MEDICAL DEVICE AUTHORITY, MALAYSIA

LATEST COUNTRY UPDATES

A Comprehensive Overview of Policy Shifts, Digitalization, and Financial Compliance.

by Dr. Muralitharan Paramasua, Chief Executive, MDA

Presentation Overview

PART A: Policy Update Initiative

- Designated Devices (DMD)
- Orphaned, Obsolete, Discontinued Medical Devices (OOD) Framework
- Innovative Medical Device Pathway Framework
- Regulatory Control Over Distributors in Accordance with Act 737
- New Registration Fees for Class A
- Change Management for Registered Medical Devices

PART B: Digitalization & System Modernization

- Medcast 3.0 Development Roadmap
- Unique Device Identifier (UDI)
- e-Labelling & e-IFU
- Medical Device Centralized Reporting System (MEDCRES+)

PART C: International Strategic Collaboration

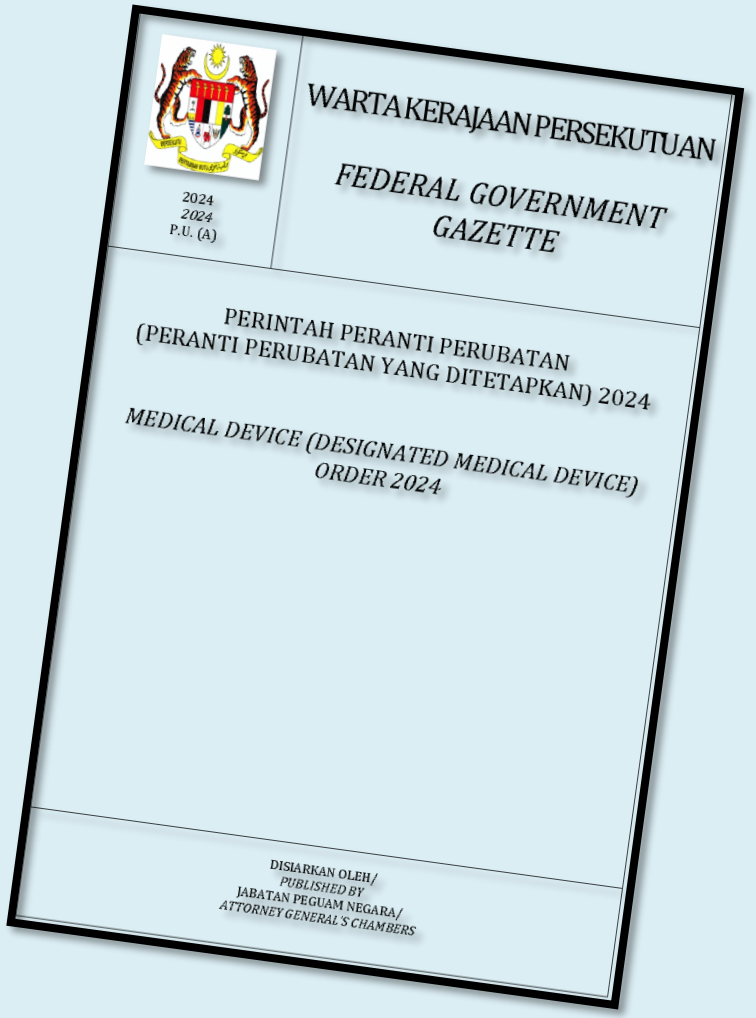
- Medical Device Regulatory Reliance Programme in Malaysia
- Who Global Benchmarking Tool (GBT)
- International Medical Device Conference (IMDEC 2026)

PART A

DESIGNATED DEVICES (DMD)

DRAFT OF MEDICAL DEVICE (DESIGNATED MEDICAL DEVICE) ORDER 2024

- Listing of DMD with its intended use
- Status: Under review by MOH Legal and AGC



