



Emergo Group assists medical device companies worldwide with registration, quality system compliance and distribution in Canada as shown below.

Medical Device Establishment Licenses (MDEL)

If you sell Class I devices and ship directly to customers in Canada and not through an established distributor, a Medical Device Establishment License is required. Selling through a distributor requires no MDEL, but you still need to follow the Canadian Medical Devices Regulations. We can prepare your MDEL application and submit it to Health Canada.

Medical Device License (MDL) applications

When compared to the US FDA 510(k) registration process, the process of securing a Canadian MDL is usually faster for Class II devices, about the same for Class III devices and more complicated for Class IV devices. We can help prepare and submit your MDL and Premarket Review Document to Health Canada. We have prepared license applications for a wide range of devices and understand how to obtain approval from Health Canada quickly and efficiently.

ISO 13485:2003 quality system compliance

For most manufacturers Emergo Group implements an integrated quality management system that meets the regulatory requirements in Canada, Europe and the United States. An audited ISO 13485:2003 quality system is mandatory for Class II, III and IV device manufacturers in Canada and we can implement ISO 13485 for you or help modify your existing quality management system to meet the additional requirements of the Canadian Medical Device Regulations (CMDR). If desired, we can also make your system compliant with Brazilian and Japanese requirements for little additional cost.

Internal and supplier audits

Class II, III and IV device manufacturers must be audited each year by a Health Canada certified Registrar. Most large European Notified Bodies are also authorized to conduct audits in Canada as Registrars and we can advise you of which Notified Bodies can also assist you with Canadian QMS compliance. If you are entering the Canadian market for the first time, we can ensure that your QMS is in full compliance with the CMDR prior to your Registrar audit, and yearly thereafter. On-site internal auditor training can also be conducted as needed.

Medical distributor qualification in Canada

We can assist you in finding and vetting qualified distributors in Canada who are committed to selling your product. We will also assist in the ongoing managing and monitoring of distributors to ensure that the quality and reputation of your brand are being maintained.

* If you already have ISO 13485:2003 and are audited by a European Notified Body, they may also be CMDCAS-accredited by Health Canada to perform audits to the Canadian Medical Devices Regulations (CMDR). A list of CMDCAS-recognized certification bodies can be found here: <http://www.scc.ca/en/programs-services/ms/cmdcas/cmdcas-recognized-certification-bodies>. In this case, you will be issued a new ISO 13485:2003 certificate that also includes CMDR in the scope of registration. Not all Notified Bodies are accredited to be Registrars in Canada.

** MDEL = Medical Device Establishment License. This is for Class I manufacturers selling directly into Canada and not through a distributor. Not required for Class II, III and IV manufacturers as they are required to obtain a Medical Device License (MDL) instead.

^ MDL = Medical Device License. This is for the device itself. Not required for Class I devices.

^^ The Premarket Review Document for Class III and IV devices may require inclusion of clinical trial data. Data from trials conducted in the US or Europe may be acceptable. Clinical data will be reviewed by your Registrar as part of your audit.