

Regulatory Requirements for Medical Device Safety & Performance

GOOD DISTRIBUTION PRACTICE FOR MEDICAL DEVICES (GDPMD)

[Appendix 4 Schedule 3 Medical Device Regulations 2012]



Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

PREFACE

Distribution is an important activity in the integrated supply-chain of medical device. Various people and entities are generally responsible for the product sourcing, procurement, transportation, delivery, storage, device tracking, installation, commissioning, service and maintenance, calibration, need to be appropriately managed and controlled to ensure the safety and performance of medical devices at the point of use. In some cases, however, a person or entity is only involved in and responsible for certain elements of the distribution process. The level of risks associated with these activities may be of similar degree as those in the manufacturing environment and the lack of control over these activities may affect safety and performance of the devices. The Good Distribution Practice for Medical Devices (GDPMD) is developed to elucidate the requirements for an appropriate management and control of these activities.

GDPMD specifies the requirements for a quality management system to be established, implemented and maintained by an establishment in carrying out activities in medical device supply-chain to comply with Malaysian medical device regulatory requirements as stipulated in Medical Device Act 2012 (Act 737). GDPMD requires an establishment to demonstrate its ability to maintain quality, safety and performance of medical devices in compliance with the Malaysian medical device regulatory requirement throughout the supply-chain. It shall be used by both the internal and external parties to determine the ability of an establishment to meet the requirements specified within.

The certification to GDPMD is to be conducted by the registered conformity assessment body. The design and implementation of GDPMD by an establishment is dependent on the types and categories and classification of medical device, size and structure of the establishment, the processes employed it deals with. It is not the intent of the GDPMD to imply uniformity in the structure of the quality management systems or uniformity of documentation.

Certification to GDPMD does not imply compliance to any written laws. It is the responsibility of the establishment to ensure that they are in compliance with all applicable laws in Malaysia. In the event of any contradiction between the requirements of GDPMD and any written law, the latter shall take precedence.

This Regulatory Requirement is the first revision of MDA/RR No 1: July 2013 Good Distribution Practice for Medical Devices.

Major modification done in this revision is:

- a) amendment to table (5) in Annex 1.*

This Regulatory Requirement cancels and supersedes the MDA/RR No 1: July 2013.

Contents	
PART 1: PRELIMINARY	4
Objective	4
Scope and application	4
Definitions	4
PART 2: ORGANIZATION AND GDPMD REGULATORY COMPLIANCE SYSTEM	6
Organization	6
GDPMD regulatory compliance system	7
General	7
Documentation	7
Document control	8
PART 3: ESTABLISHMENT RESPONSIBILITIES	8
Responsibilities and authorities	8
Designated person	9
Management review	9
Review input	9
Review output	10
PART 4: RESOURCE MANAGEMENT	10
Personnel	10
Training, competency and awareness	10
Infrastructure	10
Work environment	11
Cleanliness and pest control	11
PART 5: SUPPLY-CHAIN AND DEVICE SPECIFIC	12
Authorization	12
Communication channels	12
Receipt of stock	12
Storage and stock handling	12
Stock rotation	13
Delivery to customers	13
Control of nonconforming medical devices including returned medical devices	14
Disposal of medical devices	14
Traceability	15
Specific traceability requirements for implantable medical devices	15
Specific requirements for active medical devices	16
Outsourced activities	17
Counterfeit adulterate, unwholesome and tampered medical services	17
Secondary assembly including repackaging	17
General requirements	17
Assembly documents	18
Materials control	18
Labeling	19
Good assembly practices	19
Quality control	19
PART 6: SURVEILLANCE AND VIGILANCE	20
General	20
Medical device complaints	20
Distribution records	20
Field corrective action (FCA) and field safety notice (FSN)	21
Recall	21

Mandatory problem reporting	21
Internal audits.....	22
Corrective action.....	22
Preventive action	22

PART 1: PRELIMINARY

Objective

1. The objective of this document is to ensure the quality, safety and performance of medical device during all aspects of medical device supply-chain, which include, but not limited to, product sourcing and procurement; transportation and delivery; storage; installation, commissioning, service and maintenance, calibration and after sales service; tracking, documentation and record-keeping practices.

Scope and application

2. (1) This document, “Good Distribution Practice for Medical Devices (GDPMD)”, is made pursuant to Appendix 4 of Schedule 3 of the Medical Device Regulation 2012 and is applicable to all parties involved in the supply-chain of medical device covering authorized representatives of foreign manufacturers, importers or distributors of medical devices in Malaysia. The scope of this document does not cover manufacturers and retailers of medical devices.

