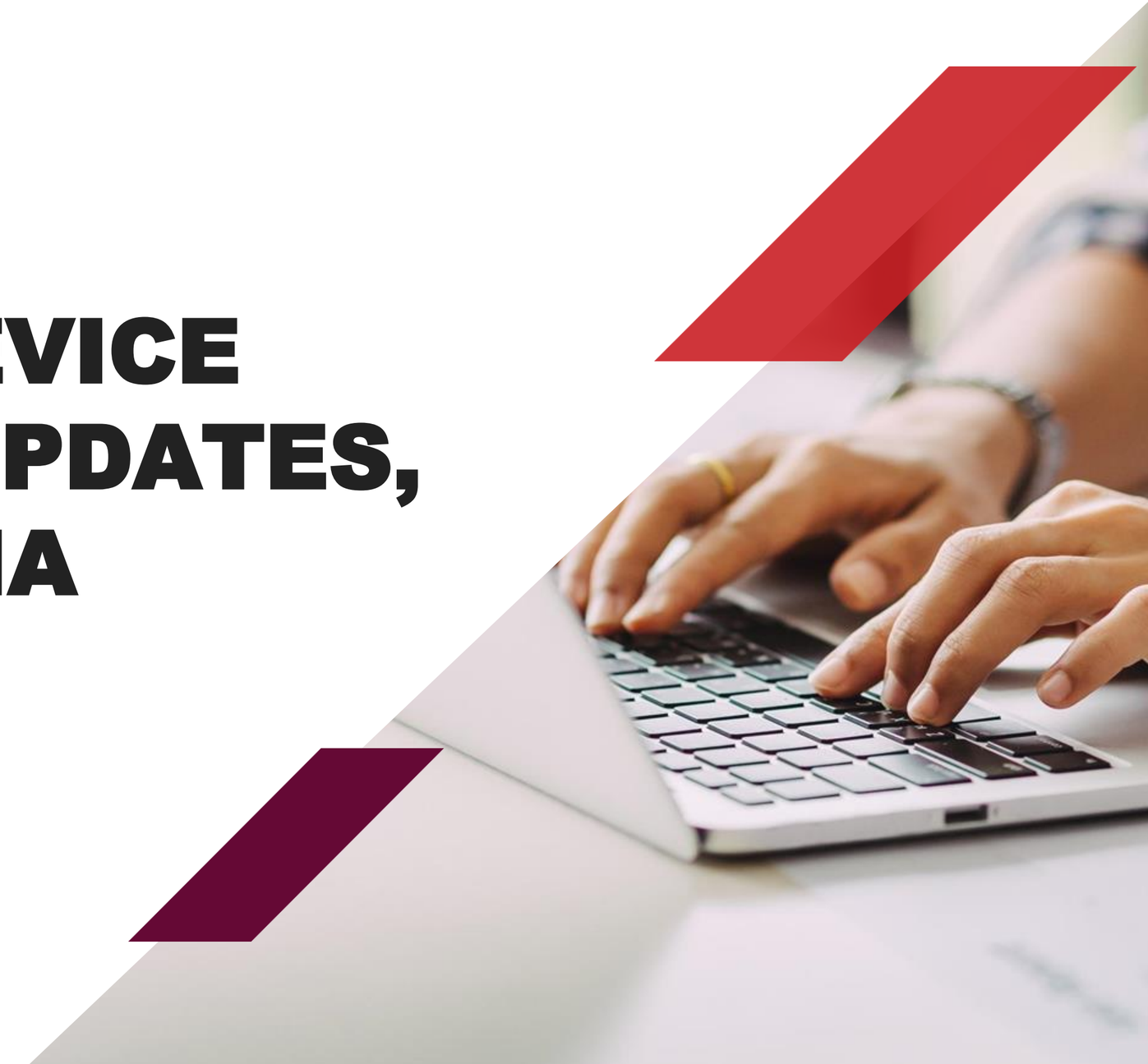
MEDICAL DEVICE REGULATORY UPDATES, MALAYSIA



