MEDICAL DEVICE AUTHORITY (MDA), MALAYSIA:

COUNTRY UPDATES

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Updates on:

- Overview Registration Process
- Statistic Medical Devices Registration & Establishment Licensing
- Development of Change Management Framework
- Efforts are being made towards strengthening the Conformity Assessment Body
- Newly Develop Online System (**MeDC@St3.0)**
- International relations matter: MOU

Overview of MD Registration Process

Based on medical device definition in Section 2 of Act 737

Apply for Product Classification

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

MeDDaSt 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)

Regulatory Oversight & Enforcement

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

VERIFICATION

FULL CONFORMITY ASSESSMENT

MHRA Regulating Medicines and Medical Devices · MHLW Ministry of Health, Labour and Welfare of Japan · FDA U.S. FOOD & DRUG ADMINISTRATION · European Union · Australian Government Department of Health · Health Canada

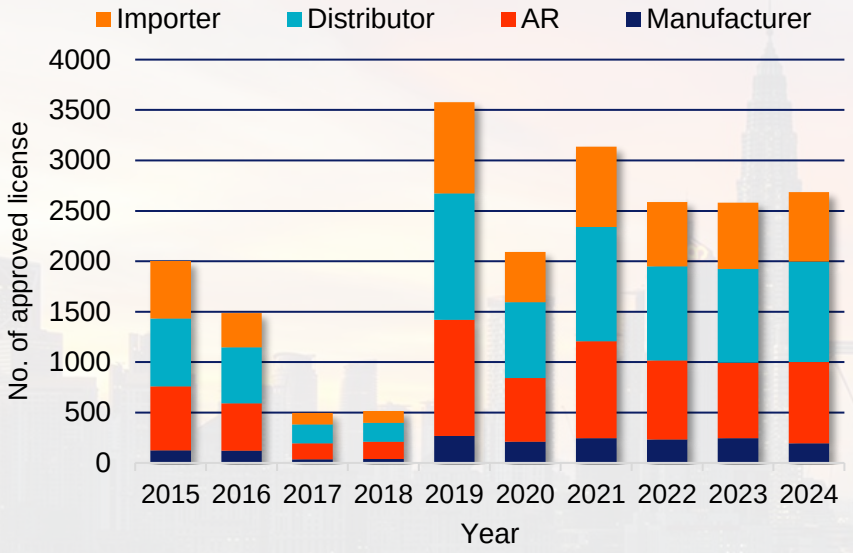
Medical Device AUTHORITY MALAYSIA

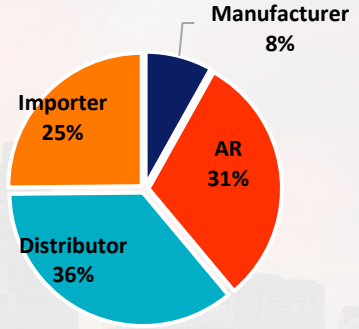
Statistics

As of Nov 2024 ~~19 Aug 2024~~

21,154

Total Establishment License Issued (2015-2024)





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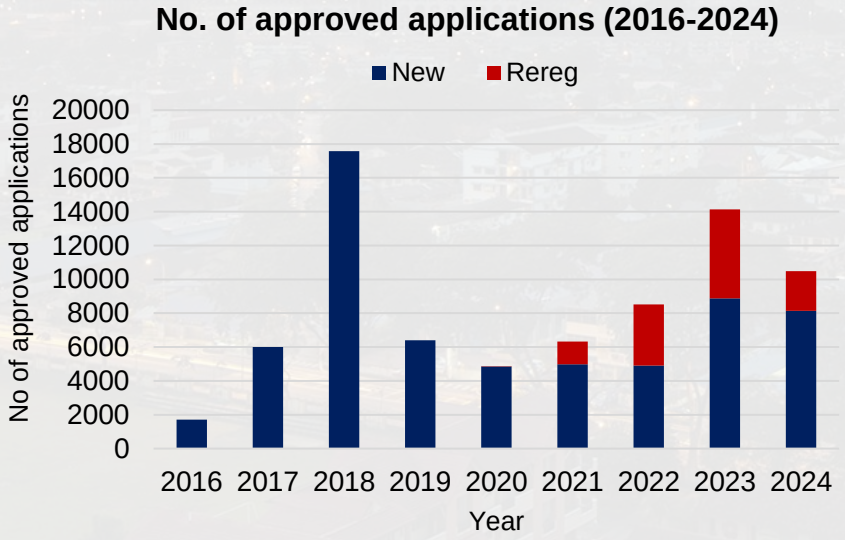
Total Registered CABs

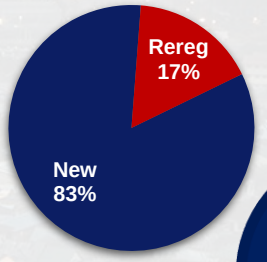
131

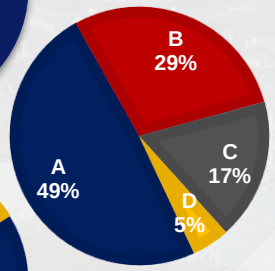
Total Registered CAB Personnel

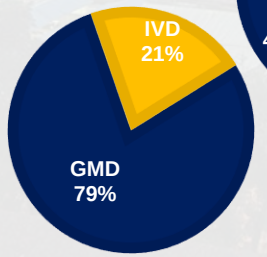
76,042

Total Registered Devices New+Rereg (2016-2024)









