Medical Devices & ASEAN Outlook

Focus on injectable products, regulatory comparison TH/ID/MY

Jingjiang, Jangsu, 10/11 July 2025

Malaysia Overview of Medical Device Registration Framework

Local Manufacturer
Authorised Representative
本地制造商

MeDC@St2.0+ MEDICAL DEVICE CENTRALISED ONLINE APPLICATION SYSTEM

14-60 working days upon submission of complete documents

Regulatory Oversight & Enforcement

Based on medical device definition

- ✓ Specify medical device intended purpose
- ✓ Rule & Grouping
- ✓ Compile technical document CSDT

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

Class	Application Fee
A	100
B	250
C	500
D	750

Class	Registration Fee
A	-
B	1000
C	2000
D	3000
Combination	5000

Re-registration

Change Notification

参考国

VERIFICATION

FULL CONFORMITY ASSESSMENT

MHRA Regulating Medicines and Medical Devices
厚生労働省 Ministry of Health, Labour and Welfare
U.S. FOOD & DRUG ADMINISTRATION
European Union
Australian Government Department of Health
Health Canada

TT Medical Management

MALAYSIA			
Class	Device	**Regulator**	
D or combination products e.g. Radiesse (+) Lidocaine 1.5CC	Injectable Implantcollagen simulator, injectable bone substitute system	Medical Device Authority	National Pharmaceutical Regulatory Agency - Require Endorsement letter of the device has drug combination
D	Filler, Hyaluronic Acid	Medical Device Authority	Not applicable
D	Type III Humanized Collagen Lyophilized Fiber	Medical Device Authority	

Malaysia

…Extracted from Medical Device Regulation 2012 , page 207

7. **Clinical evidence**

(1)The CSDT shall contain documentation on clinical evaluation to verify the clinical safety and performance of the medical device when used as intended by the manufacturer.

(2)The clinical evaluation may take the form of—

(a) a systematic review of existing bibliography;

(b) clinical experience with the same or similar medical devices;

(c) clinical investigation.

8. Use of existing bibliography

(1) The CSDT shall contain copies of all literature studies, or existing bibliography, that the manufacturer is using to support safety and effectiveness.

(2) Bibliography shall be derived from relevant publications in a peer-reviewed scientific literature and shall include the objectives, methodology and results presented in context, clearly and meaningfully.

(3) The conclusions on the outcome of the clinical studies should be preceded by a discussion in context with the published literature.

Singapore , Clinical evidence Class D

Full evaluation: Requires Clinical Evaluation Report, including publications and full reports of the studies reference. CER may come in the form of clinical investigations, published literature, or data from comparable devices.

Indonesia, Clinical Evidence Class D

CER may take the form of a systematic review of existing bibliography, clinical experience with the same or similar medical devices, or by clinical investigation- Clinical investigation is needed if only few or no clinical experience

Main brand in Malaysia

Category	Brand Examples	Key Highlights
💉 **Botox / Toxin**	Botox, Dysport, **Xeomin**, Nabota (Jeuveau)	Global leaders, widely used in certified clinics
💧 **HA Fillers**	Juvederm, Restylane, Teosyal, **Belotero**	Reversible, volumizing, ideal for facial contouring
🌿 **Collagen Stimulators**	**Radiesse**, Sculptra, AestheFill, Ellansé	Longer-lasting effects, stimulates natural collagen

Medical Device License Holder & Parallel Import Comparison

Country	License Holder Role	Who Can Be LH	Multiple LH Allowed?	Parallel Import Allowed?
Malaysia	Authorized Representative (AR)	Malaysian company registered with MDA	✅ Yes (since 2021)	✅ Yes
Singapore	Registrant (SMDR)	Local company with HSA account	✅ Yes	✅ Yes
Indonesia	Marketing Authorization Holder (MAH)	Indonesian entity with valid business license	❌ No	❌ No-single license holder only
Thailand	License Holder / Importer	Thai company registered with Thai FDA	✅ Yes (with co-license or sublicensing)	✅ Yes –license holders

Regulatory Updates:

2nd January 2026 to fully enforce import permit for each importation.

