

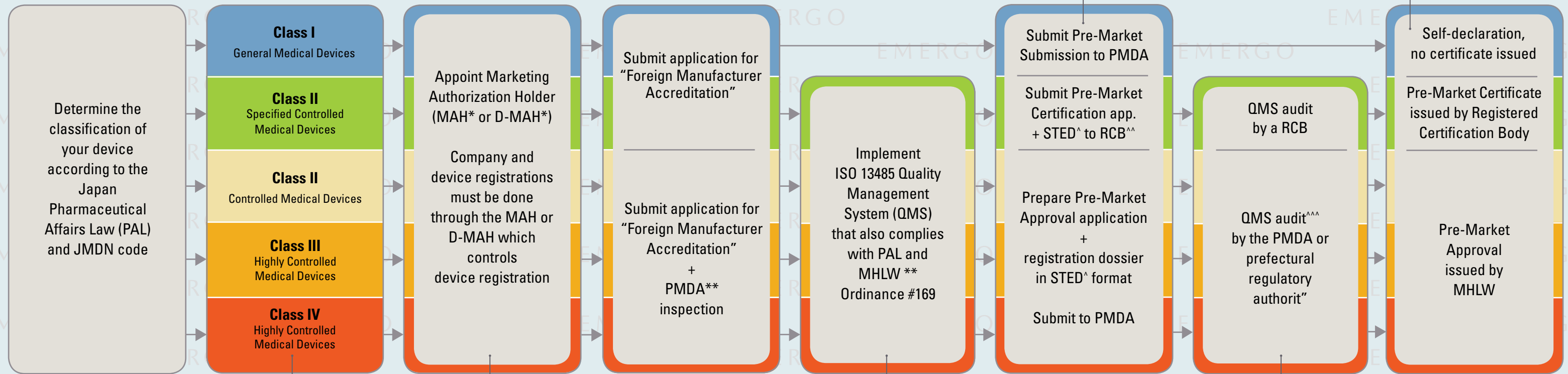
Emergo Group has been helping medical device and IVD companies with international regulatory and quality assurance issues since 1997. Whether you are entering the Japanese market for the first time or introducing another new device, we can assist with everything from quality system modification and audits, to STED preparation and distributor qualification. With offices in Japan and worldwide, Emergo Group 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 STED submission

A Summary Technical Document (STED) is similar to a US FDA 510(k) or CE Technical File, but in a standardized format. We can assist with preparing your STED documentation to ensure a successful review by the Registered Certification Body or Japanese PMDA.

Full service assistance, from application to approval

Different classes of devices require different certificates and approvals. Determining which approval process applies can be challenging. We can fully assist you with the approval and registration of your devices.



Let us help classify your device in Japan

Japan's classification system differs from the US and Europe so determining classification of your devices can be complex. Through our office in Tokyo, we can help determine the correct Japanese Medical Device Nomenclature (JMDN) code for your device.

Professional, independent MAH representation

Emergo Japan K.K. is a licensed Marketing Authorization Holder (MAH) in Japan. Hiring Emergo as your independent D-MAH (instead of appointing a distributor MAH) will ensure that your regulatory responsibilities are handled properly and give you the flexibility to switch distributors at any time. More importantly, by selecting Emergo Japan as your D-MAH, your device approvals will remain under your control.

Helping you comply with quality system requirements

Japan's Pharmaceutical Affairs Law (PAL) has specific Quality Management System requirements that are similar to ISO 13485 and FDA QSR, but with additional requirements. We can help you modify your existing QMS to comply with PAL and ensure you are ready for your PMDA or Certification Body audit.

Let Emergo make sure you are prepared for your QMS audit

The Japanese approval process is lengthy and the last thing you need is to fail your QMS audit. We will make sure you are fully prepared by conducting a pre-assessment audit and providing the support necessary to modify your QMS system as needed.

* The MAH controls the device approval in Japan. A Designated MAH (D-MAH) acts on behalf of a foreign manufacturer to register medical devices under the Foreign Special Approval System.
 ** PMDA = Pharmaceutical and Medical Devices Agency. A regulatory agency that works together with the Ministry of Health, Labour and Welfare (MHLW).
 ^ STED = Summary Technical Document. This is a harmonized submission format that is accepted for certain regulatory submissions in Japan, Australia, Europe and the USA.
 ^^ RCB = Registered Certification Body. Independent companies authorized by the MHLW to certify Specified Controlled Medical Devices and issue Pre-Market Certifications.
 ^^ PMDA may conduct audits for new medical devices, Class IV devices, and devices that require clinical investigations.