BY DR MURALITHARAN PARAMASUA
CHIEF EXECUTIVE, MDA

- **OVERVIEW OF THE MEDICAL DEVICE INDUSTRY IN MALAYSIA**

- **OVERVIEW OF MEDICAL DEVICE REGULATORY REQUIREMENTS**

- **REGULATORY UPDATES**

OVERVIEW OF THE MEDICAL DEVICE INDUSTRY IN MALAYSIA

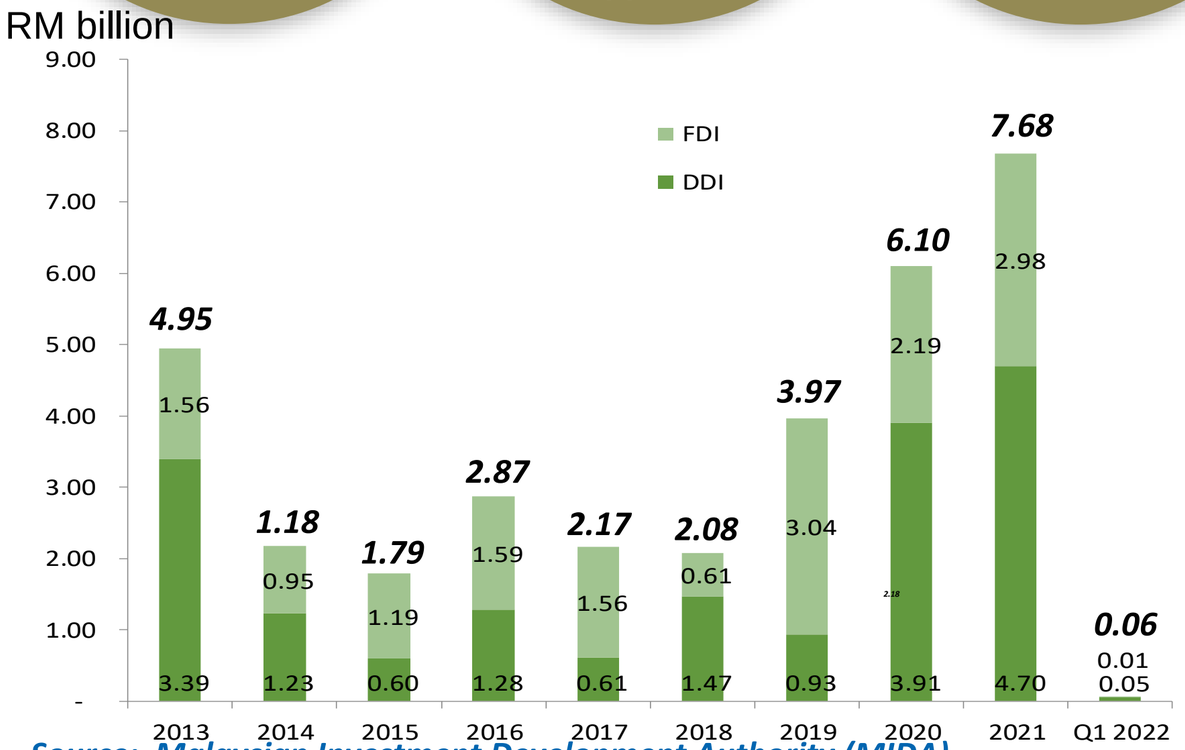
INVESTMENT PERFORMANCE IN MEDICAL DEVICES INDUSTRY

Approved Investment from 2013-March 2022

RM33.79b
investment approved

329
no. projects approved

80,224
potential jobs created



Source: Malaysian Investment Development Authority (MIDA)

Among major companies in Malaysia (in operation)

MNC

B Braun Sharing Expertise, Abbott, Ansell, Haemonetics, KLS Martin, ITL, Fresenius Medical Care, Bard, Teleflex, Tecomet, Sagami, Ambu, ResMed, CIBA Vision, Boston Scientific, Top Visco, Toshiba, Integer, Owen Mumford, SteriPack Asia, Cochlear

LOCAL

GranuLab, Hartalega, Kossan, IDEALCARE, straitsorthopaedics, muzamal, EKE Healthcare, Epsilon Group, Vigilenz, Medidata, Worldwide Medivest, YPC, Star Medik, karex, UWC, Top Glove

OVERVIEW OF MEDICAL DEVICE REGULATORY REQUIREMENT

MALAYSIA MEDICAL DEVICE REGULATORY FRAMEWORK

Pre-market

CONFORMITY ASSESSMENT

- Quality Management System (ISO 13485)
- Post Market Surveillance System
- Technical Documentation
- Declaration of Conformity

