ANNOUNCEMENT UPDATE

Implementation of the Malaysia–China Medical Device Regulatory Reliance Programme (Pilot Phase 1: 30 July – 30 September 2025)

Dear All Medical Device Industry Stakeholders,

The Medical Device Authority (MDA) extends its highest regards to all valued stakeholders.

This announcement serves to inform the industry of the implementation of the **Malaysia–China Medical Device Regulatory Reliance Programme (Pilot Phase I)**, following the recent press release. This initiative represents the first reciprocal regulatory arrangement of its kind globally, under the **Global Harmonization Working Party (GHWP)** framework. This landmark initiative marks a significant bilateral milestone in regulatory innovation and mutual trust. It further reinforces Malaysia's leadership in advancing international regulatory cooperation for medical devices.

Following the Memorandum of Understanding (MoU) signed in November 2023 between the Medical Device Authority (MDA), Malaysia, and the National Medical Products Administration (NMPA), China, both regulatory authorities have agreed to mutually recognize regulatory decisions for in-vitro diagnostic (IVD) medical devices under the Malaysia–China Medical Device Regulatory Reliance Programme (Pilot Phase 1).

The programme will be implemented from **30 July 2025 to 30 September 2025**, with the objective of enhancing regulatory efficiency and accelerating market access for eligible IVD devices in both countries.

Eligibility Criteria

Requirement	Chinese-Made IVD Devices	Malaysian-Made IVD Devices
Regulatory Pathway	Eligible for **Malaysia's Verification Pathway**	Eligible for **China's Green Channel**
Manufacturer Location	Based in China	Based in Malaysia
Facility Ownership	Manufacturer must own and operate its facility in China	Manufacturer must own and operate its facility in Malaysia
Exclusions	Third-party brand owners (e.g., rebranders, relabelers, assemblers)	Third-party brand owners (e.g., rebranders, relabelers, assemblers)
Device Classes	Class II approved by Provincial MPA or Class III approved by NMPA	Class B, C, or D approved by MDA
Priority	Priority given to applications involving **rare diseases** and **innovative medical devices**	Not stated
Application Limit	6 applications*	6 applications
Contact Email	cab.registration@mda.gov.my	info@ChinaMedDevice.com

*Refer to Appendix 1 for explanatory notes regarding the submission of applications to MDA.

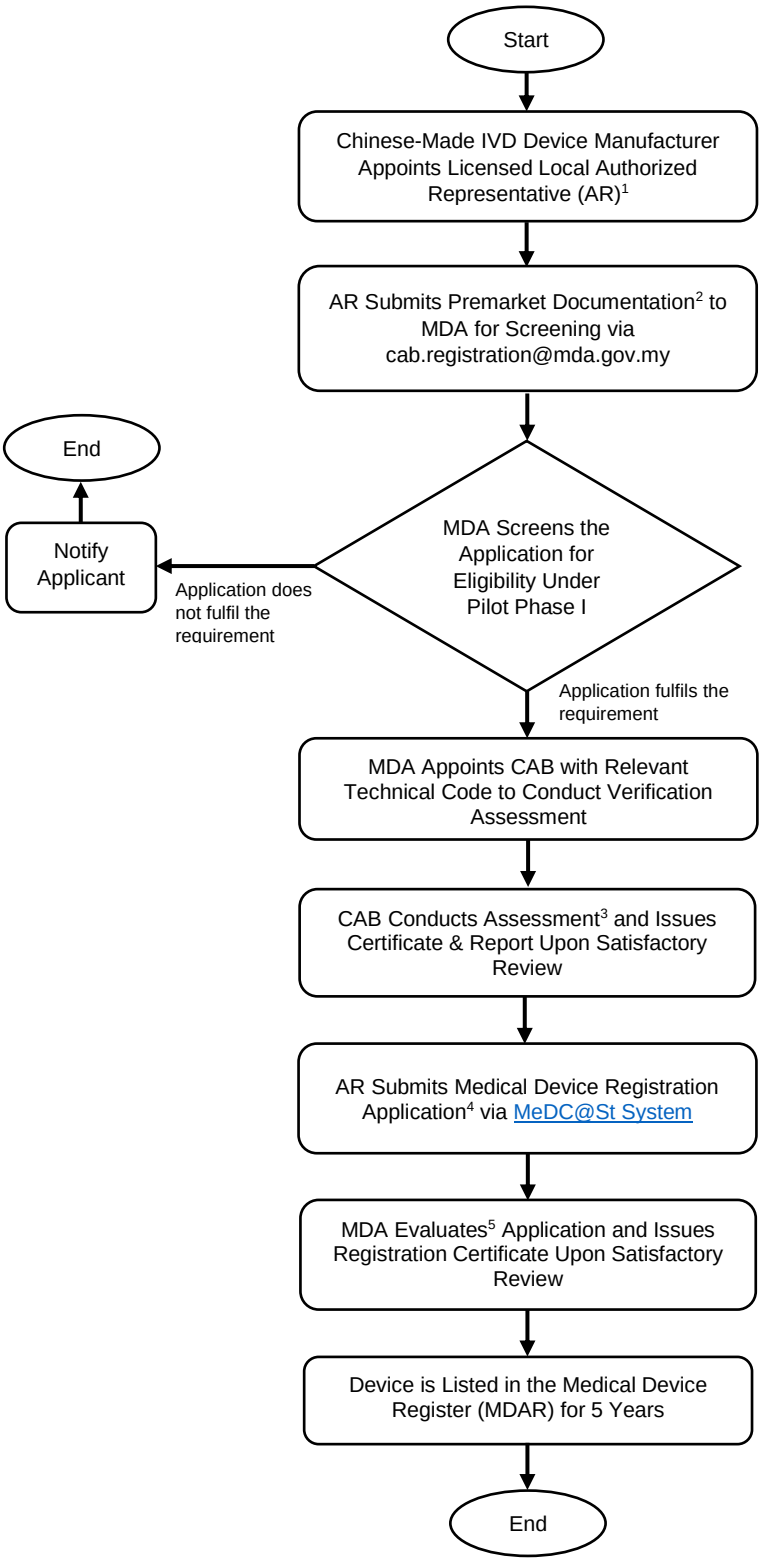
This collaborative regulatory reliance programme marks a significant milestone in enabling timely access to safe, effective, and high-quality IVD medical devices while reducing duplicative evaluations across trusted regulatory systems. MDA encourages eligible industry stakeholders to participate in this pilot initiative and consult directly with MDA for further guidance or clarification.