(2) The design and implementation of GDPMD by an establishment is dependent on the types and categories and classification of medical device, size and structure of the establishment, the processes employed it deals with. If any requirement in GDPMD is not applicable due to the type, category and classification of the medical device and supply-chain activities, a justification has to be provided for exclusion from fulfillment of that particular requirement. If any requirement in GDPMD is not applicable due to the nature and the range of the medical device and supply-chain activities, a justification has to be provided for exclusion from fulfillment of that particular requirement.

(3) When the terms “as appropriate” or “as applicable” are used to qualify a requirement in the GDPMD, it is deemed to be “appropriate” or “applicable” unless the establishment can document a justification otherwise.

(4) The certification to GDPMD is to be conducted by the registered conformity assessment body and the scope of GDPMD certification is defined in Annex 1.

Definitions

3. In this document, unless the context otherwise requires—

“active medical device” means any medical device as defined in First Schedule of Medical Device Regulations 2012;

“adverse effect” means any debilitating, harmful or detrimental effect that the medical device has been found to have or to be likely to have on the body or health of humans when such a medical device is used by or administered to humans;

“adverse event” means any event or other occurrence, that reveals any defect in any medical device or that concerns any adverse effect arising from the use thereof;

“Authority” means the Medical Device Authority established under Medical Device Authority Act 2012 (Act 738);

“customer complaint” means any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety or performance of a medical device that has been placed on the market;

“distribution” means the activities of pre (release), placement (delivery) and post-delivery of medical devices conducted by the establishment;

“distributor” means any natural or legal person in the supply-chain who, on his own behalf, places a medical device on the market and further the availability of the medical device to the end user including persons in the supply-chain involved in activities such as storage and transport on behalf of the authorized representative, importer or distributor;

“field corrective action (FCA)” is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device, which may include—

- (i) return of a medical device to the manufacturer or its representative;
- (ii) medical device modification, which may include—
 - retrofit in accordance with the manufacturer's modification or design change;
 - permanent or temporary changes to the labeling or instructions for use;
 - software upgrades including those carried out by remote access;
 - modification to the clinical management of patients to address a risk of serious injury; or
 - death related specifically to the characteristics of the device.
- (iii) medical device exchange;
- (iv) medical device destruction;
- (v) medical advice given by manufacturer regarding the use of the device.

Note: In assessing the need of the FCA the establishment is advised to use the methodology described in the ISO 14971 Medical devices – Application of risk management to medical devices;

“field safety notice (FSN)” means a communication sent out by a manufacturer or its representative to the device users in relation to a FCA;

“import” means to bring or cause to be brought a medical device manufactured in another country or jurisdiction, into Malaysia by land, sea or air;

“importer” means any natural or legal person in the supply-chain who imports a medical device into Malaysia;

“installation qualification (IQ)” means a documented demonstration that facilities and operations are installed as designed and specified and are correctly interfaced with systems, with protocols that should include—

- (i) engineering drawings and documents;

- (ii) building finishes;
- (iii) process and utilities flow diagrams;
- (iv) piping and instrumentation diagrams;
- (v) equipment and instrument specifications;
- (vi) manufacturers' drawings, equipment maintenance and operating manuals;
- (vii) spare lists; and
- (viii) maintenance and calibration schedules;

“place in the market” means an activity as defined in Section 2 of Medical Device Act 2012 (Act 737);

“premises” for the purpose of this document, means any location that is used for activities dealing with medical devices, including storage, manufacture, etc.

“packaging” for the purposes of this document, means the container and other packaging material in which the medical device is supplied;

“primary package” means element of packaging system that maintains the sterility and/or integrity of a medical device;

“regulatory requirement” means the requirement stipulated under Medical Device Act 2012 (Act 737) and its subsidiary legislations;

“secondary assembly” means the process of repackaging of a medical device from its original packaging into another packaging, without breach of the primary package, before the medical device is supplied.

PART 2: ORGANIZATION AND GDPMD REGULATORY COMPLIANCE SYSTEM

Organization

4. The establishment shall—

- (i) define the organization structure with the aid of an organizational chart and indicate the responsibility, authority and interrelationship of all key personnel;
- (ii) define the duties and responsibilities with written job descriptions for every level of the organization;
- (iii) ensure managerial and technical personnel have the authority and resources needed to carry out their duties; and
- (iv) set up and maintain a GDPMD regulatory compliance system and identify and correct deviations from the established system.