CAB verifies evidence of conformity

Placement on Market

MEDICAL DEVICE REGISTRATION

- Assurance of safety & performance of medical device
- Marketing approval

ESTABLISHMENT LICENSING

- Compliance to Good Distribution Practice (GDPMD) for AR, Importer & Distributor
- Compliance to advertising requirements
- License to import / export / distribute medical devices

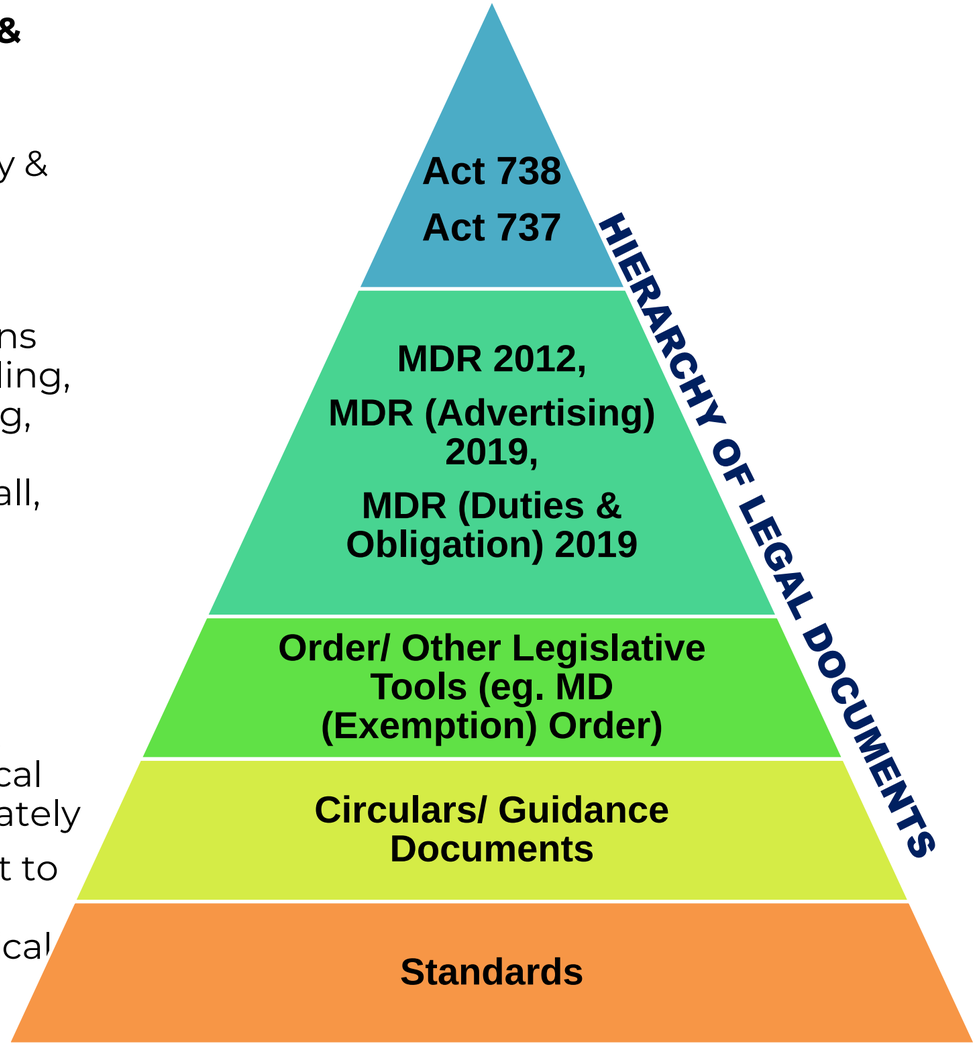
Post-market

SURVEILLANCE & VIGILANCE

- Monitoring of continuous safety & performance of medical device
- Carry out post-market obligations (complaint handling, incident reporting, Field Corrective Action (FCA), recall, etc.