Thank you.

CAB Registration Unit (CABRU)
Pre-Market Control Division (BKPP)
Medical Device Authority (MDA)
Ministry of Health (MoH)
Level 5, Prima 9 (Block 3547)
Prima Avenue II, Persiaran APEC
63000 Cyberjaya, Selangor Darul Ehsan
Date: 30th July 2025

Explanatory Notes: Submission of Class B, C and D Chinese-Made IVD Devices to MDA for Malaysian's Verification Pathway

This appendix provides guidance for Chinese manufacturers intending to submit IVD medical devices under the Malaysia-China Medical Device Regulatory Reliance Programme (Pilot Phase 1), specifically for access via **Malaysia's Verification Pathway**. The following notes outline the steps, documentation, and contact procedures for successful submission:



[1]Explanatory Note:
AR must hold a valid Establishment License issued by the MDA in accordance with the Act 737.

[2]Explanatory Note:
Submission must include the following documentation (only a complete application will be processed):

- *Quality Management System (QMS): ISO 13485, MDSAP, QSR (FDA 21 CFR Part 820), or Japan MHLW Ordinance 169*
- *Medical Device Information: Device name, intended use, classification, rule, and grouping*
- *CSDT Documentation:*
  - *Executive Summary*
  - *Essential Principles of Safety and Performance (EPSP)*
  - *Summary of design verification & validation*
  - *Pre-clinical and software validation studies*
  - *Clinical performance*
  - *Labelling, Instructions for Use (IFU), brochures*
  - *Risk analysis*
  - *Manufacturing process information*
- *Post-Market Surveillance (PMS)*
- *Declaration of Conformity (DoC)*
- *Class II registration certificate by Provincial MPA or Class III registration certificate by NMPA*
- *For detailed requirements, refer to the MDA/GD/0070 Guidance Document: Submission Guide for Conformity Assessment by Way of Verification Process (MeDC@St)*

[3]Explanatory Note:
The conformity assessment shall be conducted in accordance with the MDA/GD/0068 Guidance Document for Conformity Assessment Body (CAB) – Guide for Conducting Conformity Assessment by Way of Verification.

[4,5]Explanatory Note:
For detailed requirements, refer to the MDA/GD/0070 Guidance Document: Submission Guide for Conformity Assessment by Way of Verification Process (MeDC@St)