DMD LIST

1. **Medical Laser**

   Alexandrite laser, Fractional CO2 laser, Nd:YAG laser, Diode laser, Ruby laser, Erbium YAG laser, Pulse-dye laser

2. **High Intensity Focus Ultrasound (HIFU)**
3. **Liposuction devices**

PART A

ORPHANED, OBSOLETE, DISCONTINUED MEDICAL DEVICES (OOD) FRAMEWORK

Provision: Medical Device (Exemption) Order 2024

- **Guidance Document on Control of Obsolete and Discontinued Medical Device in Healthcare or Related Facilities**
  - Outline the requirements on applying for confirmation of the status of obsolete and discontinued medical devices, including post-market responsibilities of establishment, healthcare facilities and user
  - Status - has completed the public comment stage and is currently under deliberation for finalization and approval (Target publish: Sept 2025)

- **Guidance Document on Control of Orphaned Medical Device in Healthcare or Related Facilities**
  - Outline the requirements on applying for confirmation of the status of orphaned medical devices, including post-market responsibilities of healthcare facilities and user
  - Status- in deliberation stage (Target publish: December 2025).

- **Guidance Document on management of medical device**
  - Outline the requirements related to testing & commissioning, maintenance, installation, disposal, and personnel competency for medical devices, including those that are OOD
  - Status- in deliberation stage (Target publish: Q1 2026).

PART A

INNOVATIVE MEDICAL DEVICE PATHWAY FRAMEWORK

Regulatory Framework for Innovative Medical Devices has been approved by MDA Board.

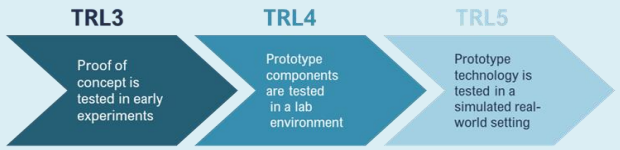
- Regulatory advice and evaluation on research recommendation for the development of innovative medical device through:
  - **Early Development Review (TRL 3-5)**

    Fee:RM1,000 (max 2 hours per session)

  - **Pre-Commercial Review (TRL 6-9)**

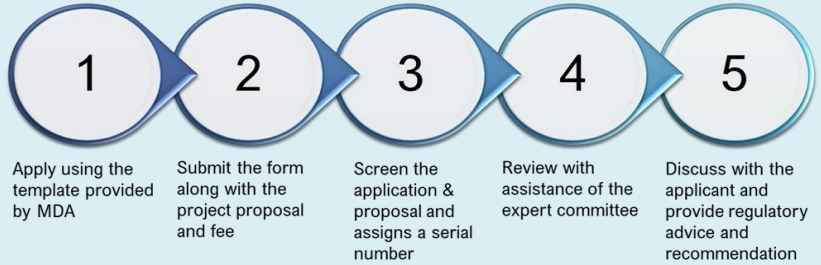
    Fee: RM1,500 (max 2 hours per session)

- *Publicly announce the implementation of Framework in August 2025*



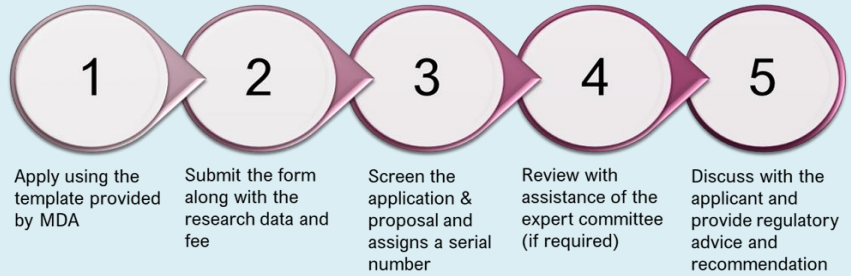
Early Development Review Process

1. Recommendations for forward planning on specific EPSP data requirements
2. Other general regulatory advice which may includes:
   - Advisory on compliance
   - Bridging to the related stakeholders
   - Financial assistance by other agencies
   - Clinical investigators/CRM/ethic committee/hospital sites
   - Industrial partners
   - Sandbox coordinator