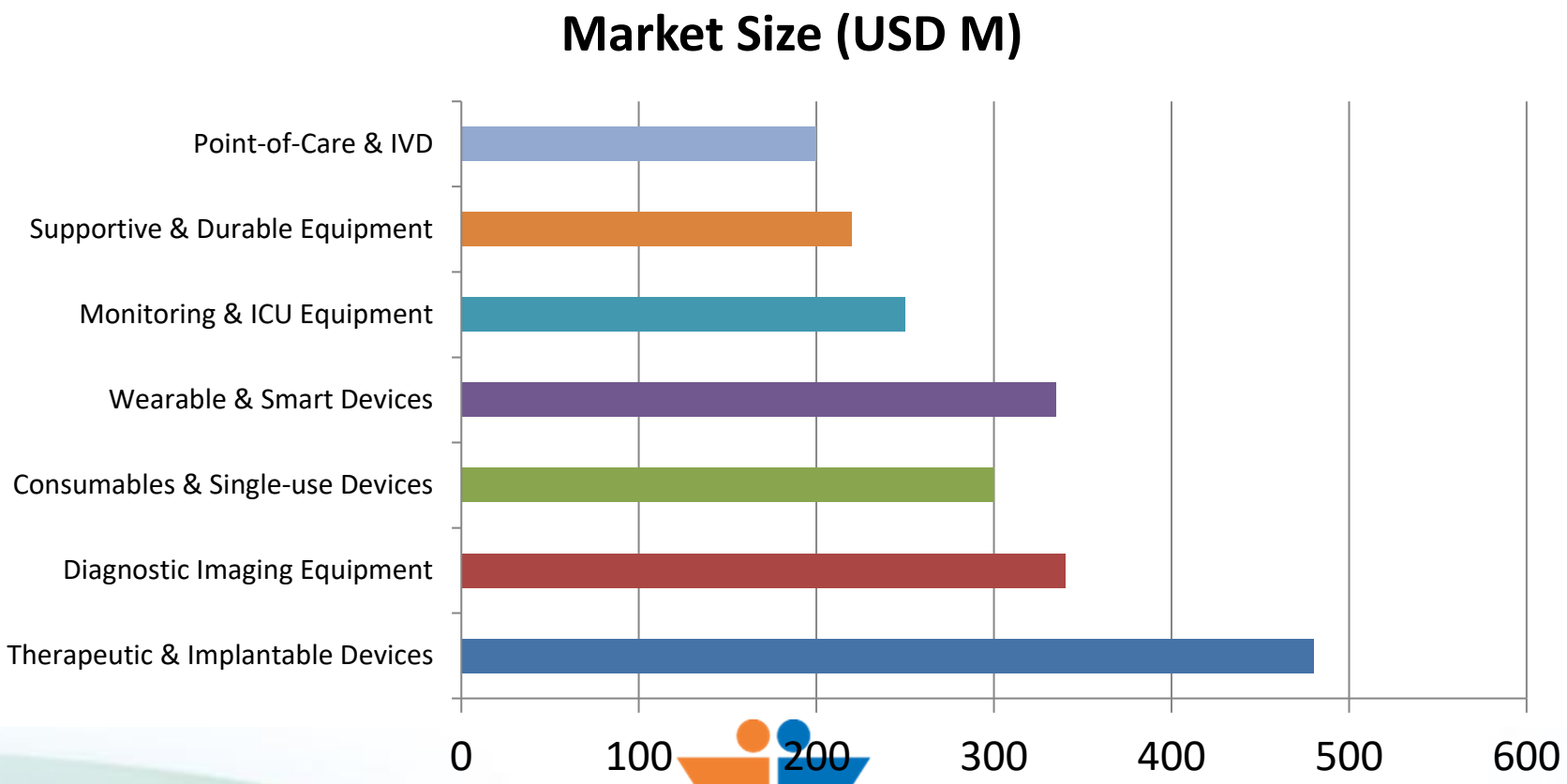
Medica Device Authority (MDA), Malaysia actively establishing reliance with other countries with the Asia Pacific Region.