GDPMD regulatory compliance system

General

5. The establishment shall—

- (i) establish, document and implement a GDPMD regulatory compliance system and maintain its compliance with the regulatory requirements;
- (ii) identify the processes needed for the GDPMD regulatory compliance system and their application for all categories of medical devices, regardless of the type or size of the organization;
- (iii) determine the sequence and interaction of these processes;
- (iv) determine criteria and methods needed to ensure that both the operation and control of these processes are effective in ensuring compliance;
- (v) ensure the availability of resources and information necessary to support the operation and monitoring of these processes;
- (vi) monitor, measure and analyze these processes;
- (vii) implement actions necessary to achieve planned results and maintain the effectiveness of these processes to ensure compliance;
- (viii) manage the processes in accordance with the regulatory requirements; and
- (ix) identify and control outsourced processes in accordance with the regulatory requirements.

Documentation

6. (1) The establishment shall establish and maintain a Regulatory Compliance Manual which shall include the following information—

- (i) establishment's profile, activities/operations, compliance to medical device regulatory requirements and obligations of the establishment, including those outsourced processes or activities/operations;
- (ii) the scope of the GDPMD regulatory compliance system, including details of, and justification for any exclusion and/or non-application;
- (iii) the medical devices it deals with and their status of compliance;
- (iv) procedures required by GDPMD regulatory compliance system and reference to them;
- (v) documents needed by the establishment to ensure the effective planning, operation and control of processes for compliance; and
- (vi) records required by the GDPMD regulatory compliance system;
- (vii) information regarding—
 - the premises where activities are conducted;
 - personnel conducting the activities; and
 - the medical device conformity assessment and the registration holder;

- (viii) detailed description on how the relevant and applicable regulatory requirements are addressed for each medical device specified in the scope of the GDPMD regulatory compliance system;
- (2) For each type of medical device it deals with, the establishment shall establish and maintain a file containing documents that define—
 - (i) product specifications and installation qualifications (if applicable);
 - (ii) complete distribution process and, if applicable, installation and servicing.

Document control

- 7. (1) The establishment shall—
 - (i) control the documents required by GDPMD regulatory compliance system; and
 - (ii) establish a documented procedure for the control of documents.
- (2) All documents shall be prepared, approved, signed and dated by an authorized person.
- (3) The establishment shall give appropriate authorization on any change on authorized person permitted to carry out the task in sub-clause (2).
- (4) When a document has been revised, the control system shall prevent unintended use of the superseded version.
- (5) The establishment shall—
 - (i) establish and maintain records of GDPMD regulatory compliance system that are legible, readily identifiable and retrievable;
 - (ii) establish a documented procedure to define the controls for the identification, storage, protection, retrieval, retention time and disposition of records; and
 - (iii) retain the records for a period of time—
 - specified by relevant regulatory requirements; or
 - at least equivalent to the lifetime of the medical device product as defined by the product owner of the medical devices; or
 - no less than two years from the date that the medical device is shipped from the establishment, whichever is the longest.

PART 3: ESTABLISHMENT RESPONSIBILITIES

Responsibilities and authorities

- 8. The establishment shall—

- (i) ensure that responsibilities and authorities are defined, documented and communicated within the establishment; and
- (ii) establish the interrelation between all personnel who manage, perform and verify works that affect quality, safety and performance of medical device and shall ensure the independence and authority to perform these tasks.

Designated person

9. The establishment shall appoint a designated person who shall have the defined responsibility and authority that includes—

- (i) ensuring the GDPMD regulatory compliance system is established, implemented and maintained;
- (ii) reporting to top management on the performance of the GDPMD regulatory compliance system, as well as to identify and correct deviations from the established GDPMD regulatory compliance system;
- (iii) ensuring the awareness on obligations to comply with regulatory requirements and any other applicable statutory requirements and any decision thereof made by top management throughout the establishment and supply-chain; and
- (iv) liaising with external parties on matters relating to the Malaysian medical device regulatory requirements.

Management review

10. The management shall—

- (i) review its GDPMD regulatory compliance system at planned intervals, to ensure its compliance to Malaysian medical device regulatory requirements;
- (ii) ensure the review includes assessment of the status of compliance and the need for changes; and
- (iii) maintain records of management reviews.

Review input

11. The input for management review shall include—

- (i) results of internal and external audits;
- (ii) customer complaints/feedback;
- (iii) GDPMD regulatory compliance system and medical device compliance;
- (iv) surveillance and vigilance activities including field safety corrective actions, advisory notes, recalls and adverse event /incident reporting;
- (v) feedback from manufacturer;
- (vi) feedback and directives from the Authority;
- (vii) status of preventive and corrective actions;

- (viii) follow-up actions from previous management reviews;
- (ix) changes that could affect the GDPMD regulatory compliance system; and
- (x) recommendations for compliance.

Review output

12. The output from the management review shall include any decisions and actions related to—

- (i) the corrective and preventive actions required;
- (ii) the effectiveness of the GDPMD regulatory compliance system and its compliance with the Malaysian medical device regulatory requirements; and
- (iii) resource needs.