USAGE & MAINTENANCE

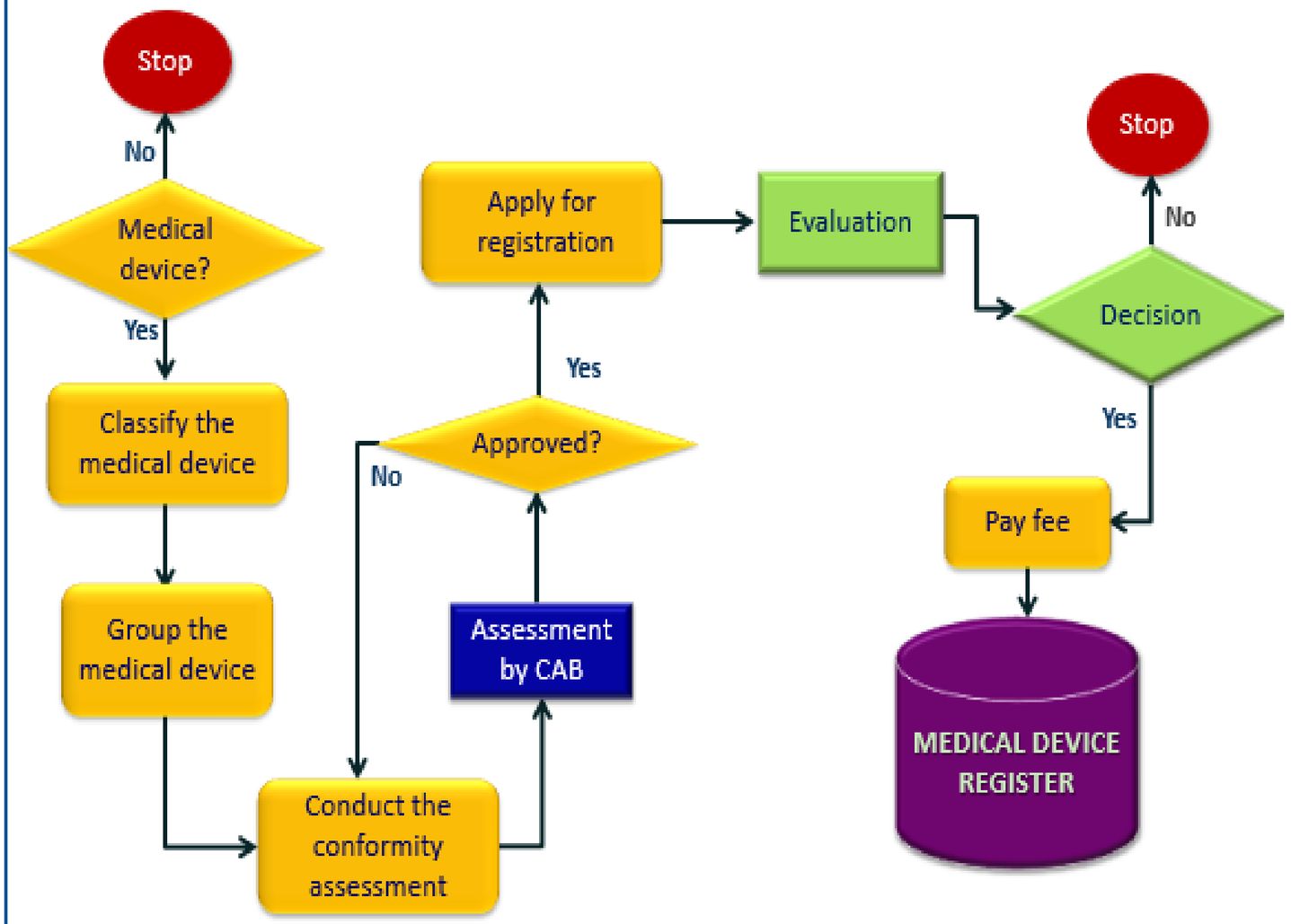
- Use, maintain & dispose off medical devices appropriately
- Apply for permit to use/operate designated medical devices



MDA monitors compliance to requirements & takes appropriate actions in accordance with the provisions of the law

