

## Summary

- The **global medical device market size reached 508 billion USD in 2024** and is expected to show steady growth over the next 5 years. USA accounted for the largest share of the global market in 2024, at 35.6%, whereas **Japan accounted for 5.7% of the global market, with 28.9 billion USD.**
- Japanese medical device manufacturers are **slowly expanding their share of overseas sales**, and the Japanese government is increasingly investing in the **digitalization of the medical device manufacturing process**. Both trends present opportunities for overseas medical device manufacturers, especially those involved in manufacturing AI-powered medical devices and Software as a Medical Device (SaMD), to collaborate with Japanese firms.
- The global medical device market is dominated by US companies, most of which have a presence in the Japanese market.
- Most major **Japanese medical device manufacturers have had business alliances with overseas companies, particularly from Europe**, for joint research and the sale of overseas medical devices in Japan.
- Medical devices in Japan are regulated under the “Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices” (PMD Act), primarily by 2 organizations: the **Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA).**
- Japan’s **high dependency on import of medical devices**, up to 90% for certain medical device categories, can be a significant supply chain vulnerability.
- The Japanese government is attempting to resolve the above challenges by **offering subsidies for startups and SMEs planning to enter the market**, as well as streamlining the process of creating a medical device-related startup and providing consultation services related to SaMD regulations.
- **Overseas medical device startups expanding into Japan, tend to be from other Asian countries** such as South Korea and Taiwan, but startups from Europe and the US tend to access the Japanese market by forming partnerships with major Japanese manufacturers, as well as medical device distributors, to act as channels to sell their products in Japan.