Pre-commercial Review

1. Recommendations on the sufficiency of acquired EPSP data and potential strategies for enhancement
2. Introduce Initiative 2 to facilitate the registration process & market access
3. Additional related regulatory advice which may includes:
   - Advisory on compliance
   - Bridging to the related stakeholders (eg. MyIPO for IP application process)
   - Financial assistance by other agencies
   - Clinical investigators/CRM/ethic committee/hospital sites
   - Industrial partners
   - Sandbox coordinator



PART A

REGULATORY CONTROL OVER DISTRIBUTORS IN ACCORDANCE WITH ACT 737

A tenderer supplying medical devices to healthcare institutions offering tenders is considered an **establishment that places medical devices on the market.**

The above-mentioned tenderer **shall be licensed with the Medical Device Authority** (MDA) and comply with all legal requirements stipulated under the Medical Device Act 2012 (Act 737) and its subsidiary regulations.

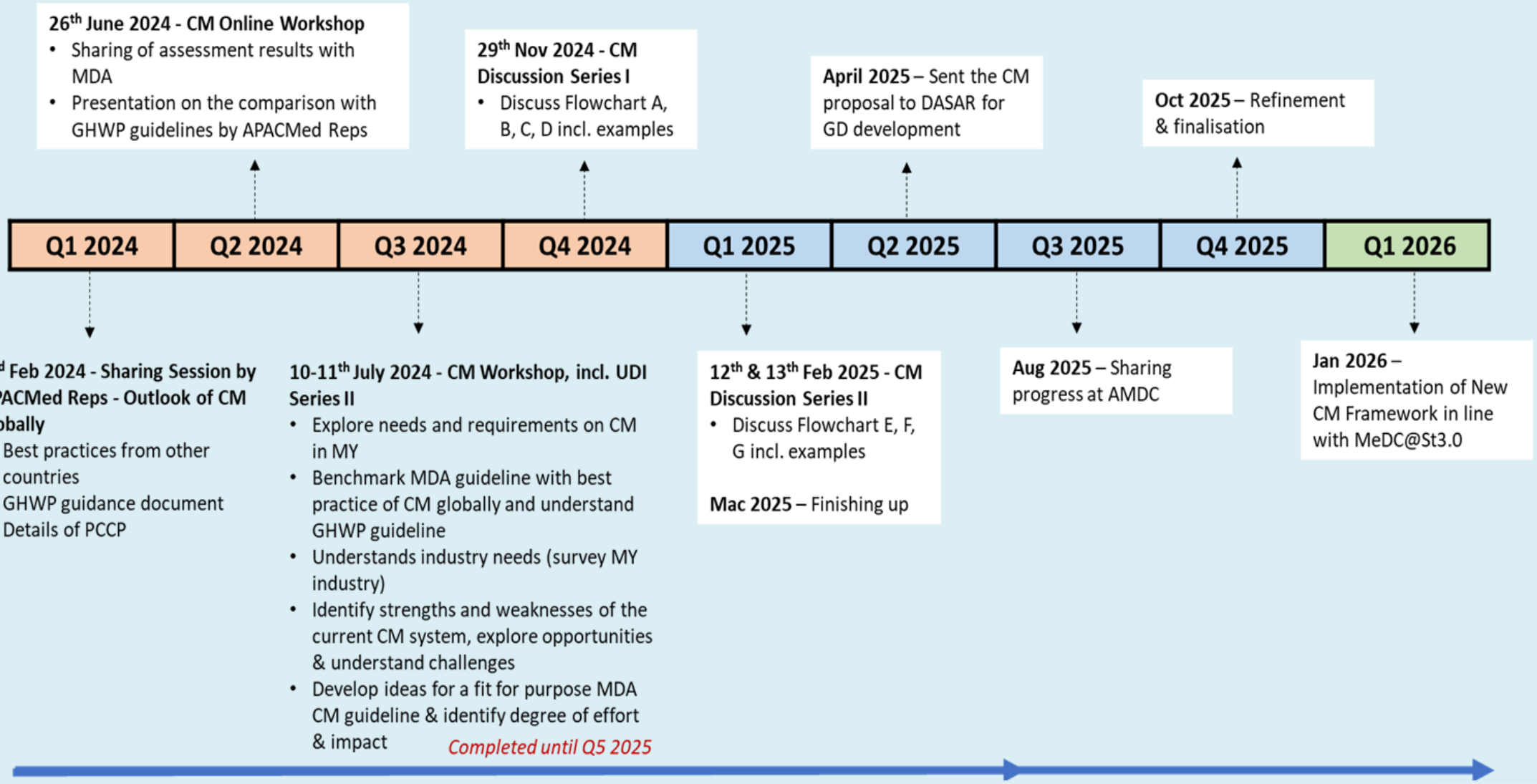
NEW FEES FOR CLASS A MEDICAL DEVICES REGISTRATION

