

# Kenyataan Media

## *PRESS RELEASE*

### **Malaysia Leads The World In Medical Device Regulatory Reliance**

**KUALA LUMPUR, 16 JULY 2025** – The Ministry of Health Malaysia is proud to announce a historic advancement in international regulatory collaboration with the launch of the Medical Device Regulatory Reliance Programme between Malaysia and China.

This world-first initiative, announced during the HIMSS APAC Health Conference & Exhibition 2025 in Kuala Lumpur, represents a strategic breakthrough in accelerating access to safe and innovative medical technologies while reinforcing Malaysia's position as a global regulatory leader.

The programme, following the signing of a Memorandum of Understanding between the Medical Device Authority (MDA) and China's National Medical Products Administration (NMPA) in November 2023, enables both countries to recognise each other's regulatory decisions for pre-market approvals. Malaysian IVD devices now qualify for China's Green Channel, and Chinese IVD devices may use Malaysia's Verification Pathway, reducing approval timelines to 60 and 30 working days respectively.

This arrangement reduces regulatory duplication, accelerates market access, and improves patient access to quality healthcare technologies. It also strengthens Malaysia's role as a regional regulatory hub and enhances global investor confidence in the country's regulatory ecosystem.

The Ministry of Health and MDA welcome industry participation in this historic initiative. Stakeholders are encouraged to engage directly with MDA for consultation. This programme reinforces Malaysia's commitment to future-ready, efficient, and transparent healthcare regulation that benefits both patients and the global health industry. This reliance initiative will officially commence on 30 July 2025.

**DR. MURALITHARAN PARAMASUA**

Chief Executive

Medical Device Authority Malaysia (MDA)

16 July 2025