

# An overview of Canada's regulatory process for medical devices and how we can help.

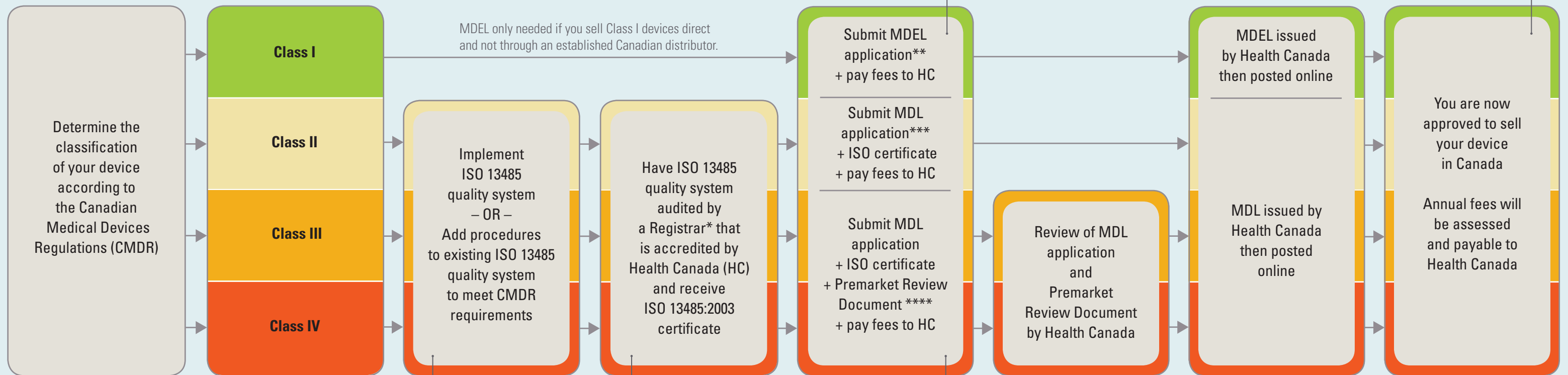
Emergo Group has been assisting medical device and IVD companies with international regulatory and quality assurance issues since 1997. Whether you are entering the Canadian market for the first time or introducing another new device, we can assist with all aspects of compliance from ISO 13485 implementation and audits, to Health Canada license applications and distributor qualification. With offices in North America, Europe, Asia and Australia, Emergo can help you obtain regulatory approval, maintain compliance and increase your sales in the world's largest and fastest growing medical device markets.

## Let Emergo prepare your establishment license application

If you sell Class I devices and ship directly to customers in Canada, we can prepare your Medical Device Establishment License (MDEL) and submit it to Health Canada.

## We help find and manage distributors

We can assist you in finding and qualifying distributors in Canada and can also manage distributors to ensure they are fully committed to selling your devices.



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## An Emergo quality system meets most global requirements

An audited ISO 13485:2003 quality system is mandatory for Class II, III and IV device manufacturers in Canada. 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). An Emergo quality system also meets the quality system requirements of US FDA QSR and European CE Marking.

## Independent audits ensure ongoing compliance

We can conduct an audit of your quality system prior to your Registrar audit, or periodically thereafter, to ensure compliance with CMDR and ISO 13485:2003. If we implement your quality system, a pre-assessment audit is included. On-site training on the Canadian requirements can also be conducted for employees.

## Let us prepare your CMDR medical device license applications

We can help prepare and submit your Medical Device License (MDL) and Premarket Review Document to Health Canada. We have done so for a wide range of devices and understand how to obtain approval quickly.

\* If you already have ISO 13485:2003 and are audited by a European Notified Body, they may also be accredited by Health Canada to perform audits to the Canadian Medical Device Regulations (CMDR).

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 direct 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 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.