Medical Devices & GDPMD Awareness

Prepared by : Harvestnet SB

Medical Device Industry

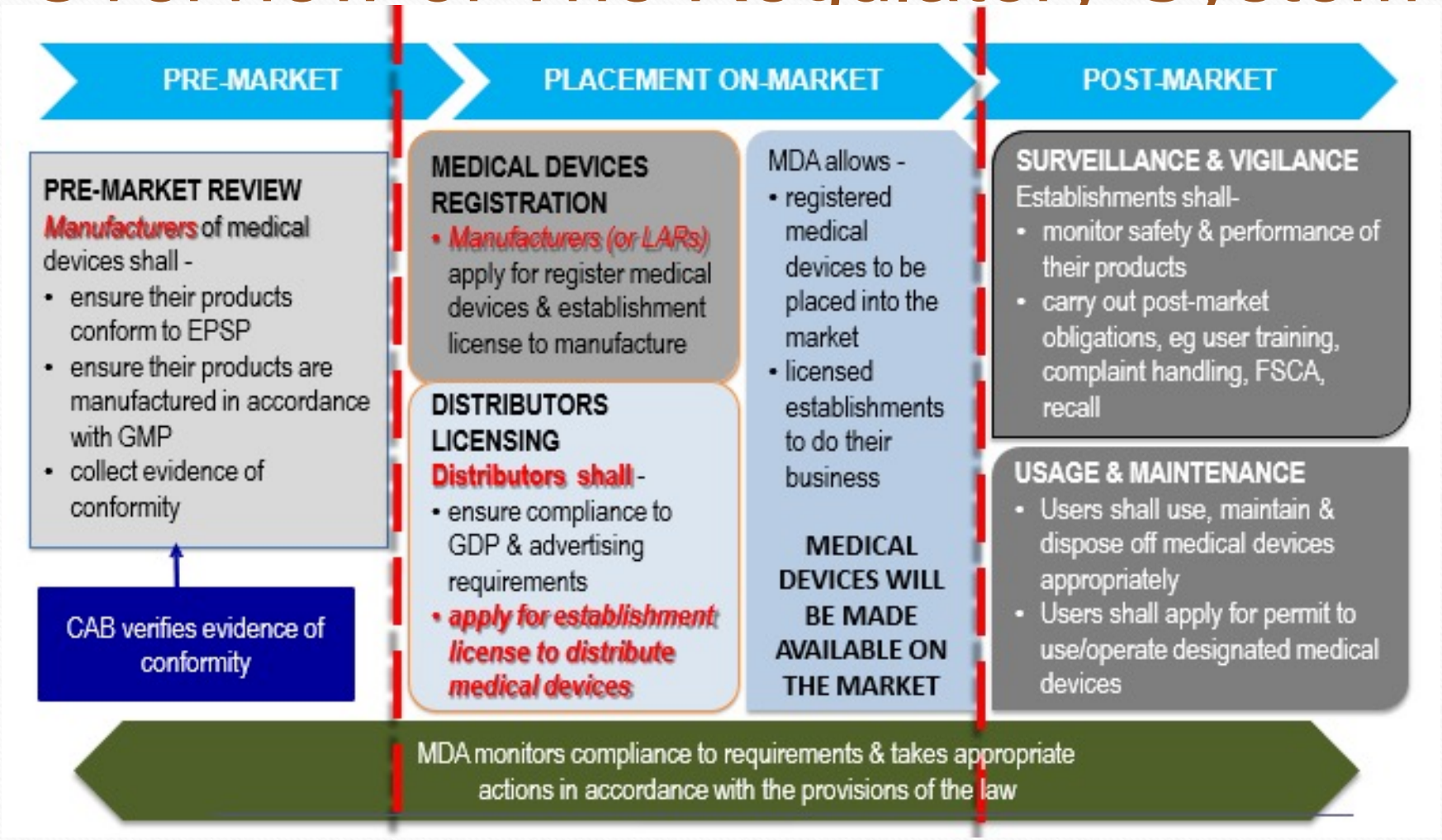
Introduction

In Malaysia, the medical device industry is a highly diversified industry that produces a broad range of products and equipment ranging from medical gloves, implantable devices, orthopedic devices and dialyzers to diagnostic imaging equipment and minimal invasive surgical equipment and other devices which can be used for medical, surgical, dental, optical and general health purpose.

