



ANNOUNCEMENT UPDATE

Malaysia–China Joint Evaluation Pilot Programme (Pilot Phase 2: 1st July to 30 September 2026)

Dear Medical Device Industry Stakeholders,

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

Following the success of the Malaysia–China Medical Device Regulatory Reliance Programme (Pilot Phase I) in 2025, MDA is pleased to announce the commencement of the second phase: **The Malaysia–China Joint Evaluation Pilot Programme**. This initiative is conducted under the Global Harmonization Working Party (GHWP) Common Evaluation Reliance Practice (CERP) framework.

The second phase introduces a **Joint Evaluation** approach. Unlike the previous reliance model, this phase enables collaborative, simultaneous assessment by both the MDA and NMPA. This milestone aims to enhance regulatory efficiency and market access through bilateral collaborative assessment, reducing duplicative evaluations to accelerate access to safe, effective, and high-quality medical devices in both markets while maintaining rigorous safety standards.

Eligibility Criteria

Requirement	Malaysian-Made Devices	China-Made Devices
Regulatory Pathway	Full Conformity Assessment	Special Channel Pilot Programme
Manufacturer Requirements	Must be based in Malaysia (own & operate the manufacturing facility)	Must be based in China (own & operate the manufacturing facility)
Device Classes	Class B, C, or D (GMD or IVD)	Class II or Class III (GMD or IVD)
Prior Registration Status	The device must not have obtained registration certificates in Malaysia or China	The device must not have obtained registration certificates in China or Malaysia
Submission Authority	MDA, Malaysia	NMPA, China
Contact Email	cab.registration@mda.gov.my	info@ChinaMedDevice.com

Notes: Refer to Appendix 1 for explanatory notes regarding the submission of applications to MDA. This programme is not open to third-party brand owners, including rebranders, relabelers, or contract assemblers.

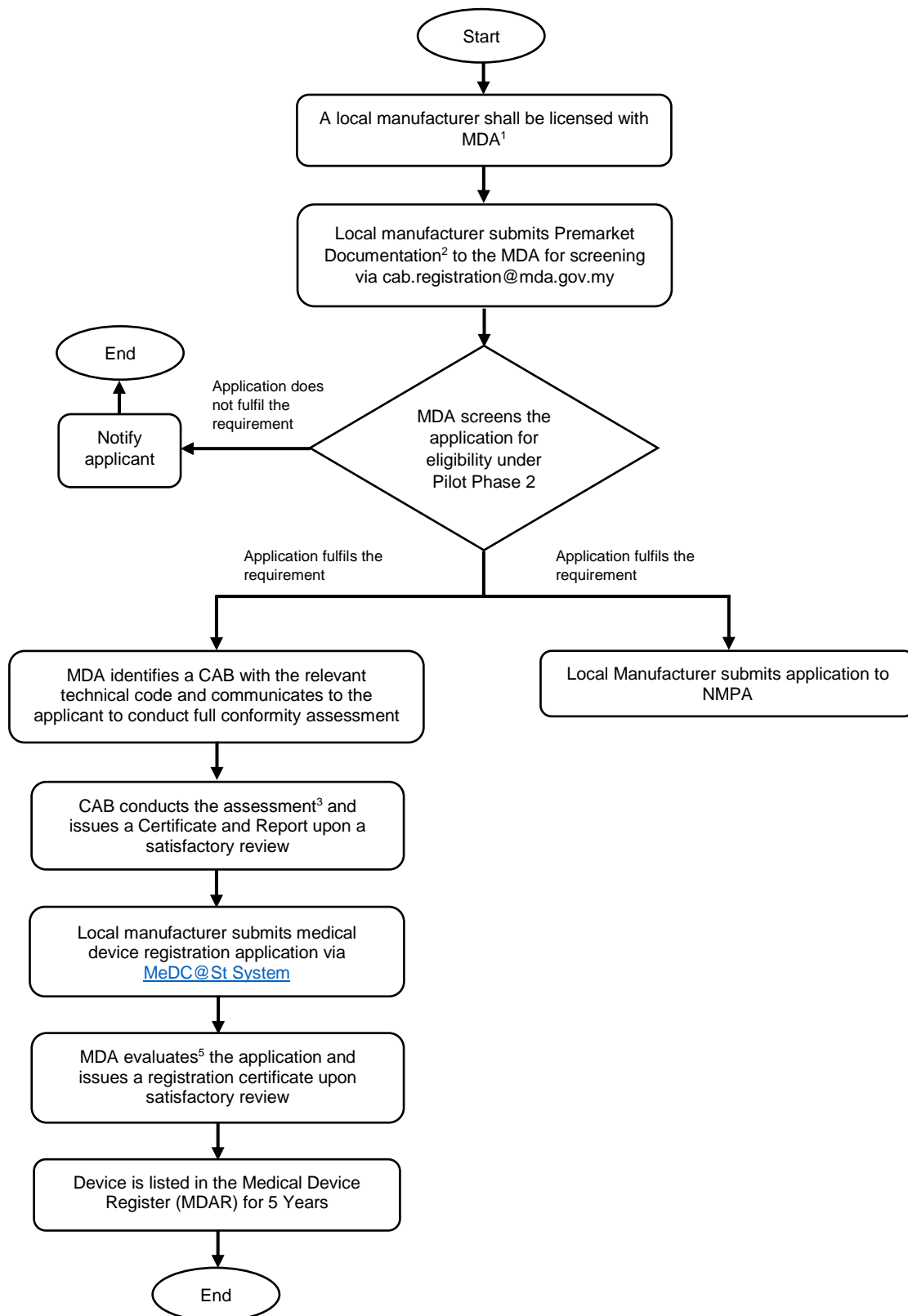
MDA encourages **eligible local manufacturers** to participate in this pilot initiative. Stakeholders are invited to consult directly with MDA for guidance or clarification regarding participation and submission requirements.

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: 15 June 2026

Process Flow & Explanatory Notes: Submission of Class B, C, and D Devices

This appendix provides step-by-step guidance for manufacturers intending to submit applications under the Malaysia–China Joint Evaluation Pilot Programme (Pilot Phase 2)



Explanatory Notes: Submission of Class B, C and D Devices to MDA

¹Explanatory Note: Establishment Licensing

The local manufacturer shall hold a valid Establishment License issued by the MDA in accordance with the Act 737.

²Explanatory Note: Submission of Premarket Documentation for Screening

Submission must include the following documentation (only complete applications 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)

³Explanatory Note: Conformity Assessment

The full conformity assessment shall be conducted in accordance with the [MDA/GD/0031 Conformity Assessment for Medical Device](#)