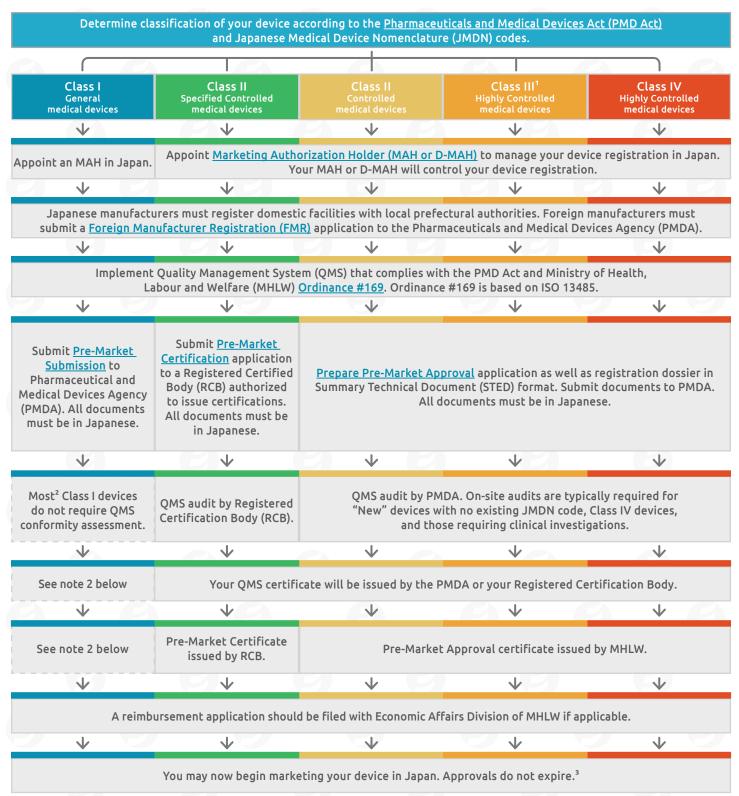


## Japan The Regulatory Process for Medical Devices



- 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.



## 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 <sup>2</sup>	Does not expire	Does not expire	Does not expire	Does not expire	Does not expire
Registration renewal should be started this far in advance. <sup>3</sup>	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	Simple Complex	Simple Complex	Simple Complex	Simple Complex
Overall cost of gaining regulatory approval. <sup>5</sup>	Low High	Low High	Low High	Low High	Low High

## Notes

- 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.
- 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.