STRUCTURE OF MEDICAL DEVICE REGULATORY SYSTEM

Prepared by : UPSIZZE

Overview of The Regulatory System



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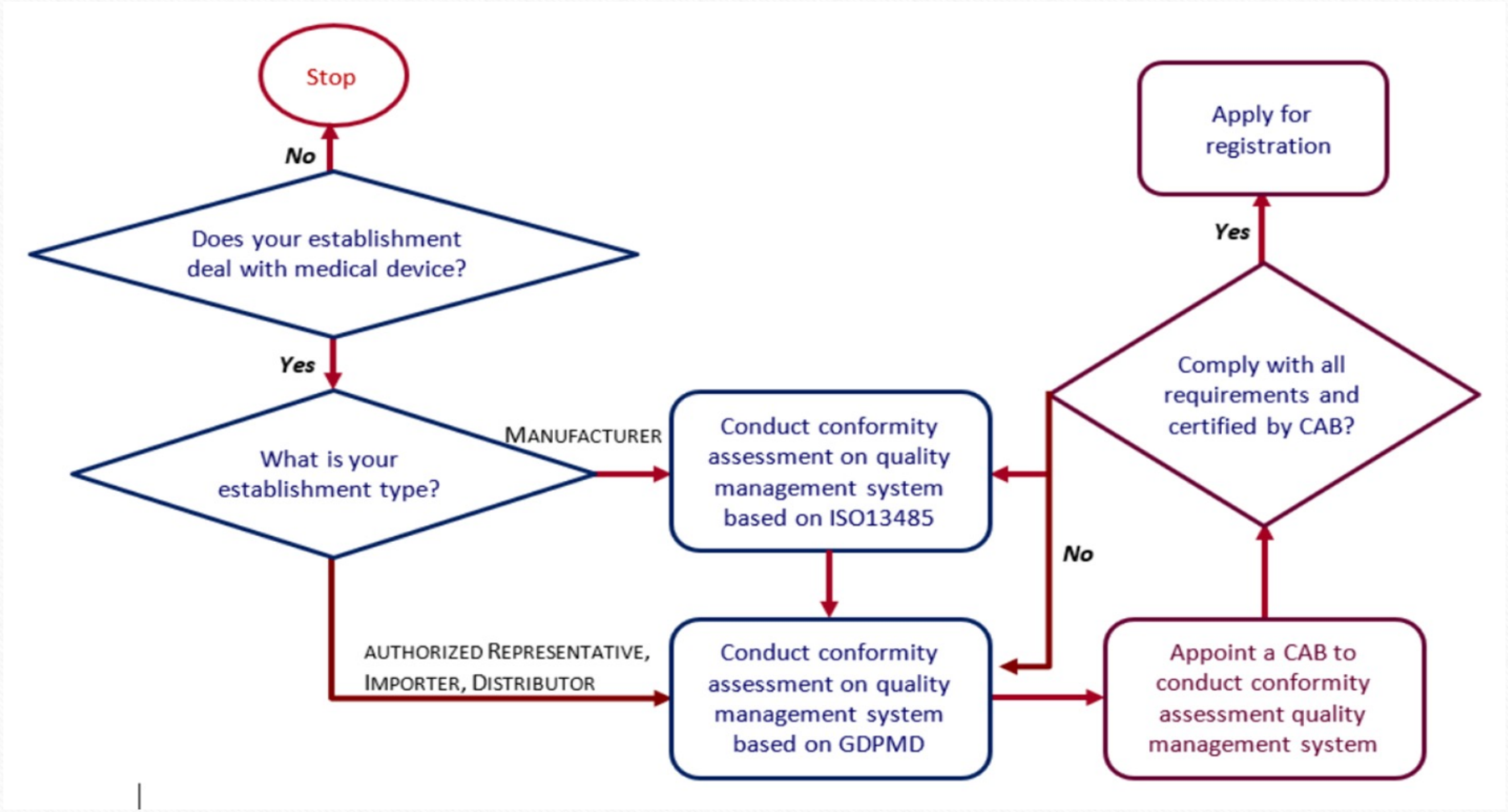
The process for Application of Establishment