PART 4: RESOURCE MANAGEMENT

Personnel

13. (1) Key personnel in charge of managing activities/operations within the scope of the establishment including technical support shall be competent and possesses appropriate professional knowledge, education, training, skills and experience.

(2) Skills of personnel providing post market technical support for active medical devices shall conform to the requirements and/or standards recognized by the Authority.

(3) The establishment shall possess an adequate number of competent personnel involved in all activities/operations in the supply-chain of the medical devices in order to ensure the quality, safety and performance of the medical device are maintained.

Training, competency and awareness

14. The establishment shall—

- (i) determine the necessary competence for the key personnel;
- (ii) provide training to satisfy these needs;
- (iii) evaluate the effectiveness of the training; and
- (iv) maintain records of education, training, skills and experience.

Infrastructure

15. (1) The establishment shall determine, provide and maintain the infrastructure needed to achieve conformity to specified requirements which includes, as applicable—

- (i) buildings, workspace, workshop and associated utilities;
 - (ii) tools, measuring and test equipment; and
 - (iii) supporting services (such as transport or communication).
- (2) The establishment shall, as applicable—
- (i) ensure that the premises and equipment used are suitable , secure, safe and adequate in accordance with the manufacturer and regulatory requirements to ensure proper conservation and distribution of medical devices;
 - (ii) establish documented requirements for maintaining the premises and equipment, including their frequencies; and
 - (iii) maintain records of such maintenance activities.

Work environment

16. The establishment shall, as applicable—

- (i) determine and manage the work environment needed to achieve conformity to regulatory requirements;
- (ii) establish documented requirements for health, cleanliness and clothing of personnel if contact between such personnel and the medical devices or work environment could adversely affect quality of the medical devices;
- (iii) establish documented procedures or work instructions to monitor and control the conditions for work environment that could adversely affect quality of the medical devices;
- (iv) ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are appropriately trained or supervised by a trained person; and
- (v) establish special arrangements and document the control of contaminated or potentially contaminated medical devices, work environment or personnel.

Cleanliness and pest control

17. (1) The establishment shall, as applicable—

- (i) establish documented requirements for the cleaning of premises, including frequency and methods; and
- (ii) maintain records of cleaning.

(2) The establishment shall—

- (i) establish a pest control program to identify and prevent pest infestation; and
- (ii) maintain records of pest control program.

PART 5: SUPPLY- CHAIN AND DEVICE SPECIFIC

Authorization

18. The establishment shall—

- (i) obtain appropriate authorization from the relevant party to become authorized representative, importer or distributor of medical devices; and
- (ii) establish and maintain written agreement with the relevant party pertaining to supply of information required for regulatory matters relating to medical devices it deals with.

Communication channels

19. The establishment shall—

- (i) establish and maintain communication channels and feedback mechanisms with the relevant party such that all relevant and updated medical device information can be disseminated to the related parties effectively;
- (ii) be responsible to manage and to communicate with users, public and Authority on matters pertaining to medical devices it deals with;
- (iii) establish and maintain efficient communication channels with the manufacturers, such that all relevant medical device information and updated device information can be disseminated to the related parties effectively;
- (iv) establish feedback mechanism for collecting comments and complaints from users and public, to be forwarded to the relevant party as applicable;
- (v) as applicable, establish mechanism to provide information on maintenance services, including calibration, provision of spare parts and other services, to the users.

Receipt of stock

20. The establishment shall—

- (i) establish and implement inspection or other activities necessary to ensure that medical devices received meets the specified requirements; and
- (ii) maintain records of verification.

Storage and stock handling

21. (1) The establishment shall—

- (i) identify storage measures for specific medical devices and stored in accordance with the manufacturer's instructions;
- (ii) provide suitable and adequate storage to ensure proper conservation of

the medical devices; and

- (iii) maintain an updated distribution records of medical devices it deals with, including the make, model, batch number, serial number, and quantity of the devices, as appropriate.
 - (iv) establish adequate precautions and control to prevent deterioration or damage of the medical devices;
- (2) Where quarantine status is ensured by storage in separate areas, these areas must be clearly marked and access restricted to authorized personnel.
- (3) Any system replacing physical quarantine should provide equivalent security.
- (4) Medical device presenting special risks of abuse, fire or explosion (such as combustible/flammable liquids and solids and pressurized gases) should be stored in a dedicated area(s) that is subject to appropriate additional safety and security measures.
- (5) Broken or damaged medical device should be identified and withdrawn from usable stock and stored separately.