94 Registered ISO13485 Auditors

122 Registered GDPMD Auditors

108 Registered Verification Technical Personnel

70 Registered FCA Technical Personnel

MDA-APACMed Collaboration Effort to Develop Change Management Framework in Malaysia

Photo courtesy of APACMed

2 Feb 2024

Sharing Session by APACMed - Outlook of change management globally

- Best practices from other countries
- GHWP guidance document
- Details of PCCP

26 June 2024

Change Management: Online Workshop

- Sharing of assessment results with MDA
- Presentation on the comparison with GHWP guidelines by APACMed Representative

10-11 July 2024

Change Management Workshop, including UDI Implementation

- Explore needs and requirements on CM for MD in Malaysia
- Benchmark MDA guideline with best practice of CM globally and understand GHWP guideline
- Understands industry needs (survey Malaysia industry)
- Identify strengths and weaknesses of the current CM system and explore opportunities and understand challenges
- Develop ideas for a fit for purpose MDA CM guideline
- Get feedback on ideas and adapt a fit for purpose CM for the future and develop a realisation plan

Workshop Outcome

High Effort, Low Impact • PCCP • Reliance & Recognition	**High Effort, High impact (3- 5 years)** • 2 categories change • Decision tree • CM for QMS certification
Low effort, Low impact • SME	**Low effort, High impact (Quick Win) (1 year)** • FCA related change • Grouping related change • Change management document (focus on FAQ) • Reagent replacement and instrument family policy • Expand scope for bundling submission

29 Nov 2024

MDA-APACMed Change Management Discussion

- Approach focusing on the flowchart: A & B in the GHWP change management document.
- Discuss real life scenarios and applications of decision tree to cater local requirements.
- Agree on the documents to be submitted.

MDA-CAB Collaboration Effort to Enhance Conformity Assessments in Malaysia

1 Sept 8, 2023

MDA-CAB Dialogue 2023

- CAB Performance Challenges (e.g., late re-registration, inadequate training, conflict of interest)
- Turnaround Time for Medical Device Certification
- Conformity Assessment for Medical Gas Systems

2 Sept 29, 2023

MDA-CAB Collaboration on EU MDR

Purpose: Collaboration with 7 local CABs to assist Malaysian manufacturers in accessing the European market under the European Union Medical Device Regulation (EU MDR).

3 Nov 14, 2023

MDA-CAB Collaboration to Enhance MeDC@St 3.0

Focus: Enhancing the CAB Online Registration Application Form with user-friendly features and improved validation.

4 Dec 6-7, 2023

MDA-CAB Workshop 2023

- Assessment consistency in GDPMD Certification
- TAT consistency in all Conformity Assessment Certification
- Assessment consistency in GMD & IVD Certification
- Robust checklist for Clinical Evaluation
- Assessment consistency in Medical Gas Certification

5 Mar 1, 2024

MDA-CAB Workshop 2024 (Series I)

- Mutual GDPMD Report Template
- Mutual Certification Processes Turnaround Time (TAT)
- Mutual Verification Report (GMD & IVD) Template

Implementation Phases: Amendment (Apr), Pilot (May-Oct), Full (Nov)

6 Oct 23, 2024

MDA-CAB Dialogue 2024

Highlights: CAB Registration Updates, MeDC@St 3.0, ASEAN Recognition

7 Oct 24-25, 2024

MDA-CAB Workshop 2024 (Series II)

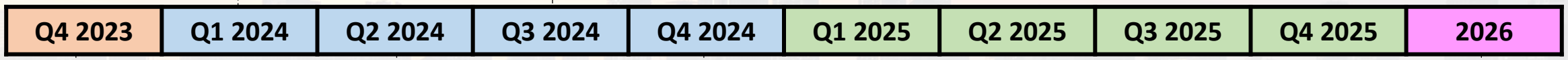
- Finalize GDPMD & Verification Report Templates
- Mutual Full Assessment Report Template
- Finalized Checklist for Clinical Evaluation
- Finalized Checklist for Medical Gas System

MeDC@St3.0 Development Timeline – License & Registration Modules

- Project development
- Gap analysis
- Process flow & requirements finalization
- 1st CN workshop with APACMed 2 Feb
- UDI discussion with DASAR 8 Mac

- 3rd CN workshop with APACMed 10-11 July to refine CN requirements
- Gap analysis
- MDR Module BRS starts

- Development & Testing phase begins
- Feedback collection & system refinement



- **Project Kick-Off** 6th Sept
- 1st BRS 10-12 Oct
- 2nd BRS 25-27 Oct
- Online survey 8-15 Nov
- 3rd BRS 15-17 Nov
- Industry engagement 5 Dec
- Q4 2023 project progress presentation to CE, 18 Dec

- Gather input on application form incl. UDI from industry & BPP
- Gap analysis
- 2nd CN workshop with APACMed 26 June
- License Module BRS starts

- End of Q4 2024 project progress presentation
- BRS finalization based on the collected input

- MeDC@St3.0 implementation phase

Completed until Q3 2024

International relations matter: MOU

- Pakistan, Philippines, Singapore-(on-going)
- NMPA, China (29/11/2023)
- MFDS, Korea (6/2/2024)

THE END

THANK YOU