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Canada
The Regulatory Process for Medical Devices

Determine the classification of your medical device according to Schedule 1, Part 1 of the Canadian Medical Devices Regulations (CMDR) SOR/98-282 as published by Health Canada.

Class I	Class II	Class III	Class IV
	Implement an ISO 13485:2003 compliant quality management system which includes the additional specific requirements of the CMDR. ISO 13485 certification, used to demonstrate compliance with European regulations, does not meet Canadian requirements. Updates to the existing procedures, or new procedures, must be implemented.		
	Have ISO 13485 quality system (re)audited by a Registrar accredited by Health Canada under the Canadian Medical Devices Conformity Assessment System (CMDCAS). Several large European Notified Bodies also act as Registrars recognized by Health Canada. Your new ISO 13485 certificate will be issued upon successful completion of the audit.		
Apply for Medical Device Establishment License (MDEL).* Documents must be submitted in English or French.	Prepare Canadian Medical Device License (MDL) application for your device. Compared to a US 510(k) application, MDL applications are simpler for Class II devices and about the same for Class III devices. Class IV MDL applications are comparable to a US PMA application. Note that an MDL application is for the device itself whereas an MDEL is a permit for the distributor/importer, or a manufacturer of Class I devices. Documents must be submitted in English or French.		
Submit MDEL application, prepare mandatory procedures and pay Health Canada fees.	Submit MDL application, Fee Form, labeling (IFU), Declaration of Conformity and ISO 13485 (CMDCAS) certificate. Pay Health Canada fees.	Submit MDL application plus Declaration of Conformity, ISO 13485 (CMDCAS) certificate, Fee Form, labeling (IFU) and Premarket Review Document following the STED format, which may include the requirement for clinical data. Clinical data collected outside Canada is generally accepted. Pay Health Canada fees.	
	Health Canada reviews MDL application (Class II, III and IV) and Premarket Review Document (Class III and IV only).		
Approved applications will be posted on the Health Canada website and your MDEL certificate will be emailed to you.	Issued licenses will be posted on the Health Canada website, and copies of your MDL will be emailed to you. Note: For Class IV MDLs Health Canada will post a summary of their decision on their website.		
You may now begin marketing your device in Canada. Licenses do not expire as long as you renew your registration and pay the annual fees to Health Canada. Failure to file your renewal and pay fees by the annual deadlines will result in your license(s) being revoked.			

* An MDEL is not required for retailers OR when using an importer/distributor with their own MDEL. If a manufacturer of a Class I device chooses not to apply for an MDEL, then no application or fees are due to Health Canada, but a qualified importer or distributor (with an MDEL) must be appointed before the device may be marketed in Canada.

This is a simplified overview of the process. Health Canada may choose to audit your submission and request more documents, which will add time to your approval.

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Canada
Time, Cost, and Complexity of Registration

Device classification in Canada →	Class I*	Class II**	Class III**	Class IV**
How long you should expect to wait after submission until approval is granted.[1]	2-4 months	1-2 months	4-5 months	6-8 months
Validity period for device registrations.[2]	1 year	1 year	1 year	1 year
Registration renewal should be started this far in advance.[3]	2 months	2 months	2 months	2 months
Complexity of the registration process for this classification.[4]	Simple — Complex	Simple — Complex	Simple — Complex	Simple — Complex
Overall cost of gaining regulatory approval.[5]	Low — High	Low — High	Low — High	Low — High

Notes

1. The time frames shown above are typical for the majority of medical device submissions but assume that your device does not contain animal tissue, medicinal substances or employ entirely novel technology. Your length of approval will depend on the quality and completeness of your technical documentation and how much time you take to address additional information requests from authorities after submission. YOUR SUBMISSION(S) MAY TAKE MORE TIME THAN WHAT IS SHOWN ABOVE.

2. Registrations remain valid for one year as long as you do not make changes to the device, intended use or indications for use. Registrations must be renewed annually. Failure to pay fees will result in license(s) being revoked.

3. We recommend starting the renewal process no later than the time period specified above. However, please consult with your distributor or regulatory expert well before this suggested time to avoid any lapse in your registration.

4. Our rating of the complexity of the registration process is based on our experience and the opinion of nearly 1,000 QA/RA professionals worldwide who were asked to rate the difficulty of registering a device in each country in January 2014. The European CE Marking process is considered the mid-point to which all other markets are compared.

5. Low = Less than US$5000; Midpoint = US$15000-$30000: High = More than US$50000. Overall cost includes registration application fees, product testing, submission preparation consulting and translation of registration documents but not IFU. Does not include cost of implementing, auditing, or updating a quality management system compliant with ISO 13485 plus Canadian Medical Devices Regulations (CMDR).

6. Although it is not a requirement of Health Canada that your medical device be labeled with an electrical safety mark, a Health Canada issued Medical Device Licence does NOT imply exemption from Canadian electrical requirements, which are mandated by Provincial and Territorial electrical safety authorities, and not by Health Canada. If your device is an electrical device, customers within Canada may require that your medical device have an electrical safety mark of conformity (e.g. such as a CSA or UL mark), before they will purchase the device.

* Class I devices do not require a Medical Device License (MDL), however, if you plan to ship your class I device directly to an end customer (and not through an established Canadian distributor) you will require a Medical Device Establishment License (MDEL). MDEL applications are reviewed by Health Canada.

** Class II, III, and IV devices require a Medical Device License (MDL), and a required element for the MDL applications/registration dossiers is certification to ISO 13485:2003 + CMDR, which must be reviewed by a Registrar recognized by Health Canada. Many of these Registrars are also European Notified Bodies. Health Canada is currently in the process of transitioning to ISO 13485:2016 and MDSAP (Medical Device Single Audit Program). This transition will occur through until January 1, 2019.

This is a simplified overview of the process. Health Canada may choose to audit your submission and request more documents, which will add time to your approval.

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