Stock rotation

22. The establishment shall—

- (i) establish a system to ensure stock rotation;
- (ii) separate medical devices beyond their expiry date or shelf life from usable stock and clearly labeled ; and
- (iii) dispose the expired medical devices in accordance with clause 25.

Delivery to customers

23. The establishment shall—

- (i) verify that the registered medical device is accompanied by certificate of registration and license and other applicable documents and instructions for use;
- (ii) ensure that the medical device bears a type, batch or lot number, model and serial number or other elements of identification as well as name, trade name and address of the manufacturer and/or distributor organization;
- (iii) ensure the designated medical devices should only be sold and/or distributed to persons or entities that are entitled to acquire such medical devices as specified by the regulatory requirements by obtaining the proof of such authority prior to the distribution of medical devices to such person;
- (iv) provide documentation of all medical devices supplied to customers to ascertain the date, the name of the medical device, the quantity supplied, the batch or lot number and/or model and serial number and the name and address of the distributor and addressee;
- (v) keep the record of delivery transactions as the proof of medical devices supplied to customers;

- (vi) obtain all relevant conditions for storage and transportation, installation, testing and commissioning requirements, user and service manuals, spare parts list and relevant certificates from the manufacturer and provide to the customer ;
- (vii) ensure the delivery of medical devices adhere to the conditions specified by the manufacturer;
- (viii) establish adequate and specialized methods of delivery to achieve safe and secure delivery of medical device from the point of collection to the point of delivery; and
- (ix) ensure the delivery of medical devices which present special risks of abuse, fire or explosion are stored in safe, dedicated and secure areas, and transported in safe, dedicated and secure containers and vehicles, and shall comply with the applicable regulatory and/or statutory requirements.

Control of nonconforming medical devices including returned medical devices

24. The establishment shall—

- (i) establish documented procedures for handling of returned medical device and shall be treated as a non-conforming medical device;
- (ii) ensure that medical device which does not conform to essential principles of safety and performance as stipulated in Act 737 and its subsidiary legislations, is identified and controlled to prevent its unintended delivery and use;
- (iii) define the controls and related responsibilities and authorities for dealing with nonconforming medical device in a documented procedure;
- (iv) deal with nonconforming product by one or more of the following ways—
 - by taking action to eliminate the detected nonconformity; and
 - by authorizing its delivery and use under concession;
- (v) ensure that nonconforming medical device is delivered and used by concession only if the regulatory requirements are met;
- (vi) maintain records of the justification and identity of the person(s) authorizing the concession;
- (vii) maintain records of the nature of nonconformities and any subsequent actions taken, including concessions obtained from the manufacturer and the Authority; and
- (viii) take action appropriate to the effects, or potential effects, of the nonconformity, when nonconforming product is detected after delivery.

Disposal of medical devices

25. The establishment shall—

- (i) establish a documented procedure for the disposal of medical devices in accordance with regulatory requirements and any other applicable statutory

- requirements;
- (ii) ensure, if the medical device have not been immediately sent for disposal, they shall be kept in a clearly segregated, safe and secured area and identified in accordance with regulatory requirements and any other applicable statutory requirement; and
- (iii) maintain records of the disposal.

Traceability

26. (1) The establishment shall—

- (i) maintain an updated records providing traceability of medical devices throughout the supply-chain being dealt with, which include the make, model, batch number, serial number, and quantity of devices, as appropriate;
- (ii) retain the records for a period of time—
 - specified by relevant regulatory requirements; or
 - at least equivalent to the lifetime of the medical device as defined by the manufacturer of the medical devices; or
 - no less than two years from the date that the medical device is shipped from the establishment, whichever is the longest;
- (iii) ensure all parties involved in the supply-chain shall be identifiable; and
- (iv) establish measures to ensure traceability of the medical device throughout distribution channels from the manufacturer/importer to the customer and to the patient.

(2) Records including expiry dates and batch records shall be part of a secure distribution documentation enabling traceability.

Specific traceability requirements for implantable medical devices

27. (1) The establishment shall establish a tracking record for all implants especially the following high-risk medical devices down to patient level—

- (i) mechanical heart valves;
- (ii) implantable pacemakers, their electrodes and leads;
- (iii) implantable defibrillators, their electrodes and leads;
- (iv) implantable ventricular support systems; and
- (v) implantable drug infusion systems.

(2) If tracking is not possible for any individual medical devices (e.g. the tracking does not have the patient's consent), the tracking system is still required as follows—

- (i) to track the medical devices down to the healthcare facility level; or
- (ii) to keep track of the following—

- the date of the medical device was put into service or implanted into a patient, and
- the date the device permanently retired from use or for an implanted medical device, the date it was explanted.

