



Medical  
Device  
Certification  
in Japan

# Japan Pharmaceutical and Medical Device Act

Understanding the requirements

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# Japanese Medical Device Regulations

To place a medical device on the Japanese market requires compliance with the Pharmaceutical and Medical Device Act (PMD Act), issued by the Ministry of Health, Labour and Welfare (MHLW). The PMD Act replaced the Japanese Pharmaceutical Affairs Law (JPAL) in November 2014.

Japan is one of the most established medical device markets globally. It remains a key focus for medical device manufacturers looking to expand their international operations. High demand for new technology makes this market an opportunity for continued growth.

The Act requires manufacturers to demonstrate both product conformity and a Quality Management System (QMS) complying with Ministerial Ordinance No. 169, 2004.

Compliance to the PMD Act is assessed by either the Pharmaceutical and Medical Devices Agency (PMDA), or designated Registered Certification Bodies (RCBs), which review technical documentation based on product classification.

BSI is designated as an RCB for all Class II and designated Class III devices.

## The certification process

The regulatory requirements for your product are determined by its classification. The Japanese system uses a risk-based classification which aligns with the principles outlined by the International Medical Device Regulators Forum (IMDRF).

### Determine classification to understand regulatory requirements

#### Class I General Medical Devices: Pre-market submission (Todokede)

Low risk to the human body

Marketing notification (Todokede) to PMDA required, no product approval necessary

#### Class II and Class III (partial) controlled medical devices: Pre-Market Certification (Ninsho)

Low risk to the human body

Where the MHLW has established certification standards, these products can be reviewed by an RCB. Where no certification standard exists, devices must be submitted to the PMDA for MHLW approval.

#### Class III and Class IV specially controlled medical devices: Pre-market approval (Shonin)

Medium/high risk to the human body or highly invasive

The MHLW reviews class III and IV devices against approval standards, or review guidelines where no standards have been established.

Class	Examples
I	Surgical instruments including scalpels and tweezers, X-Ray film
II	MRI scanners, digestive catheters, electronic endoscopes
III	Artificial bones, dialyzer, mechanical ventilator
IV	Pacemaker, artificial heart valves, stents

## What has changed from JPAL to PMD Act?

- The Marketing Authorization Holder (MAH – the legal manufacturer in Japan) will be responsible for QMS and Good Vigilance Practice (GVP).
- All Class II devices' design control activities will be covered in the QMS audit (Article 30-36, ISO 13485 Clause 7.3).
- Standalone software becomes a Class II device.
- Manufacturers will be requested to "be registered".
- The current license/accreditation will stay in force until the certificate expires.
- The package insert requirements have changed, and pre-market submission (Todokede) of the package insert to the PMDA will be required for pharmaceutical products and Class IV devices.

Manufacturers require a representative in Japan to liaise with the regulatory authorities and RCBs on their behalf.

Manufacturers without an office in Japan must have a Marketing Authorization Holder (MAH) to fulfill the requirement.

## Important information for compliance with the PMD Act

- 1 The MHLW have published two key Ministerial Ordinances (MO) which detail requirements of medical device manufacturers and MAHs:
  - MO No. 169 – Standards for Manufacturing Control and Quality Control for Medical Devices and In Vitro Diagnostic Reagents;
  - MO No. 135 – Standards for Good Vigilance Practice (GVP).
- 2 The QMS for medical devices specifies the requirements for Class II, III and IV products, and some Class I products as specified by the MHLW.
- 3 The GVP for medical devices specifies the requirements for class I, II, III and IV products.
- 4 PMDA/MHLW and Certification Bodies will accept an MDSAP certificate in place of the on-site assessment for MO No.169.

## Why chose BSI for your certification?

**Local experts** – our knowledgeable product and system assessors are experts on the Japanese requirements.

**Efficiency** – we can conduct combined audits under MDSAP to meet your regulatory needs for many global markets in one visit.

**Confidence** – our stringent review process combines speed with experience, integrity, independence and predictability.

**Experience** – we have over 1750 combined years' industry and regulatory experience with a broad range of devices.

**Global access** – we operate in over 150 countries with more than 100 years of experience and offices around the world.

“Our mission is to ensure patient safety while supporting timely access to global medical device technology. We strive to set the global standard in thorough, responsive, predictable conformity assessments, evaluations and certifications.”



# Global expertise

## Certification services

CE Marking

ISO 13485 (QMS)

MDSAP Auditing – Australia, Brazil, Canada,  
Japan and USA

Health Canada CMDCAS

Japan PMD Act

Brazil INMETRO 60601 Auditing and combined  
INMETRO, ISO 13485 and CE Marking Auditing

Hong Kong CAB

Malaysia CAB

Taiwan TCP

## Medical Device Single Audit Program - MDSAP

The MDSAP is an international initiative led by Regulatory Authorities (RA) in different countries, to implement a program where Auditing Organizations (AO) can conduct a single audit of a medical device manufacturers' QMS/GMP requirements that would be accepted by multiple regulators. Participating RAs include: Australia, Brazil, Canada, Japan, and USA.

BSI is an accredited AO, and already has experience auditing against the requirements.

Learn more about the Medical Device Single Audit Program through BSI's [online resources](#) and [webinars](#).

## Talk to BSI

BSI has experience with regulatory requirements in many global markets.

To find out more about our global services, call us on **+1 800 862 4977** or visit our website: [bsigroup.com/medical](http://bsigroup.com/medical)

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