



Emergo Group assists medical device companies worldwide with registration, representation and distribution in Australia as shown below.

### ARTG device submissions in Australia

Given that the Australian Therapeutic Goods Administration (TGA) recognizes European CE Marking, most device manufacturers entering the Australian market already have CE Marking certification for their device. CE certificates are used as "Manufacturers Evidence" when submitting devices for inclusion in the Australian Register of Therapeutic Goods (ARTG). We can assist with ISO 14971, clinical data evaluations, labeling reviews, post market surveillance and more.

### GMDN code research and registration

All medical devices require registration with the TGA. Australia uses Global Medical Device Nomenclature (GMDN) codes to classify devices. However, the database that contains the GMDN codes is not available to the public and requires a subscription. As a sponsor, our Sydney office has access to this system and can fully assist you in determining the proper GMDN code for your device and registering it in the ARTG.

### Independent sponsor regulatory representation in Australia

Companies without a physical presence in Australia must appoint a Sponsor to represent them through the registration process and postmarket activities. Emergo Group 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.

### Australian quality system requirements

Australia's medical device regulations largely mirror the European process. As such, most non-Australian manufacturers are able to show their Notified Body CE certificate as proof of compliance with TGA regulations for devices classified as Class I measuring and higher. Most manufacturers therefore apply for CE Marking before entering the Australian market. We can assist you with implementing or upgrading your Quality Management System to meet US, European, Canadian, Japanese and Australian regulations.

### Distributor search and qualification in Australia

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

\* If you have been issued a CE certificate by a Notified Body, this is accepted as part of your device registration in Australia.

\*\* GMDN = Global Medical Device Nomenclature

\*\*\* ARTG = Australian Register of Therapeutic Goods

<sup>4</sup> No application fee for Class I, non-sterile or non-measuring devices.

<sup>5A</sup> The TGA reviews Design Dossiers for Class III, Active Implantable, animal derivative and certain other high risk devices.

<sup>5A</sup> The Device Listing Fee is due July 1 each year and is not prorated. If you register your device in March, for example, you will pay the full fee for the current year and pay it again in July 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.