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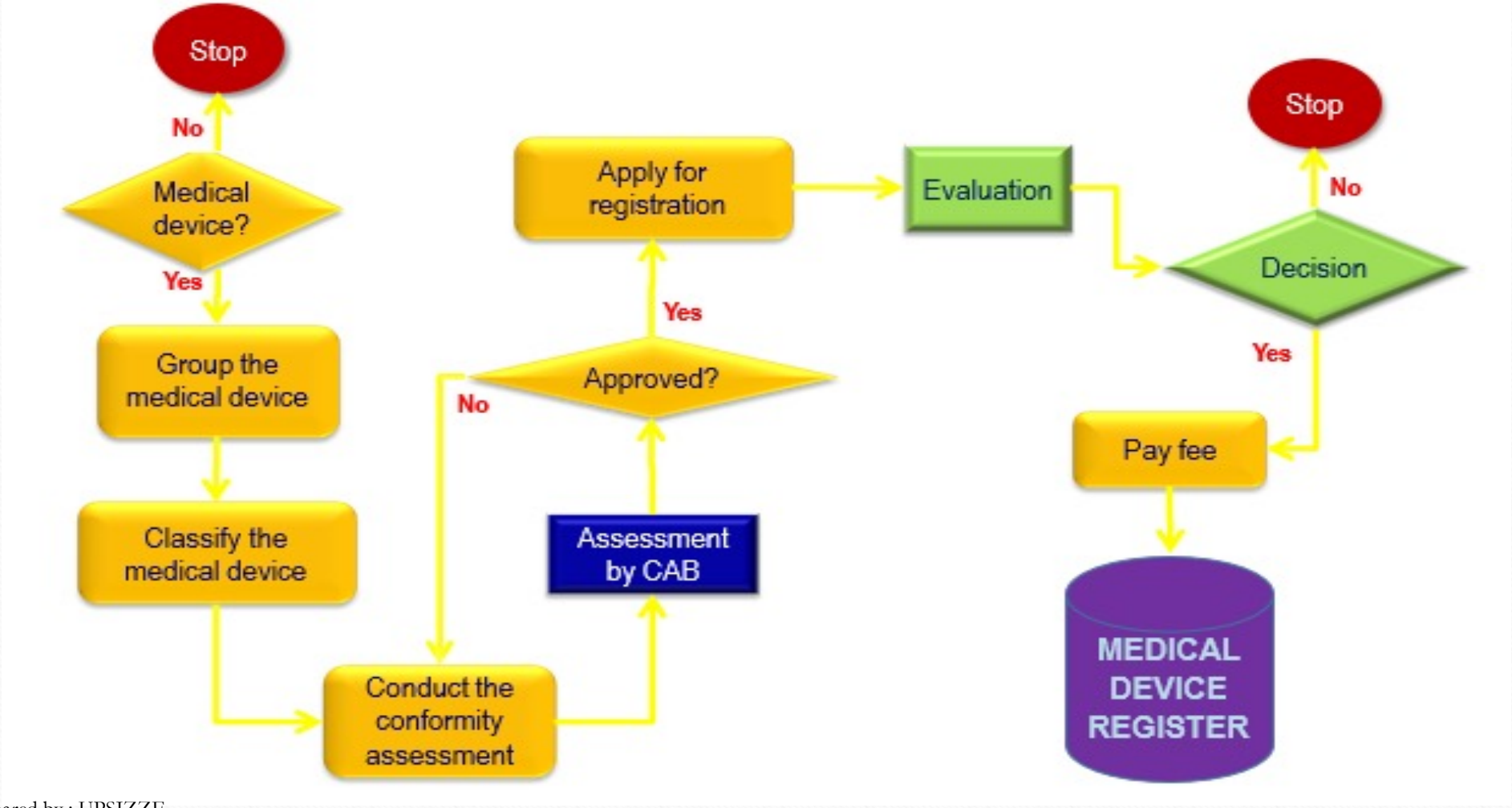
Medical device registration in general



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Medical Device Supply-Chain

PLACEMENT ON-MARKET	POST-MARKET
• Distribution • Transportation • Storage & Stock handling • Delivery • Installation • Second assembly	• Traceability • Vigilance • FSCA • Maintenance & calibration • Disposal • Complaint handling • Return of medical device