OVERVIEW OF MEDICAL DEVICE REGULATORY REQUIREMENT

MEDICAL DEVICE REGISTRATION PROCESS



ESTABLISHMENT LICENSE PROCESS

QMS
- Establish, implement & maintain

PMS
- Establish, implement & maintain

Conformity Assessment
- Engage a CAB to carry out assessment and certification

Apply for Establishment license

Evaluation by MDA

Licensed

Medical Device AUTHORITY MALAYSIA

REGULATORY UPDATES

NEW POLICIES

1. Withdrawal of Circular Letter No. 1/2014 effective 17 June 2021
- Allows for registration of a medical device by multiple Authorized Representatives, effective 17 June 2021
- the implementation of a single license for each activity/role of an establishment

2. Full registration of COVID-19 Self-test Kit (Dateline for CA & SA – 3rd March 2022)

3. E-permit application system for importation of medical devices following gazettement of Customs Prohibition Order 2023, effective from 1st June 2024.

REGULATORY UPDATES

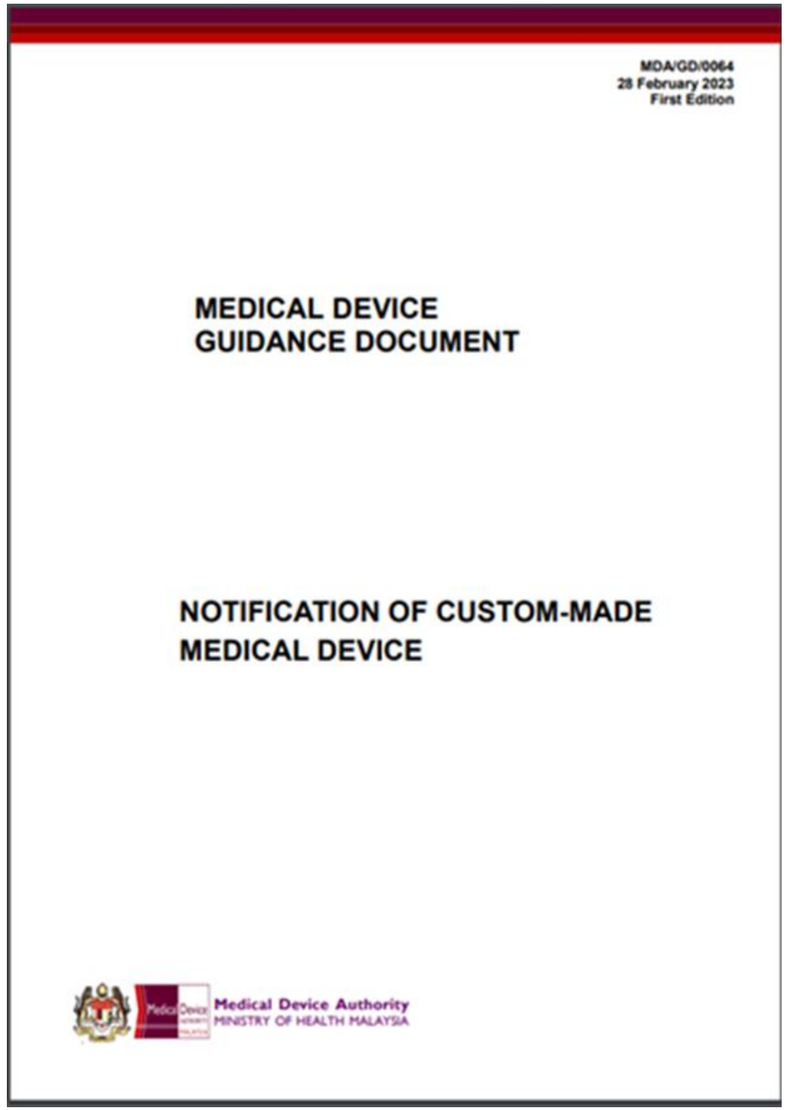
Circular Letter Of The Medical Device Authority

NO.	CIRCULAR LETTER NO.	TITLE	EFFECTIVE DATE	DOWNLOAD
1	1/2023	Permission for Placement in The Market of Human Immunodeficiency Virus (HIV) Disease Self-Test Kits	14th August 2023	Malay / English
2	3/2022	Refurbishment of Medical Device	9th May 2022	Malay / English
3	2/2022	Control of Orphaned, Obsolete and Discontinued Medical Device in Hospital or Healthcare Facilities Institution or Any Related Facilities	9th May 2022	Malay / English
4	1/2022	Exemption from the Conformity Assessment Process by the Conformity Assessment Body (CAB) for Registration of COVID-19 Test Kit.	9th May 2022	Malay / English

https://portal.mda.gov.my/doc-list/circular-letter.html

REGULATORY UPDATES

UPDATE ON PUBLICATIONS OF GUIDANCE DOCUMENTS



- 42 guidance documents have been published in MDA website.
- In 2023 to date, 5 guidance documents were published as follows:

