

Kenyataan Media

PRESS RELEASE

MDA FORGES STRATEGIC PARTNERSHIP WITH JAPAN TO STRENGTHEN MEDICAL DEVICE REGULATORY COOPERATION

TOKYO, 10 JUNE 2026 – Medical Device Authority (MDA) has strengthened its international collaboration with Japan through the signing of a Memorandum of Cooperation (MoC), establishing a framework for regulatory cooperation in the field of medical devices.

The signing took place in conjunction with the Official Visit of the Prime Minister of Malaysia YAB Dato' Seri Anwar Ibrahim to Japan from 8 to 10 June 2026.

The memorandum was signed by YBrs. Ts. Dr. Muralitharan Paramasua, Chief Executive of MDA, and Mr. Naoki Miyamoto, Director General of the Ministry of Health, Labour and Welfare (MHLW) of Japan.

Under the MoC, both authorities will promote the exchange of information and regulatory cooperation in the field of medical devices and related regulatory matters, including scientific collaboration, personnel training, and cooperation in multilateral regulatory fora.

In addition to the signing, both parties reached several key outcomes during the bilateral engagement, including:

- Strengthening regulatory cooperation between Malaysia and Japan, particularly in expediting the evaluation and registration of medical devices in both countries, as well as in post-market surveillance frameworks;
- Japan's in-principle support for the signing of a MoC between the Global Harmonization Working Party (GHWP) and the International Medical Device Regulators Forum (IMDRF), aimed at further aligning harmonisation efforts among the members of both organisations;
- A commitment to review the requirements relating to the Certificate of Free Sale (CFS);
- Japan's support for Malaysia's bid to become an APEC Center of Excellence (CoE); and
- Japan's agreement to assist in identifying suppliers of finished medical devices facing shortages in Malaysia.

During the visit, MDA also called on two medical device companies namely Kaneka Medix Corporation and SPHinX Inc., which are currently in discussions to introduce innovative technologies into Malaysia. Kaneka Medix focuses on neurovascular devices for minimally invasive treatment, while SPHinX is developing smart polymer-based diagnostic technologies to enhance the accuracy of disease detection. Both technologies hold strong potential to strengthen the nation's treatment and diagnostic

capabilities, while also creating opportunities for strategic collaboration within the local medical device industry.

For local industry players, the partnership also opens pathways to expand into international markets. By gaining greater familiarity with Japan's globally recognised regulatory framework, Malaysian manufacturers will be better positioned to elevate their competitiveness on the global stage.

This collaboration also reflects MDA's commitment to strengthening Malaysia's medical device regulatory framework in line with National Industrial Master Plan 2030 and the World Health Organization's Good Reliance Practices (GRoIP), with the aspiration of facilitating more efficient and timely access to safe, effective, and quality medical devices.

As the sector continues to grow as a key contributor to national trade and economic growth, MDA remains dedicated to advancing regulatory excellence in support of a sustainable and resilient healthcare ecosystem.

**Release by:
Medical Device Authority**