GDPMD

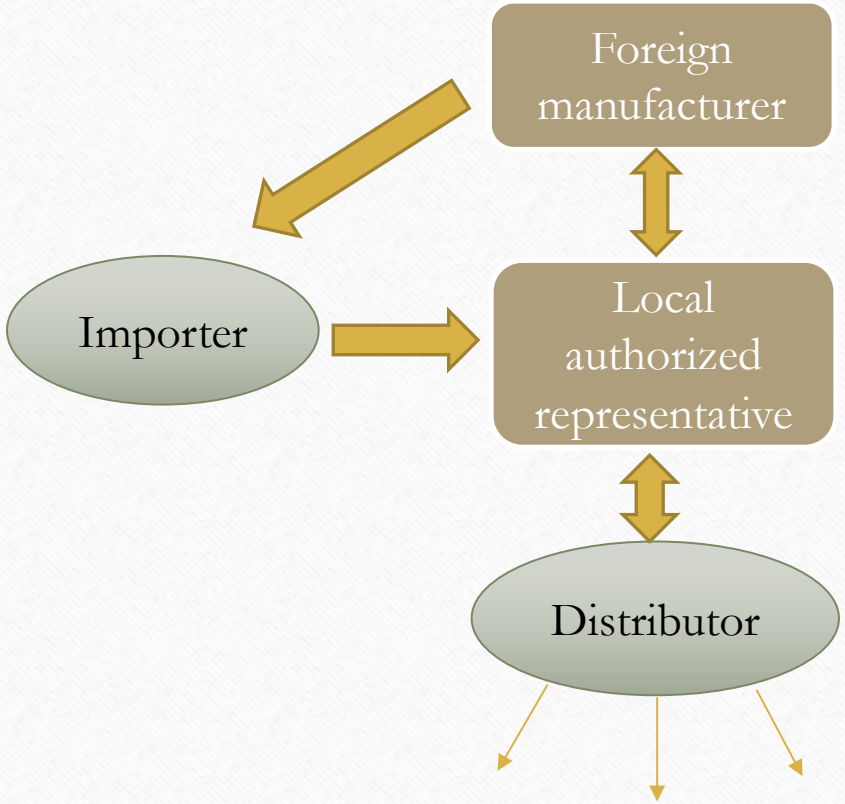
What is it?

- GDPMD specifies requirements for the control of activities in medical device supply-chain.
- GDPMD requires establishment to demonstrate ability to maintain safety and performance of medical devices through the supply-chain.
- Ensure medical device safety & performance throughout the supply-chain.

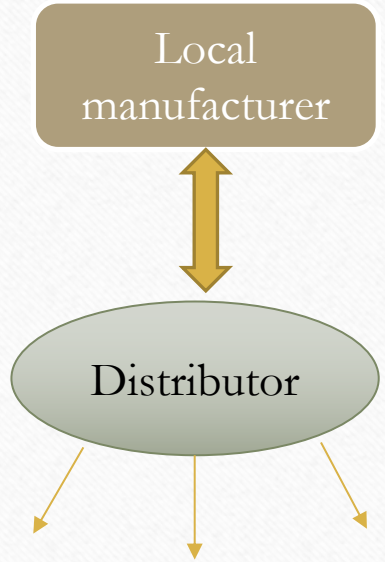
Why GDPMD?

- To achieve the goal to protect public health and safety by ensuring safety and performance of medical devices.
- To provide a clear legal framework regarding the obligations of those in supply-chain.
- To make those in the supply-chain responsible and accountable for medical devices the are dealing with.

Who Will Be Affected?