(3) The establishment shall submit surveillance reports to the Authority at least once a year for all the above stated medical devices.

Specific requirements for active medical devices

28. (1) The establishment shall establish and maintain documented procedures and work instructions for performing installation, testing and commissioning and maintenance activities in accordance with Malaysian Standard MS 2058 - Code of Practice for Good Engineering Maintenance of Active Medical Devices and any other requirements as specified by the Authority.

(2) The establishment shall—

- (i) establish and maintain documented procedures, work instructions and reference materials, tools and test equipment and reference measurement procedures, for performing servicing activities including calibration, repair, maintenance and verifying that they meet the regulatory requirements and applicable standards;
- (ii) establish documented requirements which contain acceptance criteria for installation, testing and commissioning of the medical device;
- (iii) establish installation qualification and maintain adequate installation and inspection instructions for medical devices requiring specified installation requirements, and where appropriate, test procedures;
- (iv) ensure proper installation, testing and commissioning;
- (v) ensure equipment used for testing, maintenance and conservation of medical devices are calibrated or verified at specific intervals;
- (vi) ensure the calibration and maintenance of test equipment conforms to the applicable standards; and
- (vii) maintain testing and commissioning, installation, calibration and maintenance service records.

(3) The establishment shall, as appropriate—

- (i) establish an appropriate technical support which include maintenance service, training, calibration, management of spare parts, workshop setup and management;
- (ii) establish maintenance management mechanism to support the customers;
- (iii) ensure the technical and maintenance support services for active medical devices conform to the applicable regulatory requirements.

Outsourced activities

29. The establishment shall—

- (i) ensure control over outsourced process within the scope of the GDPMD;
- (ii) establish requirements to ensure that the outsourced activities conform to specified requirements;
- (iii) ensure the type and extent of control applied to the supplier are dependent on the impact on meeting the requirements of GDPMD;
- (iv) ensure, for outsourced activities, the supplier of outsourced activities is audited as part of the establishment's system unless the supplier is already certified to GDPMD covering the scope of the outsourced activities; and
- (v) develop written agreements with outsourced party to ensure that appropriate measures are taken to safeguard the safety and performance of the medical devices, including maintaining appropriate documentation and records, and such agreements should be in accordance with regulatory requirements and any relevant statutory requirements.

Note: Establishment shall ensure control over outsourced processes does not absolve the establishment of the responsibility of conformity to GDPMD, statutory and regulatory requirements.

Counterfeit adulterate, unwholesome and tampered medical services

30. The establishment shall, upon finding in this distribution network any counterfeit, adulterate, and tampered medical devices—

- (i) physically segregated from other medical devices to avoid any confusion;
- (ii) clearly label any counterfeit, adulterate, and tampered medical devices found in the distribution network as “Not for Sale” or other similar phrases/words; and
- (iii) inform the Authority and manufacturer immediately.

Secondary assembly including repackaging

General requirements

31. (1) The establishment shall plan and carry out secondary assembly of medical devices under controlled conditions and shall include, as applicable—

- (i) the availability of information that describes the characteristics of the medical devices;
- (ii) the availability of documented procedures, documented requirements, work instructions, and reference materials and reference measurement procedures as necessary;
- (iii) the use of suitable equipment;
- (iv) the availability and use of monitoring and measuring devices;

- (v) the implementation of monitoring and measurement activities;
 - (vi) the implementation of release of medical devices, their delivery and post-delivery activities; and
 - (vii) the implementation of defined operations and packaging of medical devices.
- (2) The establishment shall—
- (i) establish and maintain a record for each batch of medical devices that provides traceability and identifies the amount assembled and the amount approved for distribution; and
 - (ii) ensure the batch record shall be verified and approved by qualified personnel.

Assembly documents

32. The establishment shall ensure—

- (i) batch assembly record is kept for each batch or part batch assembled which carries the batch number and the quantity of bulk medical devices to be packed;
- (ii) the assembly shall be made or completed at time each action is taken to trace all significant activities concerning the assembly of medical device; and
- (iii) the records are retained for a period of time—
 - as specified in the regulatory requirements; or
 - at least equivalent to the lifetime of the medical device as defined by the product owner of the medical device; or
 - no less than two years from the date that the medical device is shipped from the establishment, whichever is longest.

