Regulations, 44.
Listing of medical devices: Yes
Details: Medical devices that are imported or sold in Canada (except Class I medical devices) must be licensed before being imported or sold in Canada.

Import controls
Import controls: Yes
Details: No person can import or sell a class II, III, or IV medical device unless the manufacturer holds a license for that device. Medical Device Regulations, 26.

Post market controls
Post Market Surveillance: Yes
Details: Manufacturers and importers must have surveillance systems in place. Medical Devices Regulations, 59-61.2.

Inspection (QMS): Yes
Details: In an application for a license for a medical device, one must include a copy of a QMS certificate stating that the system satisfies National Standard of Canada CAN/CSA-ISO 13485:03. Medical Device Regulations, 32.
Canada recognizes a person as a registrar for the purposes of issuing, renewing, suspending QMS certificates under certain circumstances. Medical Device Regulations, 32.1.

Enforcement: Yes
Details: An inspector may enter any premises upon reasonable grounds of belief of violations of the Food and Drugs Act and examine and/or sample any article. Food and Drugs Act, 23.
The Minister may direct a manufacturer to stop the sale of a class I medical device in certain cases. Medical Device Regulations, 25.
The Minister may suspend a medical device license in certain circumstances. Medical Device Regulations, 40.
The Minister may suspend or cancel establishment license in certain circumstances. Medical Device Regulations, 49-51.1.

Adverse event reporting: Yes
Details: The manufacturer, importer, and distributor of a medical device must maintain records on:
- reported problems on the characteristics/safety of the device, including any complaints after the device was first sold in Canada and
- all actions taken in response to those problems Medical Device Regulations, 57.
The manufacturer and importor of a medical device must make a preliminary and final report to the Minister on any incident occurring inside or outside of Canada and involving a device that is sold in Canada that is related to a failure of the device and has led to death or a serious deterioration in the health or a patient or other person. Medical Device Regulations, 59.

Field safety corrective action monitoring: Yes
Details: The manufacturer, importer, and distributor of a medical device must establish and implement procedures that will enable investigation of problems and recall of the device. Medical Device Regulations, 58.

Advertising: Yes
Details: No person may advertise any device in a manner that is false, misleading, or deceptive or likely to create an erroneous impression. Food and Drugs Act, 19-20.

Labelling: Yes
Details: No person may label any device in a manner that is false, misleading, or deceptive or likely to create an erroneous impression. Food and Drugs Act, 19-20.
Further, a label of a medical device must include information such as the name of the device, the name/address of the manufacturer, etc. Devices sold to the publish must have such required information in English or in French at minimum. Medical Device Regulations, 21-23.