1. MDA/GD/0057, Medical Gas System-Requirements for Registration (Second Edition);
2. MDA/GD/0061, Classification of Rehabilitation, Physiotherapy and Speech Therapy Device (Second Edition);
3. MDA/GD/0033, Medical Face Mask and Respirator (Second Edition);
4. MDA/GD/0064, Notification of Custom-made Medical Device(First Edition).
5. MDA/GD/0065, Placement Of HIV Self-Test (HIVST) Kit In Malaysia Market (First Edition)

Any changes to the requirements in the guidance document will be indicated by a black line sign at the left of the guidance document for ease of reference.

https://portal.mda.gov.my/doc-list/guidance-document.html

INDUSTRY FACILITATION – CONSULTATION SERVICES

- **Consultation services (industry players and other stakeholders may request for consultation sessions on regulatory matters or other related matters).**
- **On-to-one, classroom, or any other arrangements**
- **Identified training package or by request**

MDA-CORE

Organizing and participating in trainings, seminars, webinars and exhibitions.

- Industry seminars
- User awareness
- Hands on trainings
- Occasional webinars
- International exhibitions
- And other events

MALAYSIAN STANDARDS FOR MEDICAL DEVICES AND HEALTHCARE FACILITIES - UPDATES

Published in year 2023:

- MS ISO 15189:2022, *Medical laboratories – Requirements for quality and competence*
- MS 2757:2023, *Cleansing services for healthcare facilities – Code of practice*
- MS 2758:2023, *Healthcare waste management services in healthcare facilities*

Indigenous standards: Maintenance of medical devices – will be revised in 2024

1. Scope
2. Normative references
3. Terms and definitions
4. General
5. Responsibilities
6. Testing & commissioning and acceptance
7. User maintenance
8. Scheduled maintenance
9. Unsheduled maintenance
10. Mechanisms to avoid failure or breakdown during use
11. Uptime
12. QAP
13. Maintenance Management Information System (MMIS)
14. Management of warranties
15. Decommissioned active medical device
16. Disposal of active medical device
17. Processes for handling hazardous/ contaminated active medical device
18. Incidents investigation and reporting
19. Alerts, safety, field corrective action and recall notices
20. User training
21. Genuine parts
22. On-site library
23. Workshop setup
24. Safety, health and environment
25. Advisory service
26. Procurement of active medical device
27. Risk management
28. Technical audit
29. Manpower
30. Technical training
31. Active medical device replacement plan

Remove: Annex A: BTP Competency

Added:

Annex B:Maintenance consumables and Annex D:Routine Inspection Checklist

Annex F: Examples of ESP printed report

Annex L: Spare part management

Annex N: Job Designation

Annex P: Eg. Active medical device replacement plan

MS2058:2018

Indigenous standards: Testing, Commissioning and Acceptance of Medical Device

MS 2739:2021

Requirement for installation	Site Preparation	Medical device installation
Calibration	Testing and comissioning	Inspection of non-active medical device
Issuance of T&C Certificate	Training	Acceptance

MALAYSIAN STANDARD

MS 2739:2021

Requirements for installation, testing and commissioning and acceptance of medical devices – Code of practice

ICS: 11.040.01

Descriptors: medical device, medical electrical equipment, code of practice, biomedical engineering, maintenance, services, active medical device, testing, commissioning, acceptance

DEPARTMENT OF STANDARDS MALAYSIA

Indigenous standards: Disposal of Medical Device

MS 2650:2015 GUIDANCE ON DISPOSAL OF MEDICAL DEVICES

HEALTHCARE FACILITY

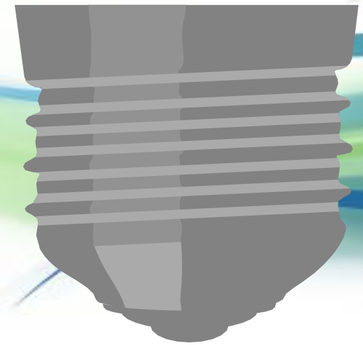
- ensure disposal process comply to the standard requirement
- establish management structure
- designate personnel to establish the procedures, supervise and coordinate the disposal
- appoint approved contractor

