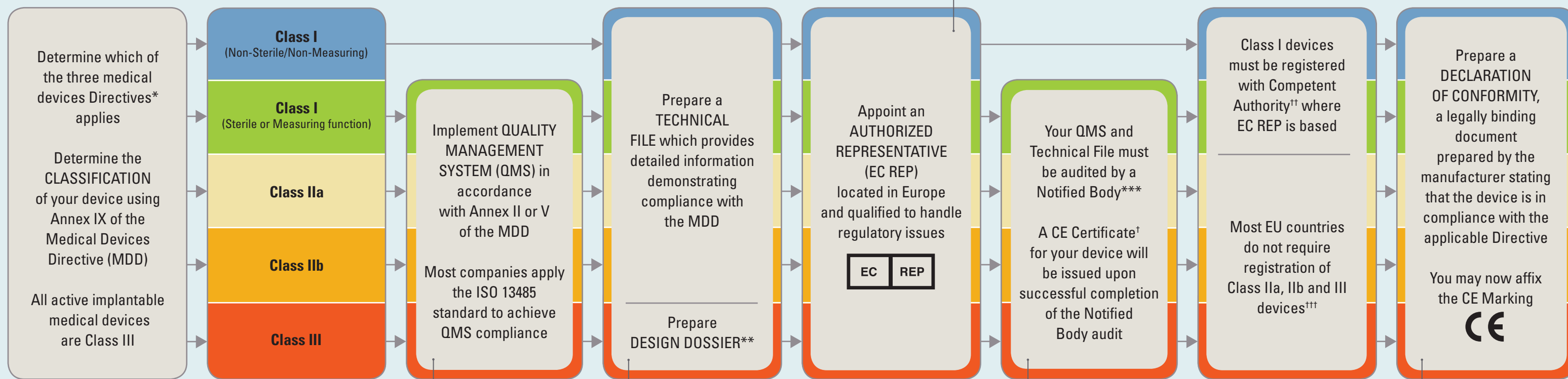


An overview of Europe's regulatory process for medical devices and how we can help.

Emergo Group has been helping medical device and IVD companies with international regulatory and quality assurance issues since 1997. Whether you are entering the European market for the first time or introducing another new device, we can assist with everything from ISO 13485 implementation and audits, to Technical File preparation and distributor qualification. With offices in Europe, North America, Asia and Australia, Emergo can help you obtain regulatory approval, maintain compliance and increase your sales in the world's largest medical device markets.

Independent, professional regulatory representation

Emergo acts as an Authorized Representative (EC REP) for hundreds of medical device companies worldwide. Although a local distributor can fulfill this role, hiring a professional, independent EC REP gives you the freedom to switch distributors at any time. This is particularly important given that the EC REP name must appear on your labeling throughout Europe. Emergo also provides in-country representation in Australia, China, Japan and the United States.



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An Emergo QMS meets most global requirements

Most manufacturers implement a Quality Management System by applying the ISO 13485:2003 standard and we can assist you with implementation. If you already have a FDA QSR compliant quality system, we can modify your existing system to meet ISO 13485 and ensure that it complies with Canadian requirements as well.

Technical Files, an Emergo specialty

Emergo has compiled Technical Files and Design Dossiers for a wide range of devices from simple surgical instruments to high risk implants. We can also assist with ISO 14971, clinical data evaluations, labeling reviews and more.

Let Emergo assess the compliance of your QMS

Emergo can conduct a pre-assessment audit prior to your final Notified Body audit. If we implement your ISO 13485:2003 quality system, this pre-assessment audit is included. We can also provide on-site training on CE Marking, the Medical Devices Directive and internal auditing for your employees.

We can help find and manage distributors

With 31 countries and over 20 languages, finding distributors in Europe can be a challenge. We can find, analyze, select and manage the right distributors and ensure that they are fully committed to selling your devices.

* European Directives that apply to medical devices include the Medical Devices Directive (93/42/EEC), which was amended by Directive 2007/47/EC, and the Active Implantable Medical Devices Directive (90/385/EEC). This chart does not apply to IVD devices which are subject to the In Vitro Diagnostic Devices Directive (98/79/EC).
 ** Class III devices require substantial clinical trial data. Clinical trials conducted in Europe must be pre-approved by a Competent Authority. Existing clinical data may be acceptable. All data are reviewed and approved by a Notified Body.
 *** Notified Body = EU accredited third party authorized to conduct audits of medical device companies and their devices.
 † A CE Certificate (issued by a Notified Body) is not applicable to Class I, non-sterile, non-measuring devices since you will "self-declare" conformity with the Directive.
 †† Competent Authority = Term used to describe national Ministries of Health which are responsible for ensuring compliance with the Directive in their national market.
 ††† Italy currently requires registration of all devices, regardless of classification. Some countries require registration of high risk devices.