



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

Device classification in Japan

Japan's classification system differs from the US and Europe so determining classification of your device(s) can be complex and is based on Japanese Medical Device Nomenclature (JMDN) codes. Through our full service office in Tokyo, we can help determine the correct JMDN code for your device, the first step the ensuring a smooth registration process.

Japan PMDA medical device and company registration

Japan's Pharmaceutical and Medical Devices Agency (PMDA) requires manufacturers to prepare pre-market applications (Class II, III and IV) plus registration dossiers in Summary Technical Document (STED) format, etc. and pre-market submission (Class I). Japan does not accept European CE Marking certificates or national ministry approvals although European, US or Canadian approval aids the registration process. Our Tokyo team can prepare your registration documents to ensure a successful review by the Registered Certification Body or Japanese PMDA. We can also assist with obtaining Foreign Manufacturer Accreditation on your behalf.

Independent MAH representation in Japan

The Marketing Authorization Holder (MAH) plays a critical role for the manufacturer in Japan. In fact, the MAH has far more responsibility for the manufacturer's device in Japan than any other regulatory liaison worldwide, including the Authorized Representative in Europe. Emergo Japan K.K. is a licensed Type 1 Marketing Authorization Holder in Japan. Using Emergo as your independent D-MAH, instead of appointing a distributor MAH, will ensure that your regulatory responsibilities are handled properly. This also gives you the freedom to appoint new distributors at any time. More importantly, by selecting an independent D-MAH, your device approvals will remain under your control.

Compliance with Japan PAL and MHLW Ordinance 169

Japan's Pharmaceutical Affairs Law (PAL) and MHLW Ordinance #169 have 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 ISO 13485 or US FDA compliant QMS to comply with Japan's requirements and ensure that you are ready for your PMDA or Registered Certification Body audit.

Quality system audits

The Japanese approval process is lengthy and few manufacturers can afford the delay of failing an audit by the PMDA or Registered Certification Body. We will make sure you are fully prepared by conducting a pre-assessment audit and providing the support necessary to modify your QMS system so it is fully compliant with MHLW Ordinance #169.

Japanese medical distribution partner evaluation

Japan has a complex social and business culture that is difficult for westerners to understand. This, combined with obvious language issues, makes screening distribution partners extremely challenging. Our Tokyo office can assist you with the process of finding evaluating and managing distributors in Japan.

* 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.

^ STED = Summary Technical Document. This is a harmonized submission format that is accepted for certain regulatory submissions in Japan, Australia, Europe and Canada.

^^ RCB = Registered Certification Body. Independent companies authorized by the MHLW to certify Specified Controlled Medical Devices and issue Pre-Market Certifications.

^^^ PMDA may conduct on-site audits for new medical devices, Class IV devices, and devices that require clinical investigations.