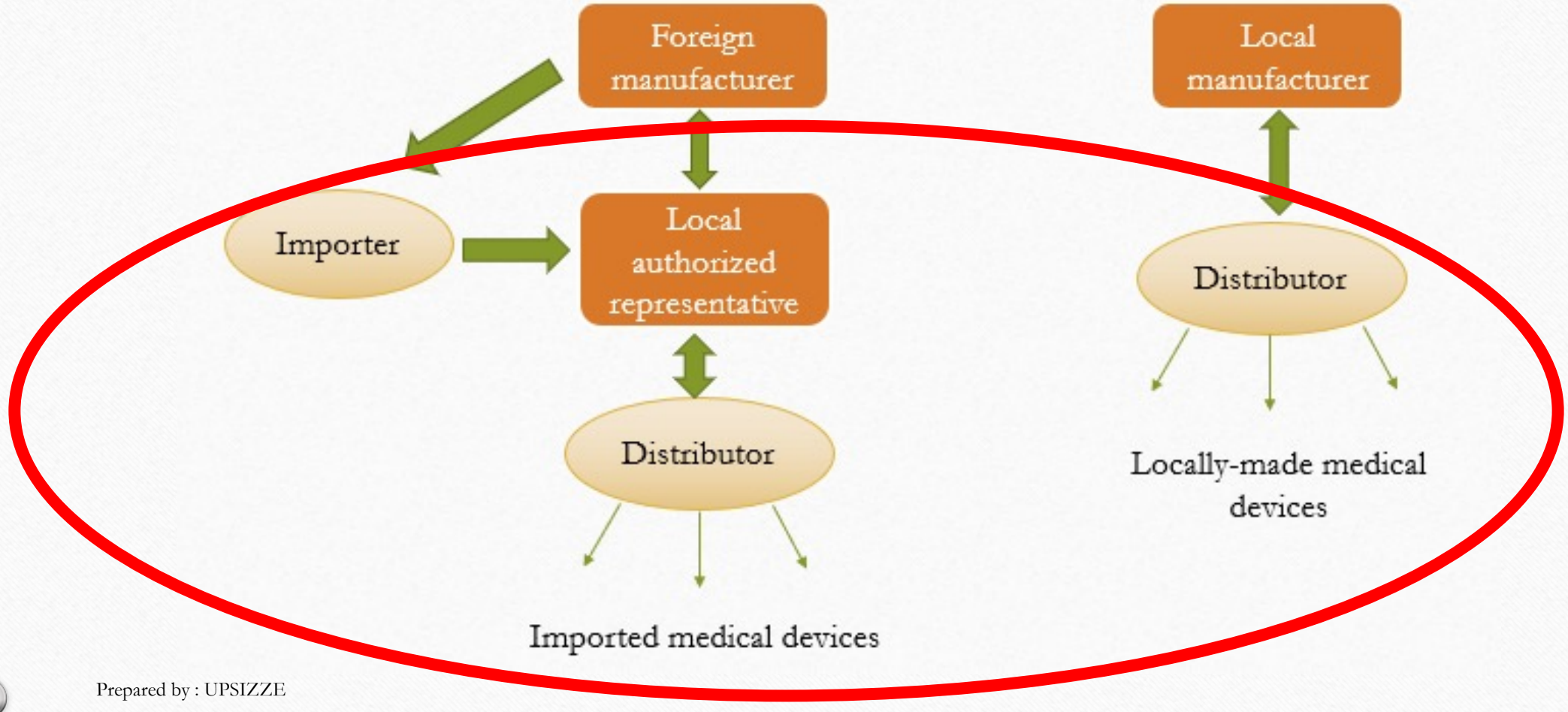


Imported medical devices

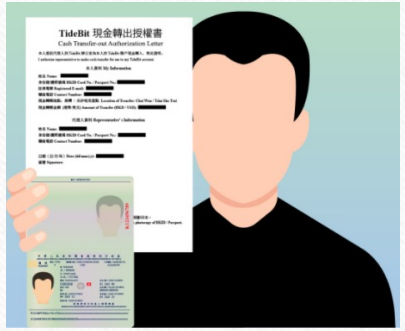


Locally-made medical devices

Scope of GDPMD?



Authorized Representative (AR)



- Any person explicitly designated by a manufacturer, to represent it within Malaysia, in respect of matters raised by the Authority, with regard to the manufacturer's obligations under the Malaysian medical device regulatory system.
- AR must be natural or legal person with business registration in Malaysia.
- AR must maintain linkage with its foreign manufacturer and should be able to obtain the support of its foreign manufacturer whenever required.

Distributor

- is a person or company that is appointed by an authorized representative or a manufacturer to distribute/further registered medical device under the latter's jurisdiction in the market.
- A distributor shall only distribute medical device that is authorized by the authorized representative/manufacturer

Importer

- is a person or company that is appointed by an AR to bring in registered medical device under the latter's control from foreign country.
- An importer is only allowed to import registered medical device that is authorized by the authorized representative to import

Content of GDPMD

PART 1 : PRELIMINARY

PART 2 : ORGANIZATION & GDPMD REGULATORY COMPLIANCE SYSTEM

PART 3 : ESTABLISHMENT RESPONSIBILITIES

PART 4 : RESOURCE MANAGEMENT

PART 5 : SUPPLY-CHAIN AND DEVICE SPECIFIC

PART 6 : VIGILANCE AND CORRECTIVE ACTION

PART 1: PRELIMINARY

1. Objective

- To specify the requirement for the Good Distribution Practice For medical Devices (GDPMD).

PART 1: PRELIMINARY

2. Scope and Application

- Application to:
  - Authorized representatives
  - Importer
  - Distribution

- Manufacturers are not covered (ISO 13485).

