

# Gain market access in Japan with PMD Act

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## Japanese Pharmaceutical and Medical Device Act (PMD Act)

The distribution of medical devices / in-vitro diagnostics in Japan is regulated in accordance with the Pharmaceutical and Medical Device Act (PMD Act) regulation by the Ministry of Health, Labour and Welfare (MHLW). The former regulation, Japanese Pharmaceutical Affairs Law (JPAL) was replaced by PMD Act on November, 25, 2014. The revision includes third party certification systems for Class III designated medical devices and expansion of the responsibility of quality management system to legal manufactures.

Because of the complexities of PMD Act and the involvement of Japanese and international governmental bodies, BSI can provide the necessary information which can help you understand the Japanese classification rules of your device, the review process and the QMS requirements.

### The preferred choice for PMD Act regulatory affairs managers

BSI Japan certified 20% of PMD Act third party medical devices in 2015, our extensive expertise enables us to build long-term relationships with all our customers. BSI Japan's accreditation as a third party by MHLW covers the scope:

- All Class II Medical Device
- Designated Class III Medical Device