Highly recommend by The Asia Pacific Medical Technology Association (APACMed) other countries government agency to learn from Malaysia medical device framework and registration process.

Malaysia Medical Device Market Segments

Estimated Market Size by Product Category (USD Millions)

Market Segmentation by Product (2022–2024)



Strategic Opportunities for Foreign Manufacturers

Opportunity Area	Description	Why It Matters
High-Demand Segments	Diagnostics, patient monitoring, renal care, orthopaedic, IVD, surgical tools	Rising NCDs, aging population, rural expansion
Manufacturing Base	Set up local production (e.g., Penang, Johor, Selangor)	Lower costs, ASEAN access, tax incentives, skilled labor
Public-Private Partnerships	Collaborate with MOH, public hospitals, or state initiatives	Boosts credibility, aligns with national health objectives
Digital & AI Integration	Imaging, diagnostics, hospital management software	Malaysia is pushing hospital digitalization and AI-enhanced diagnostics
Mid-Tier & Rural Solutions	Affordable, compact devices for smaller clinics and hospitals	Large untapped market in rural and tier-2 facilities
Local Licensing & AR	Appoint authorized representative (AR) and local distributors	Speeds up MDA registration, ensures compliance

ASEAN Focus – Malaysia & Singapore

T T Medical Management

Melisa-印尼、马来西亚注册服务

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Thursday, July 10 – Morning Session: Thailand and ASEAN

Time	Topic	Speaker(s)	Notes
09:00–09:30	**Opening Remarks & Agenda Overview**	ALAND Group Siam Trade Development	ASEAN context, Thailand market positioning
09:40–10:10	**Geopolitical Landscape and Tariffs**	ALAND Group Siam Trade Development	China–US–EU, RCEP, FTAs, Preferential Rules of Origin
10:10–11:10	**Thai FDA Regulatory Framework – Food & Supplements**	**Diego Sala** **Nitwaree Kanjanasurakit**	Definitions, ingredient types, registration, export
11:10–11:50	**Local Manufacturing Strategies & Export from Thailand**	Diego Sala	BOI, company setup, Thai Foreign Business Act – Case Study: Vitamin C market

Thursday, July 10 – Afternoon Session: Russia & ASEAN

Time	Topic	Speaker(s)	Notes
13:00–13:40	**Regulatory Framework in Russia**	**Irina Shchemerova** Siberian Wellness	Russian Local vs. export regulation Europe, Vietnam, Thailand comparison
13:40–14:10	**ASEAN Focus – Indonesia**	**Syifa Amirta Sani** Inspiry Indonesia Konsultan	Indonesian Key regulations, harmonization
14:10–15:00	**ASEAN Focus – Malaysia & Singapore**	**Melisa Leeau** TT Medical Management	Malaysia and Singapore: Product registration, ASEAN gaps
15:00–17:00	**Round Table and Team Outing**	-	-

Friday, July 11 – Morning Session: USA and TARIFF MITIGATION

Time	Topic	Speaker(s)	Notes
09:00–11:00	**Introduction to US FDA Regulations**	**US Regulatory Team** (remote)	USA Import/export, registration, claims, enforcement
11:00–12:00	**US Tariff Mitigation Strategies (Panel)**	**Diego Sala** invited panelists	First Sale, FTZs, Binding Rulings, Q&A

Friday, July 11 – Afternoon Session: MEDICAL DEVICES: CHINA and ASEAN

Time	Topic	Speaker(s)	Notes
13:00-14:00	**Introduction to China NMPA – VMS**	**Aland** VMS Regulatory Team	XBEC, registration, licensing for vitamins, minerals, supplements
14:00–15:00	**Introduction to China NMPA – Medical Devices**	**Jland** Collagen Type III team	Medical-grade supplements, borderline classifications, recombinant collagen
15:00–16:30	**Medical Devices & ASEAN Outlook**	**15:00 Nipapat Phuakyod** **15:30 Anggita Septiani** **16:00 Melisa Leeau**	Focus on injectable products, regulatory comparison TH/ID/MY
16:30	**Final Regulatory Remarks & Q&A**	**Diego Sala**	Summary discussion and participant questions