COMPETENT PERSON

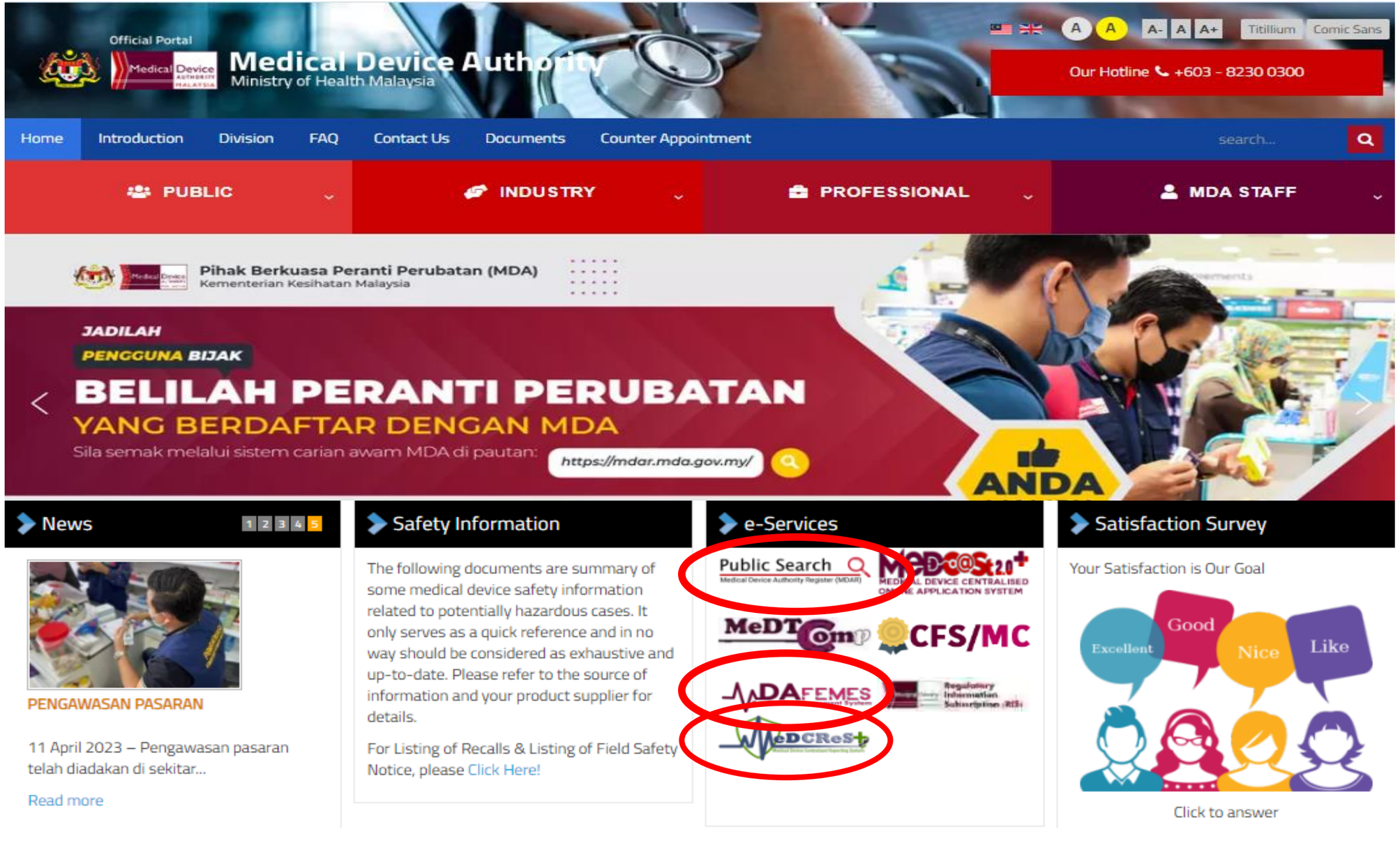
- Coordinate the whole process of disposal
- Determine type of waste
- Maintain record