Type of Fee	New Class A Fee (RM)
Application Fee	500
Registration Fee	750
Note: Draf MDR 2012 is still under review by MOH Legal advisor	

PART A

CHANGE MANAGEMENT FOR REGISTERED MEDICAL DEVICES

MDA-APACMED Collaboration Effort to Develop Change Management Framework in Malaysia - Timeline



PART B

MEDCAST 3.0 DEVELOPMENT ROADMAP

2023

Project Initiation

- System Development Plan
- Industry Engagement: Survey & MeDC@St 3.0 Briefing Phase I

2024

Analysis & Design

- Development of BRS, SRS & SDS.
- Industry Engagement: Change Management Workshop with APACMed

2025

Development & Testing

- Database, Application, Design Development & Testing
- Industry Engagement: Survey & MeDC@St 3.0 Briefing Phase II, incl. UDI

2026

Quick Win 1 Launch

- Quick Win 1 Launch
- User Manual & Training
- Quick Win 2 Analysis & Design

Quick Win 1

3 Core Modules:

- EL, Q2
- MDR, Q3
- CAB, Q4

Key Highlights

- Integrated Core Modules
- Automated EL & MDR Renewal
- Agile Change Management
- PCCP Inclusion for SaMD
- UDI Database Integration

2027

Quick Win 2

- Digitalisation of Manual Processes (e.g., Product Classification, Advertisement Modules)

Development & Testing

- Database, Application, Design Development & Testing of Other Modules

2028

Quick Win 2 Launch

- Quick Win 2 Launch
- MeDC@St 3.0 Full Implementation
- User Manual & Training
- Post Implementation Review

Updated as of 27 Nov 2025

PART B

UNIQUE DEVICE IDENTIFIER (UDI)

Proposed UDI Implementation Timeline (MDA)

*once decided and assuming MeDC@St 3.0+ is completed

2024

Pilot Survey

UDI framework development including a pilot survey for Class D and B medical devices and data analysis

2026

Transition Phase

Voluntary implementation phase for all medical device classes

2027

Class D Mandatory Phase 1

UDI implementation for all Class D medical devices

2028

Other than Class D Mandatory Phase 2

UDI implementation for other than class D medical devices

2030

Full UDI Compliance

Full UDI compliance in Malaysia

PART B

E-LABELLING & E-IFU

Implementation of e-labelling for home-use medical devices and Software as Medical Device (SaMD) that does not have physical packaging.

- Status: currently revising **Section 4.12** Electronic Labelling in the Guidance Document **MDA/GD/0026: Requirements for Labelling of Medical Devices** to incorporate specific requirements for e-labelling applicable to home-use medical devices.(Target public comment & publish:Q3 2025).

