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ASIA EDITION

Malaysia and Singapore sign MoU to fast track medical device market access

26 August 2025 | News

A testament to the commitment of both countries to work together towards advancing regional economicintegration

The Medical Device Authority (MDA) of Malaysia and the Health Sciences Authority (HSA) of Singapore have 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.

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.

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:

1. 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.
2. 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.