Materials control

33. The establishment shall ensure—

- (i) for each delivery, the incoming medical devices are checked for integrity of package and seal, for correspondence between delivery note and the supplier's labels, and for compliance with quality specification;
- (ii) medical devices with breached primary package are not used for secondary assembly;
- (iii) medical devices in the storage area are appropriately labeled;
- (iv) appropriate procedures or measures are taken to assure the identity of the contents of each packing of the medical devices;
- (v) bulk containers from which quantities of the medical devices have been drawn are clearly identified;
- (vi) medical devices requiring special storage conditions are placed in areas which are designed and equipped to provide the desired conditions;
- (vii) the storage and conditions are continuously monitored and recorded;
- (viii) the actual storage temperature are expressed quantitatively;

- (ix) the purchase, handling and control of all packaging materials are accorded attention similar to that given to starting materials;
- (x) packaging materials are issued for use only by authorized personnel in accordance with the documented procedure;
- (xi) when setting up a program for the packaging operations, particular attention is given to minimize the risk of cross-contamination, mix-ups or substitutions; and
- (xii) different medical devices shall not be packaged in close proximity unless there is physical segregation.

Labeling

34. The establishment shall ensure the repackaged medical devices bear all original labeling (including instruction for use, label and any other information sheet or leaflet, etc) and all labeling information, except for quantity and the distributor identity.

Good assembly practices

35. The establishment shall ensure—

- (i) all medical devices and materials used for assembly are checked before use by a designated person for quantity, identity and conformity with the packaging instructions;
- (ii) line clearance are performed prior to commencement of the assembly operation;
- (iii) the correct performance of any printing operation which is carried out separately or in the course of packaging are checked and recorded.
- (iv) printing by hand is re-checked at regular intervals;
- (v) assembly equipment/apparatus are cleaned according to detailed and written procedures and stored only in a clean and dry condition;
- (vi) assembly equipment/apparatus do not present any hazard to the medical devices;
- (vii) the parts of assembly equipment/apparatus that come into contact with the medical devices do not affect the quality of the medical devices and present any hazard; and
- (viii) control equipment shall be calibrated and checked at defined intervals and adequate records of the calibration shall be maintained.

Quality control

36. The establishment shall ensure—

- (i) finished medical device assessment shall embrace all relevant factors, including assembly conditions, a review of packaging documentation, compliance with finished medical device specification and visual examination of the final finished pack; and
- (ii) the process of secondary assembly shall not compromise the conformity of the medical device to essential principles of safety and performance, as stipulated in Act 737 and its subsidiary legislations.

PART 6: SURVEILLANCE AND VIGILANCE

General

37. The establishment shall establish and implement a documented procedure for monitoring safety and performance of medical devices imported, exported and placed in the market.

Medical device complaints

38. (1) The establishment shall—

- (i) establish and implement a documented procedure for handling complaints regarding medical devices;
- (ii) all complaints and other information concerning potentially defective and counterfeit medical devices shall be reviewed including the description of the action to be taken and reporting to all relevant parties, where appropriate;
- (iii) any complaint concerning a defective medical device shall be recorded and thoroughly investigated to identify the origin or the reason for the complaint;
- (iv) maintain records of the complaint, investigation and any subsequent actions taken; and
- (v) where necessary, appropriate follow-up action should be taken after investigation and evaluation of the complaint.

(2) The establishment should put in place a system by which the complaints, the response received from the medical device manufacturer, or the results of the investigation of the complaint, are shared with all the relevant parties.

Distribution records

39. The establishment shall—

- (i) document all activities relating to the distribution of medical devices including all applicable receipts, storage, delivery and disposal; and
- (ii) the records shall contain at least the following—
 - the name, address, e-mail and telephone number of the manufacturer, authorized representative, importer, exporter, distributor and customer of the device where appropriate; and
 - the name of the device, its class and its identifier, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family.

Field corrective action (FCA) and field safety notice (FSN)

40. The establishment shall—

- (i) establish documented procedures for handling of FCA and field safety notice (FSN);
- (ii) define the responsibilities for planning, conducting and reporting of corrective actions in the documented procedure;
- (iii) establish in writing a recall or withdrawal procedure in consultation with manufacturer;
- (iv) inform the Authority prior to execution of FCA and FSN;
- (v) inform all customers to whom the medical device was distributed with the appropriate degree of urgency;
- (vi) inform overseas counterparts on the FCA and FSN if the medical devices are exported;
- (vii) request that the affected medical devices be removed immediately from usable stock and stored separately in a secure area until they are disposed of in accordance with manufacturers' instructions; and
- (viii) maintain records of all actions taken in connection with the FCA and FSN and their approval by the manufacturer and the Authority.

Recall

41. The establishment shall—

- (i) establish a documented procedure to effectively and promptly recall medical device known or suspected to be defective or counterfeit;
- (ii) ensure that the system comply with the regulatory requirements;
- (iii) the manufacturer and/or authorized representative shall be informed in the event of a recall;
- (iv) where a recall is instituted by an entity other than the manufacturer and/or authorized representative, consultation with the manufacturer and/or authorized representative should, where possible, take place before the recall is instituted;
- (v) recall information shall be reported to the Authority; and
- (vi) the progress of a recall process should be recorded and a final report issued, which includes a reconciliation between delivered and recovered quantities of products.