PART B

MEDICAL DEVICE CENTRALIZED REPORTING SYSTEM (MEDCRES+)

HOW DO YOU REPORT?

MEDICAL DEVICE CENTRALIZE REPORTING SYSTEM (MedCReSt)

Reporting an incident is compulsory!!

https://medcrest.mda.gov.my/login

MeDCReS+

Medical Device Centralized Reporting System

MEDICAL DEVICE REGULATORY RELIANCE PROGRAMME IN MALAYSIA

Type : Abridged Review

Current : Unilateral

Reference Agency: MHRA, MHLW, U.S. FOOD & DRUG ADMINISTRATION, European Union, Australian Government Department of Health, Health Canada

Unilateral

Relying Agency: Medical Device Authority Malaysia

Circular Letter of MDA No1 Year 2025 – Conformity Assessment Procedures for Medical Device Approved by Recognised Countries

Class B, C & D

Upcoming : Reciprocal

Reference & Relying Agency: HSA, Food and Drug Administration, KEMENTERIAN KESEHATAN REPUBLIK INDONESIA, NMPA 国家药品监督管理局, Ministry of Health of the Republic of Uzbekistan, EDA, GOVERNMENT OF UNITED ARAB EMIRATES

Reciprocal

Reference & Relying Agency: Medical Device Authority Malaysia

Class B, C & D

VERIFICATION

eligible for the conformity assessment process via the **verification route by a CAB** in Malaysia.

MeDeviceSt v2.0 MEDICAL DEVICE CENTRALISED ONLINE APPLICATION SYSTEM

Class A: 14-20 working days
Class B, C & D: 30 working days

Public Search – Medical Device Authority Register (MDAR)

Conduct conformity assessment procedure with registered CABs **exclude Class A* → Apply for medical device registration → Evaluation by MDA → Issuance of certificate → Register for 5 years → Place safe MD on the market

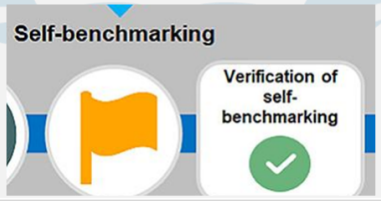
Overview of MD Registration Process

WHO GLOBAL BENCHMARKING TOOL (GBT)

MDA's WHO GBT + Medical Device Timeline

Engagement, Development , Capacity Building

1. Engagements with WHO Western Pacific Region ✓
2. Preliminary Pre-assessment ✓
3. Pre-assessment ✓
4. Self-assessment
5. Formal benchmarking by WHO



November 2023 – July 2025	August 2025 – December 2026	2027

PART C

INTERNATIONAL MEDICAL DEVICE CONFERENCE (IMDEC 2026)

IMDEC™ 2026

Revolutionizing Medical Technology: Powering Tomorrow's Era of Healthcare

26 – 28 AUGUST 2026

Hall 4-5, KL Convention Centre, Malaysia

Key Topics & Attractions

International Exhibition
Showcasing the latest in medical devices and digital health solutions from around the world

World Insight Conference
Join the for critical updates on global compliance, safety standards, and market entry

Innovation Arena
Discover breakthroughs from startups and researchers in a specialized showcase zone

MedTech Marketplace
A dedicated hub for roundtables, business matching, and connecting innovators with buyers

High-Level Participation
Brings together top-tier government leaders and industry decision-makers for policy-shaping discussions

Digital Health & AI
Explore the future of diagnostics and AI-driven healthcare solutions reshaping patient care

Why You Must Attend

10,000+ Trade Visitors

1,000+ Delegates

200+ Exhibitors

100+ Speakers

The Region`s Only Regulator-Led Event

Organised by Medical Device Authority (MDA), Malaysia

Medical Device Authority Malaysia

Be Part of ASEAN`s Premier Medical Device Event **EXHIBIT ◆ SPONSOR ◆ PARTNER**

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