EMERGO

Japan
The Regulatory Process for Medical Devices

Determine classification of your device according to the Pharmaceuticals and Medical Devices Act (PMD Act) and Japanese Medical Device Nomenclature (JMDN) codes.

Class I General medical devices	Class II Specified Controlled medical devices	Class II Controlled medical devices	Class III[1] Highly Controlled medical devices	Class IV Highly Controlled medical devices
Appoint an MAH in Japan.	Appoint Marketing Authorization Holder (MAH or D-MAH) to manage your device registration in Japan. Your MAH or D-MAH will control your device registration.			
Japanese manufacturers must register domestic facilities with local prefectural authorities. Foreign manufacturers must submit a Foreign Manufacturer Registration (FMR) application to the Pharmaceuticals and Medical Devices Agency (PMDA).				
Implement Quality Management System (QMS) that complies with the PMD Act and Ministry of Health, Labour and Welfare (MHLW) Ordinance #169. Ordinance #169 is based on ISO 13485.				
Submit Pre-Market Submission to Pharmaceutical and Medical Devices Agency (PMDA). All documents must be in Japanese.	Submit Pre-Market Certification application to a Registered Certified Body (RCB) authorized to issue certifications. All documents must be in Japanese.	Prepare Pre-Market Approval application as well as registration dossier in Summary Technical Document (STED) format. Submit documents to PMDA. All documents must be in Japanese.		
Most[2] Class I devices do not require QMS conformity assessment.	QMS audit by Registered Certification Body (RCB).	QMS audit by PMDA. On-site audits are typically required for "New" devices with no existing JMDN code, Class IV devices, and those requiring clinical investigations.		
See note 2 below	Your QMS certificate will be issued by the PMDA or your Registered Certification Body.			
See note 2 below	Pre-Market Certificate issued by RCB.	Pre-Market Approval certificate issued by MHLW.		
A reimbursement application should be filed with Economic Affairs Division of MHLW if applicable.				
You may now begin marketing your device in Japan. Approvals do not expire.[3]				

1. Some Class III medical devices are considered "Specified Highly Controlled" devices and follow the same approval route as Class II "Specified Controlled" devices (shown in green).
2. MHLW Ordinance #169 documentation is not required for most Class I device applications. However, some Class I device manufacturers do require QMS certification, including Class I NEW devices (i.e., no JMDN code).
3. Device registrations do not expire. However, QMS certificates are valid for five years and must be renewed six months prior to expiration. Pre-Market Certification applications may also be subject to annual surveillance audits. The schedule will be determined by the RCB or PMDA.

This is a simplified overview of the process. The PMDA may choose to audit your submission and request more documents, which will add time to your approval.

EmergoGroup.com/japan

5000-0617

EMERGO

Japan
Time, Cost, and Complexity of Registration

Device classification in Japan	Class I General Medical Devices	Class II Specified Controlled Medical devices	Class II Controlled Medical devices	Class III Highly Controlled Medical devices	Class IV Highly Controlled Medical devices
How long you should expect to wait after submission until approval is granted.[1]	<1 month	3-5 months	7-9 months	9-11 months	13-16 months
Validity period for device registrations[2]	Does not expire	Does not expire	Does not expire	Does not expire	Does not expire
Registration renewal should be started this far in advance.[3]	Does not expire	Does not expire	Does not expire	Does not expire	Does not expire
Complexity of the registration process for this classification.[4]	Simple – Complex: 2	Simple – Complex: 3	Simple – Complex: 4	Simple – Complex: 4	Simple – Complex: 5
Overall cost of gaining regulatory approval.[5]	Low – High: 2	Low – High: 4	Low – High: 5	Low – High: 5	Low – High: 5

Notes

1. The time frames shown above are typical for the majority of medical device submissions but assume that your device does not contain animal tissue, medicinal substances or employ entirely novel technology. Your length of approval will depend on the quality and completeness of your technical documentation and how much time you take to address additional information requests from authorities after submission. YOUR SUBMISSION(S) MAY TAKE MORE TIME THAN WHAT IS SHOWN ABOVE.

2. Device registrations do not expire, however you must renew and pay Foreign Manufacturer Registration (FMR) renewal fees. Additionally, you must renew your QMS certificate every five years and pay appropriate fees. Failure to renew your FMR or QMS certificate will result in your permission to market your device being revoked.

3. To ensure ongoing validity of your Japanese registrations, payment of Foreign Manufacturer Registration (FMR) renewal fees should be initiated at least one month before the due date. QMS certificates must be renewed six months prior to expiration.

4. Our rating of the complexity of the registration process is based on our experience and the opinion of nearly 1,000 QA/RA professionals worldwide who were asked to rate the difficulty of registering a device in each country.

5. Prices in US Dollars for a single device. 1 = Less than $5,000; 2 = $5,000 - $15,000; 3 = $15,000 - $30,000; 4 = $30,000 - $50,000; 5 = $50,000 or more. Overall cost includes registration application fees, product testing, in country representation, submission preparation consulting and translation of registration documents but not IFU. Does NOT include cost of implementing or auditing a quality management system.