

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

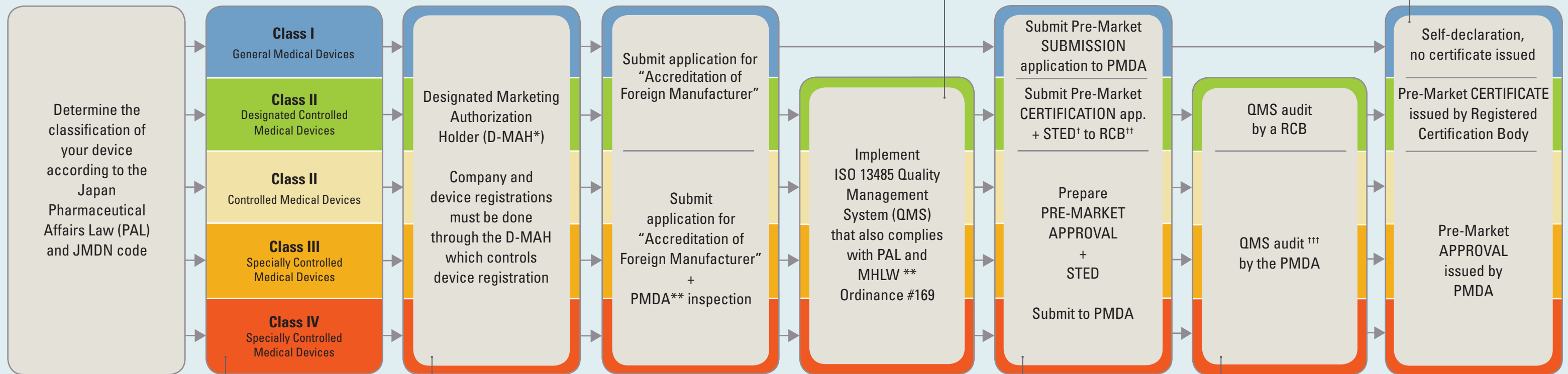
Emergo Group has been helping medical device and IVD companies with international regulatory and quality assurance issues since 1997. Whether you are entering the Japanese market for the first time or introducing another new device, we can assist with everything from quality system modification and audits,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

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.

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.



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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 JMDN code for your device.

Professional, independent MAH representation

Emergo Japan K.K. is a licensed Designated Marketing Authorization Holder (D-MAH) in Japan. Hiring Emergo as your independent D-MAH (instead of appointing a distributor) 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.

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.

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 is similar to a European Authorized Representative, but controls the device approval in Japan. A D-MAH is an independent MAH and not a distributor.
 ** PMDA = Pharmaceutical and Medical Devices Agency. This is a division of 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 compliance with specific standards and regulations.
 ††† PMDA only conducts audits for new medical devices, Class IV devices, and devices manufactured by foreign manufacturers.