



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

Medical device classification

In Europe, devices are classified using a series of rules found in Annex IX of the Medical Devices Directive* (MDD). Therefore, a product considered Class II or III in the USA or Canada might carry a different classification in Europe. Proper evaluation of classification criteria is important and we can assist you in this process.

Technical Files and Design Dossiers

Technical Files are required for all device classifications. Design Dossiers are needed for Class III devices and are much like a US FDA PMA. We have compiled Technical Files and Design Dossiers for a wide range of devices so are fully prepared to help you obtain your CE Marking certificate. We can also assist with ISO 14971, clinical data evaluations, labeling reviews and more.

ISO 13485 and quality system compliance

Emergo has procedures in place for implementing quality management systems that address regulatory requirements in most parts of the world. Most manufacturers implement a Quality Management System by applying the ISO 13485 standard and we can assist you with implementation. If you already have a US FDA QSR compliant quality system, we can modify your existing system to meet European and Canadian QMS requirements and ensure compliance with Brazilian, Japanese and other requirements as desired.

EU Authorized Representative (EC REP)

Companies without a location in Europe must appoint an Authorized Representative to act on their behalf. 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. We act as an independent Authorized Representative (EC REP) for hundreds of medical device companies worldwide.

CE Marking and ISO 13485 audits

Manufacturers that require CE certification for Class I Sterile and Measuring or higher devices are audited each year by Notified Bodies. We can conduct pre-assessment or maintenance audits prior to Notified Body audits as needed. We can also provide on-site training on CE Marking, the Medical Devices Directive and internal auditing for your employees.

European medical device distributor qualification

With 31 countries and 20+ official languages, qualifying distributors in Europe can be a challenge. Our EU based distribution management teams can find, analyze, select and manage the right distributors in specific countries 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) and the Active Implantable Medical Devices Directive (90/385/EEC), which were amended by Directive 2007/47/EC. This chart does not apply to IVD devices which are subject to the In Vitro Diagnostic Devices Directive (98/79/EC).

** Class III devices as well as implantable devices WILL LIKELY 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 manufacturers 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.

^^^ Some countries currently require registration of all devices, regardless of classification. Some countries require registration of high risk devices.