



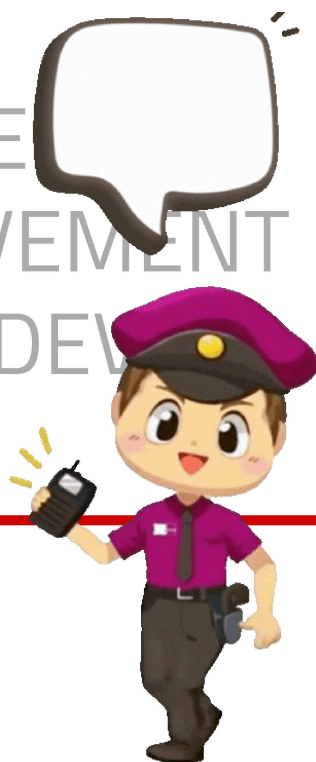
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[PRESS RELEASE] MALAYSIA–UNITED STATES AGREEMENT ON RECIPROCAL TRADE LANDMARK ACHIEVEMENT FOR THE MEDICAL DE SECTOR





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PRESS RELEASE

MALAYSIA–UNITED STATES AGREEMENT ON RECIPROCAL TRADE: A LANDMARK ACHIEVEMENT FOR THE MEDICAL DEVICE SECTOR

Cyberjaya, 28 October 2025

The Medical Device Authority (MDA) welcomes the successful conclusion of the Malaysia–United States Agreement on Reciprocal Trade, announced in conjunction with the ASEAN Summit 2025.

The agreement marks an important milestone in strengthening Malaysia's position in the global medical device landscape. Under the agreement, Malaysia retains its authority to register United States manufactured medical devices, ensuring that product safety, quality, and compliance with national requirements remain in place.

A technical footnote in Article 2.4 clarifies that Malaysia may maintain its registration requirements while avoiding duplication of conformity assessments. Acceptance of U.S. FDA approvals does not mean automatic market entry, as all medical devices must still be registered with the Medical Device Authority (MDA) to ensure safety, quality, and compliance with local regulations.

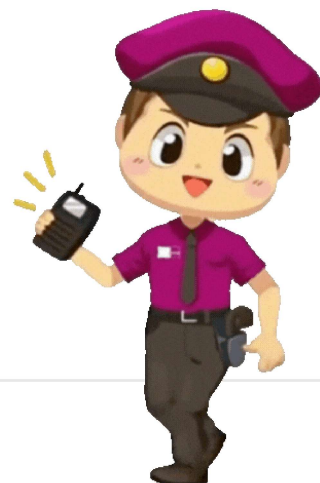
Malaysia has also retained the existing 19 percent tariff rate with tariff exemptions granted for three additional category Codes 3006.30.10, 3006.70.00, and 3808.94.10. This measure enhances industry competitiveness and access to advanced healthcare.

Malaysia has accepted the requirements to become a member of the International Medical Device Regulators Forum (IMDRF) and the Medical Device Single Audit Program (MDSAP), in line with its commitment to global regulatory harmonisation. Malaysia has been a member of both initiatives since February 2025, reflecting the nation's proactive approach toward international collaboration and regulatory excellence.



MDA congratulates the Prime Minister of Malaysia, YAB Dato' Seri Anwar Ibrahim, and the entire government machinery for their continued efforts in advancing Malaysia's role in global trade and innovation through the successful conclusion of the ASEAN Summit 2025.

Dr. Muralitharan Paramasua
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