Mandatory problem reporting

42. (1) The establishment shall establish documented procedure for incident/problem reporting to comply with the regulatory requirements, which include—

- (i) the identification of the nature of the incident/problem;

- (ii) the investigation;
- (iii) the evaluation and analysis; and
- (iv) the action to be taken.

(2) Each incident report shall lead to a final report where corrective actions are applicable.

Internal audits

43. The establishment shall—

- (i) establish a documented procedure, defining the responsibilities and requirements for planning and conducting audits and reporting of the results and maintenance of the audit records;
- (ii) plan an audit program, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits;
- (iii) define the audit criteria, scope, frequency and methods;
- (iv) conduct internal audits at planned intervals to monitor the implementation of and compliance with the requirements of GDPMD;
- (v) records of the audits and their results shall be maintained; and
- (vi) take actions to eliminate detected nonconformities and their causes without undue delay.

Corrective action

44. The establishment shall—

- (i) take action to eliminate the cause of nonconformities in order to comply with GDPMD and regulatory requirements under Act 737; and
- (ii) a documented procedure shall be established to define requirements for:
 - reviewing nonconformities (including customer complaints);
 - determining the causes of nonconformities;
 - evaluating the need for action to ensure that nonconformities do not recur;
 - determining and implementing action needed, including, if appropriate, updating documentation,
 - recording of the results of any investigation and of action taken; and
 - reviewing the corrective action taken and its compliance with GDPMD and regulatory requirements.

Preventive action

45. The establishment shall—

- (iii) determine proactive action to eliminate the causes of potential nonconformities in order to comply with GDPMD and regulatory requirements and preventive actions shall be appropriate to the effects of the potential problems; and
- (iv) establish a documented procedure to define requirements for—
 - determining potential nonconformities and their causes;
 - evaluating the need for action to prevent occurrence of nonconformities;
 - determining and implementing action needed;
 - recording of the results of any investigations and of action taken; and
 - reviewing preventive action taken and its effectiveness.

ANNEX 1**Scope of GDPMD Certification**

- (1) The GDPMD certification shall specify the following—
- (i) scope of activities performed by the establishment and medical devices dealt with by the establishment;
 - (ii) outsourced activities, if applicable;
 - (iii) any special storage and handling conditions, such as chill room or cold room for cold chain management; and
 - (iv) applicable sections of the Medical Device Act 2012 (Act 737) and its subsidiary legislations.
- (2) The following information shall be indicated in the certification of GDPMD—
- (i) information on establishment seeking certification (which include name, address and contact information);
 - (ii) information on other premises of the establishment (which include name, address and contact information), if applicable, which are involved in performing any activities within the scope of GDPMD certification and the activities they perform; and
 - (iii) information on all premises (which include name, address and contact information of all the premises), if applicable, which are involved in performing any outsourced activities within the scope of GDPMD certification of the establishment and the activities they perform.
- (3) The certificate issued by the conformity assessment body (CAB) shall bear the following information—
- (i) particulars of CAB issuing the certificate which include the name and address, company logo, registration number and the name and signature of the certification manager of the CAB; and
 - (ii) particulars of the certificate issued to the establishment which include the number, validity and expiry date of the certificate.
- (4) Scope of activities for establishment (including those activities that are outsourced) to be certified include anyone or combination of the following activities—
- (i) import;
 - (ii) storage and handling;
 - (iii) warehousing;
 - (iv) secondary assembly;
 - (v) distribution (including transportation);
 - (vi) installation, testing & commissioning (including the required facilities);
 - (vii) maintenance and calibration (including the required facilities); and
 - (viii) documentation (including traceability of medical devices).

(5) List of devices dealt with by the establishment—

NO	DEVICE CATEGORY*
1	
2	
3	

***List of device categories:**

- 01 Active implantable devices
- 02 Anesthetic and respiratory devices
- 03 Dental Devices
- 04 Electro mechanical medical devices
- 05 Hospital hardware
- 06 In vitro diagnostic devices
- 07 Non-active implantable devices
- 08 Ophthalmic and optical devices
- 09 Reusable devices
- 10 Single-use devices
- 11 Assistive products for persons with disability
- 12 Diagnostic and therapeutic radiation devices
- 13 Complementary therapy devices
- 14 Biologically-derived devices
- 15 Healthcare facility products and adaptations
- 16 Laboratory equipment
- 17 Medical software
- 18 Others: Please specify with justification for any additional categories