- Requirement that is not applicable need not be implemented but need to be justified.

PART 2: ORGANIZATION & GDPMD RCS

1. Quality Management System

- General requirements
  - Establish, document, implement and maintain QMS – Processes, resources, monitoring to manage operations.

- Documentation requirements
  - Master file – profile and operations, procedures, records, product specification
  - Control of documents
  - Control of records

PART 3 : ESTABLISHMENT RESPONSIBILITIES

1. Responsibility and authority

- Define, document and communicate responsibilities and authorities
- Establish interrelation between all personal who involve in works that affect quality

2. Management Representative

- Appoint management representative with defined responsibility and authority

3. Management Review

- Review QMS for continued effectiveness- opportunities for improvement, need for changes
- Maintain records of management review

4. Review input

- Result of audits, customer feedback, process performance and product conformity, preventative and corrective actions, follow-ups from previous reviews, changes affecting QMS, recommendations for improvements.

5. Review output

- Decisions and actions related to improvement of the effectiveness of QMS, improvement of medical device related to customer requirements, resource needs.

PART 4 : RESOURCE MANAGEMENT

1. Personnel
   - Competent, knowledgeable, skilled and experienced related to the job
2. Training, competency and awareness
   - Determine necessary competence
   - Provide training and evaluate
   - Maintain records

3. Infrastructure

- Buildings, workspace, workshop
- Measuring and test equipment
- Supporting services(as applicable) for proper conservation and distribution of medical devices
- Maintenance activities and records (as applicable)

4. Work environment

- Determine and manage work environment
- Establish requirements for health, cleanliness, clothing
- Establish procedure/ instruction to control environment
- Control of contaminated or potentially contaminated medical devices, work environment or personnel

5. Cleanliness

- Requirement for cleaning of premises
- Maintain records

6. Pest control

- Requirement for pest control program
- Maintain records

PART 5 : SUPPLY-CHAIN AND DEVICE SPECIFIC

1. Authorization

- Appropriate authorization from foreign manufacturer
- Written agreement

2. Communication channels

- With manufacturer for effective dissemination of update medical device information
- With user, public and authority to communicate pre-market and post-market matters
- For collecting comments and complaints form users and public
- For providing maintenance services to the users.

3. Receipt of stock

- Verify medical devices received meet the requirements
- Records of verification

4. Storage and stock handling

- Identify and provide suitable and adequate storage
- Maintain updated distribution records
- Establish precautions and control to prevent deterioration or damage

5. Stock rotation

- Establish stock rotation system
- Separate, label and dispose expired medical devices

6. Delivery to customers

- Verify conformity marking, required documents, element of identification, name and trade name, address of the manufacturer and/or distributor.
- Designated medical device only sold and /or distributed to entitled person or entities.
- Proof of delivery transaction
- Proper conditions for storage and transportation.

7. Return of medical devices

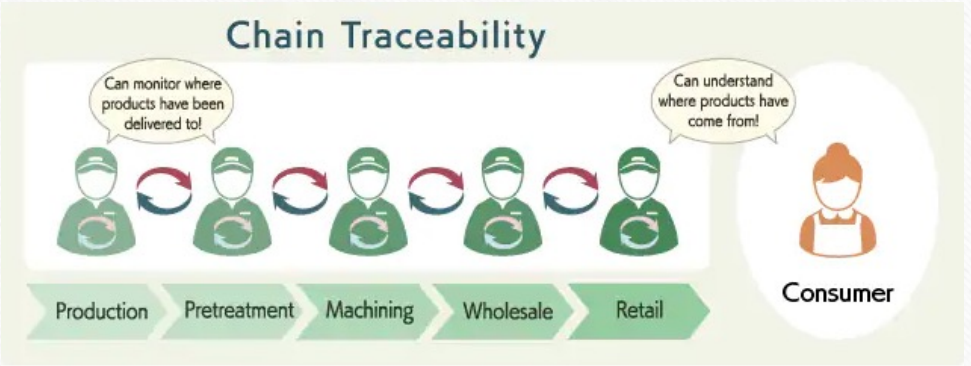
- Handle returned medical devices as non-conforming products.
- Concession and identify of authorizing personnel
- Corrective actions
- Maintain records

8. Disposal of medical devices

- Establish procedure for disposal
- Segregate medical device for disposal
- Maintain records

9. Traceability

- Maintain records providing traceability of medical devices.
- Retention period of the records.