USER

- identify medical device to disposed
- dispose medical device
- contact competent person
- decontaminate medical device



portal.mda.gov.my



https://femes.mda.gov.my/index.php

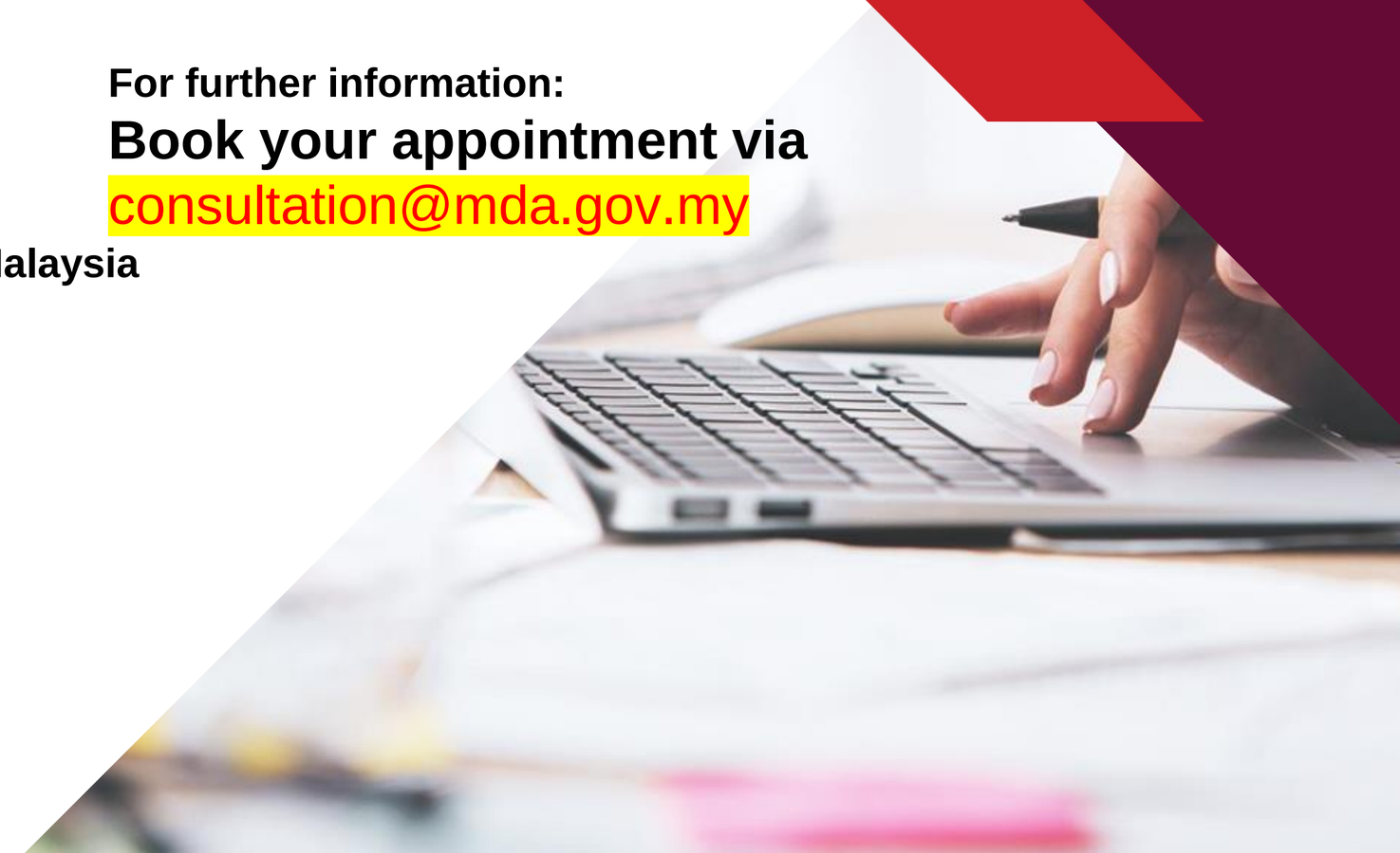
THANK YOU

Any question?

For further information:

Book your appointment via

consultation@mda.gov.my



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