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## PRESS RELEASE

### Malaysia Leads Regional Medical Device Regulatory Reliance

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The Medical Device Authority (MDA), Ministry of Health Malaysia, is proud to announce a historic milestone in regional regulatory collaboration with the official launch of the Medical Device Regulatory Reliance Programme between Malaysia and Singapore.

Announced at the 29th International Medical Device Regulators Forum (IMDRF) in Singapore, this initiative is a strategic breakthrough that accelerates access to safe and innovative medical technologies while strengthening Malaysia's position as a global regulatory leader.

Following a successful six-month pilot phase from 1 September 2025 to 28 February 2026, the programme enables Malaysia to accept registration applications for Class B, C, and D medical devices already registered in the Singapore Medical Device Register (SMDR) through the Verification Route.

This initiative marks a landmark achievement in regional regulatory reliance. By recognising Singapore's regulatory decisions, Malaysia can streamline access to innovative medical devices while maintaining the highest standards of safety, quality, and performance.

The programme also reduces regulatory duplication, accelerates approval timelines, and ensures patients in the region have faster access to high-quality medical technologies. The framework was established following the signing of a Memorandum of Understanding (MOU) on 22 August 2025, which allows both countries to recognise each other's regulatory decisions for medical device registration.

This milestone reinforces Malaysia's role as a regional regulatory hub and demonstrates its commitment to efficient, transparent, and collaborative healthcare regulation that benefits patients and the broader medical technology industry. Stakeholders are encouraged to engage directly with MDA for consultation.

**Issued by:**  
**Medical Device Authority**  
**Ministry of Health Malaysia**