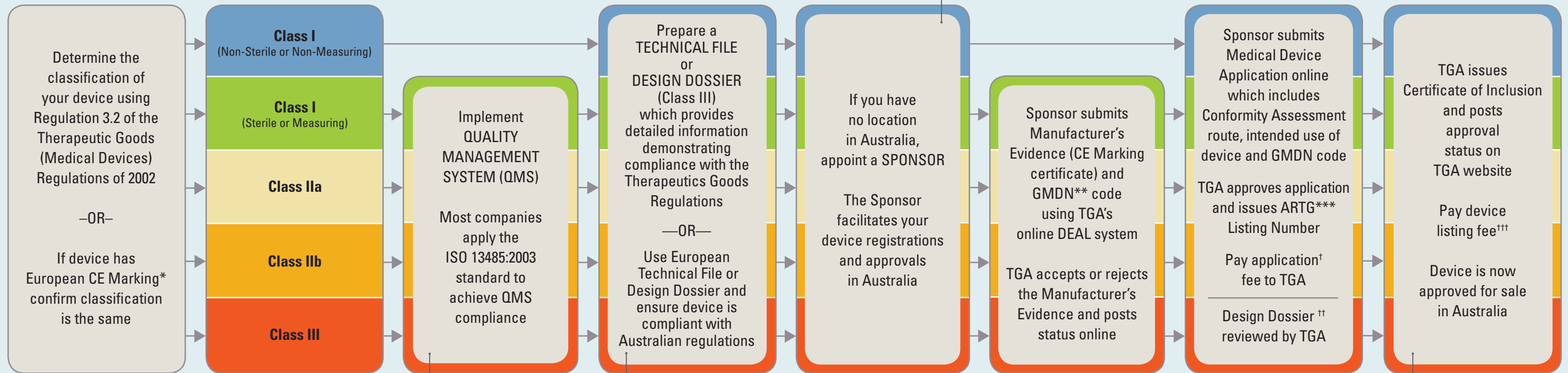


# An overview of Australia's regulatory process for medical devices and how we can help.

Emergo Group has been assisting medical device and IVD companies with international regulatory and quality assurance issues since 1997. Whether you are entering the Australian 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 Sponsor representation. With offices in Australia, Europe, North America and Asia, Emergo can help you obtain regulatory approval, maintain compliance and increase your sales in the world's largest and fastest growing medical device markets.

## Professional, independent regulatory representation

Emergo acts as an official "Sponsor" for medical device companies that export their devices to Australia. Although a local distributor can fulfill this role, hiring a professional, independent Sponsor gives you more control of your device registration, approvals and distributor selection. Emergo also offers in-country representation in Europe, China, Japan and the USA.



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### An Emergo QMS meet most global requirements

An audited quality system is mandatory for many manufacturers selling in Australia. Most companies apply ISO 13485:2003 to meet this requirement. If you do not already have this implemented, we can do so for you. An Emergo quality system – customized for your needs - also meets the requirements of European CE Marking, US and Canadian regulations.

### Technical Files, an Emergo specialty

If your device already has CE Marking, your Technical File is usually accepted in Australia. If not, we have compiled Technical Files for hundreds of devices. We can also assist with ISO 14971, clinical data evaluations, labeling reviews and more.

### Let Emergo assess the health of your QMS

We can audit your quality system or review your Technical File/Design Dossier to determine compliance with Australian regulations. If needed, we are also available to conduct audits of key suppliers.

### We can help find and manage distributors

Choosing the right distributors is key to your success in Australia. We can help you find, qualify and manage distributors and ensure that they are committed to selling your products and servicing your customers.

\* If you have been issued a CE Marking certificate by a Notified Body, this is accepted in Australia.  
 \*\* GMDN = Global Medical Device Nomenclature  
 \*\*\* ARTG = Australian Register of Therapeutic Goods.  
 † No application fee for Class I, non-sterile or non-measuring devices.  
 †† The TGA reviews Design Dossiers for Class III, Active Implantable, animal derivative and certain other high risk devices.  
 ††† The Device Listing Fee is due October 1 each year and is not prorated. If you register your device in July, for example, you will pay the full fee for the current year and pay it again in October for the next year.

IMPORTANT NOTE: In most cases, Australia has emulated the European regulatory system for medical devices and recognizes European CE Marking. This chart demonstrates the route to compliance for a device that already has CE Marking.