JOINT STATEMENT BY MEDICAL DEVICE AUTHORITY (MDA), MALAYSIA AND HEALTH SCIENCES AUTHORITY (HSA), SINGAPORE ON 22 AUGUST 2025

MALAYSIA AND SINGAPORE SIGN MEMORANDUM OF UNDERSTANDING AND LAUNCH MEDICAL DEVICE REGULATORY RELIANCE PILOT TO FAST TRACK MEDICAL DEVICE MARKET ACCESS

The Medical Device Authority (MDA) of Malaysia and the Health Sciences Authority (HSA) of Singapore signed a Memorandum of Understanding (MOU) to deepen regulatory cooperation and officially launched a 6-month pilot of the Medical Device Regulatory Reliance Programme as part of the MOU. The signing took place during the 14th ASEAN Medical Device Committee (AMDC) Meeting held in Siem Reap, Cambodia on 22 August 2025.

This strategic MOU cements a new era of regulatory convergence and industry collaboration between Malaysia and Singapore. Running from 1 September 2025 to 28 February 2026, the pilot programme will streamline the registration of Class B, C and D medical devices, delivering the following:

(1) Faster approvals through reliance on each other's regulatory assessment and approvals;

(2) Reduced duplications of reviews, cutting costs and time-to-market; and

(3) Earlier patient access to safe, innovative and high quality medical technologies.

What the Industry Can Expect

Through this pilot programme, both regulators will work closely to test streamlined pathways, refine and establish clear standard operating procedures for the reliance pathway, validate shortened processing timelines and gather stakeholders' feedback, so that an effective and scalable regulatory reliance programme can be built after the pilot.

Medical Device Registration Certificate Holders participating in the pilot can expect reduced review times for medical device registration in both countries:

a) In Malaysia: Devices registered with HSA may undergo a verification route (abridged review pathway) through MDA's Conformity Assessment Body (CAB). The review is expected to take 30 working days, compared to 60 working days under the full conformity assessment route. The device will then be registered within 30 working days.
b) In Singapore: Devices registered with MDA will benefit from an abridged review pathway, achieving up to 30% shorter review times across all Class B to D medical devices.

"This MOU marks a significant milestone in the advancement of our partnership with Malaysia MDA. By building trust in each other's regulatory systems, we can support the medical device industry with more efficient processes while ensuring patients gain faster access to safe and high quality medical devices. We look forward to a fruitful partnership and hope this pilot paves the way for broader cross-border regulatory collaborations," said Adjunct Professor (Dr) Raymond Chua, Chief Executive Officer, HSA.

"Malaysia and Singapore recognise the importance of exploring new markets to create greater opportunities for medical device industry players to expand their businesses. With strong growth potential, the medical device sector has made a significant contribution to national income and economic development, while enhancing patient access to advanced medical technologies. This strategic partnership seeks to diversify market opportunities, strengthen technical confidence in the medical device regulatory system, and stands as a

testament to the close and enduring relationship between Malaysia and Singapore," said Dr. Muralitharan Paramasua, Chief Executive, MDA.

This MOU is a testament to the commitment of both countries to work together towards advancing regional economic integration. At the conclusion of the pilot, MDA and HSA will jointly evaluate the outcomes and consider full scale implementation of the regulatory reliance programme. Interested stakeholders are encouraged to contact the respective regulatory authorities for further details.

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