10. Specific requirements for active medical devices

- Technical support
  - Establish technical support office and engineering workshop, mechanisms to provide technical support
  - Responsible for outsourced service
  - Conform to MS2058:2009
- Installation, testing and commissioning
  - Establish installation qualification, inspection instructions, test procedures.
  - Ensure proper installation
  - Maintain records
- Calibration & maintenance – conform to MS2058:2009, maintain records

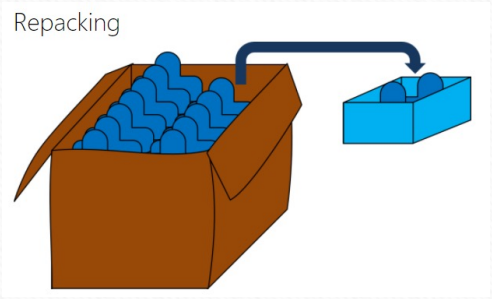
11. Outsourced activities

- Control outsourced processes
- Written agreement
- Establish criteria to ensure conformance to requirements
- Audit supplier (if not certified to GDPMD)

12. Counterfeit, adulterate, unwholesome and tampered medical devices

- Physically segregate and label counterfeit, adulterate, unwholesome and tampered medical devices found in the distribution network.
- Inform the Authority

13. Secondary assembly



- **General**: carry out under controlled condition (procedure, work instruction, reference material, suitable equipment/ devices etc.), approved record for traceability and quantity
- **Assembly document** – batch assembly records, retention period of records
- **Materials Control** – check incoming medical devices, avoid usage of medical with breached primary package, label medical devices in storage area, identification, special storage conditions, control of packaging operation and materials

13. Secondary assembly (cont..)

- **Labeling**: ensure original (including instruction for use, label and any other info sheet or leaflet etc.) for repackaged medical devices
- **Good assembly practices**: check medical devices and materials to be used, clear line, check and record performance of printing operation, clean and store of assembly equipment/ apparatus, ensure assembly equipment/ apparatus
- or its parts do not affect the quality of present ang hazard to the medical devices, calibrate control equipment, maintain records.

13. Secondary assembly (cont..)

- **Quality control**: assess finished medical device on all relevant factors (including assembly conditions, packaging documentation, compliance with specification, visual examination of finished pack),secondary assembly of medical shall conforms to the EP.

PART 5 : SURVEILLANCE AND VIGILANCE

1. Medical device complaints (MDA/GD/0011)

- Establish, implement complaints handling procedure
- Provide mechanism for collecting complaints
- Report adverse event to the Authority
- Maintain records

2. Mandatory Problem Reporting (MDA/GD/0014)

- Establish, implement procedure for incident/problem reporting
- Define responsibilities and requirements in documented procedure
- Inform Authority prior to execution of Investigation.
- Record the investigation, evaluation and action taken

3. Medical device Recall (MDA/GD/0015)

- Establish, implement recall or withdrawal procedure (Mandatory /Voluntary)
- Inform Authority prior to execution of Recall procedure.
- Record the investigation, evaluation and action taken

4. Distribution Records (MDA/GD/0012)

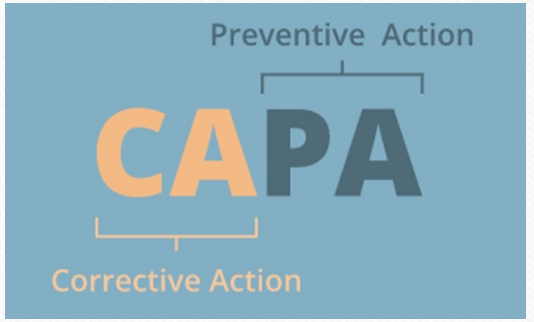
- Documents all activities relating to the distribution of medical device (all receipt, storage, delivery, disposal and etc.)

5. Internal audit

- Conduct internal audit at planned intervals
- Take action to eliminate nonconformities and their cause
- Record the verification of actions

6. Field safety corrective actions (FSCA)

- Establish procedure for handling of FSCA
  - Define responsibilities for planning, conducting and reporting of corrective actions in the procedure.
  - Inform Authority prior to execution of FSCA.
  - Maintain records



REFERENCE

- Good Distribution Practice for Medical Device (MDA/RR No 1: Nov 2015)
- Medical Device Regulations (Duties and Obligations of Establishments) 2019
- MDA Guidance Documents