

Regulatory Requirements for
Medical Device Safety &
Performance

GOOD DISTRIBUTION PRACTICE FOR
MEDICAL DEVICES (GDPMD)

DRAFT

PREFACE

Various activities in medical devices supply-chain, which include handling, transportation, storage, distribution and tracking, need to be appropriately managed and controlled to ensure safety and performance of medical devices at the point of use. 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 in-line with the recommendations made by the World Health Organisation (WHO) as part of the effort to combat counterfeit medical products¹.

GDPMD specifies the requirements for a quality system to be established and maintained by an establishment in carrying out activities in medical device supply-chain. GDPMD requires an establishment to demonstrate its ability to maintain safety and performance of medical devices throughout the supply-chain. It will be used by both 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 conformity assessment body (CAB). The design and implementation of GDPMD by an establishment is influenced by the size and structure of the establishment, the processes employed and the type of medical devices it deals with. It is not the intent of the GDPMD to imply uniformity in the structure of the quality systems or uniformity of documentation.

Conformance 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 law in force. In the event of any contradiction between the requirements of GDPMD and any written law, the latter shall take precedence.

¹ WHO IMPACT Draft Principles and Elements for National Legislation against Counterfeit Medical Products, endorsed by IMPACT General Meeting in Lisbon, 12 December 2007.

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1) OBJECTIVE

The objective of this document is to specify the requirements for the Good Distribution Practice for Medical Devices (GDPMD).

2) SCOPE AND APPLICATION

The GDPMD is applicable to local authorised representatives of foreign manufacturers (LARs), importers and distributors of medical devices in Malaysia. The scope of GDPMD does not cover manufacturers of medical devices.

If any requirement in GDPMD is not applicable due to the nature of the medical device, the establishment does not need to implement such a requirement. If an establishment identifies any requirement that does not apply to the range of medical devices it deals with, a justification has to be provided for their exclusion from fulfilment of that particular requirement.

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.

The applicable scope of GDPMD is defined in Annex 1.

3) DEFINITIONS

~~The following definitions should be regarded as generic, as definitions provided in written law take precedence:~~

active medical device means any medical device, operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, is not considered to be active medical devices;

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

conformity assessment body (CAB) means a body that is recognised by the Medical Device Authority to carry out conformity assessment under the medical device law;

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 for the purposes of this ~~technical specification document~~, means the activities of pre (release), placement (delivery) and post-delivery of medical devices conducted by the ~~company 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;

Notes:

- (i) More than one distributor may be involved in the supply chain.*
- (ii) Persons in the supply chain involved in activities such as storage and transport on behalf of the LAR, importer or distributor, are not covered under this definition.*

establishment means (a) a person who either a manufacturer, importer, or distributor who is responsible for placing any medical device in the market but does not include a retailer; and (b) LAR appointed by a manufacturer having a principal place of business outside Malaysia;

export ~~with its grammatical variations and cognate expressions~~, means to take or cause to be taken out of Malaysia by land, sea or air;

field safety corrective action (FSCA) 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. This may include:

- return of a medical device to the manufacturer or its representative (see guidance on recall);
- device modification;
- device exchange;
- device destruction;
- advice given by manufacturer regarding the use of the device

Such device modifications may include:

- retrofit in accordance with the manufacturer's modification or design change;
- permanent or temporary changes to the labelling 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.

In assessing the need of the FSCA the product owner is advised to use the methodology described in the ISO 14971:2007 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 FSCA;

import with its grammatical variations and cognate expressions, means to bring or cause to be brought into Malaysia by land, sea or air;

importer means any natural or legal person in the supply chain who is the first in a supply chain to make a medical device, manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to be marketed;

installation qualification (IQ) is a documented demonstration that facilities and operations are installed as designed and specified and are correctly interfaced with systems. The protocols should include:

- engineering drawings and documents;
- building finishes;
- process and utilities flow diagrams;
- piping and instrumentation diagrams;
- equipment and instrument specifications;
- manufacturers' drawings, equipment maintenance and operating manuals;
- spare lists; and
- maintenance and calibration schedules;

manufacturer means (a) a person who is responsible for (i) the design, production, fabrication, assembly, processing, packaging and labelling of a medical device whether or not it is the person, or a subcontractor acting on person's behalf, who carries out these operations; and (ii) assigning to the finished medical device under his own name, its intended purpose and ensuring the finished product meets the regulatory requirement; or (b) any other person who (i) assembles, packages, processes, fully refurbishes, reprocesses or labels one or more ready-made medical devices; and (ii) assigning to the ready-made medical device under his own name, its intended purpose and ensuring the finished product meets the regulatory requirement;

medical device means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article that is intended by its manufacturer to be used, whether alone or in

combination, for humans for one or more of the specific purposes of:

- diagnosis, prevention, monitoring, treatment or alleviation of any disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
- investigation, replacement, modification, or support of the anatomy or of a physiological process;
- supporting or sustaining life;
- control of conception;
- disinfection of medical devices; or
- providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body,

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means;

place in the market means to make available a medical device in return for payment or free of charge with view of distributing, using, supplying or putting into service, in Malaysia, regardless of whether it is new or reprocessed, but does not include to make available for use for clinical research or for performance evaluation of a medical device;

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 technical specification, in relation to a medical device, 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 the medical device;

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.

4) **QUALITY MANAGEMENT SYSTEM**

4.1) **General requirements**

The establishment shall:

- (i) establish, document and implement a quality management system and maintain

- its effectiveness in accordance with the requirements of GDPMD;
- (ii) identify the processes needed for the GDPMD and their application, regardless of the type or size of the organisation;
 - (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;
 - (v) ensure the availability of resources and information necessary to support the operation and monitoring of these processes;
 - (vi) monitor, measure and analyse these processes;
 - (vii) implement actions necessary to achieve planned results and maintain the effectiveness of these processes;
 - (viii) manage the processes in accordance with the requirements of the GDPMD; and
 - (ix) identify and control outsourced processes that affects conformity of product, should the establishment chooses to outsource such processes.

4.2) Documentation requirements

4.2.1) General

The establishment shall put in place the following documentation:

- (i) a master file comprising the establishment's profile and operations;
- (ii) documented procedures required by the GDPMD;
- (iii) documents needed by the establishment to ensure the effective planning, operation and control of medical device;
- (iv) records required by the GDPMD; and
- (v) any other documentation specified by the Authority.

All documented requirements, procedures and activities shall be implemented and maintained.

For each type or model of medical device, the establishment shall establish and maintain a file containing documents defining product specifications and installation qualifications (if applicable). These documents shall define the complete distribution process and, if applicable, installation and servicing.

Notes:

- (i) *The extent of the GDPMD documentation can differ from one establishment to another due to:*

- *the size of the establishment and type of activities;*
- *the complexity of processes and their interaction; and*
- *the competence of personnel.*

(ii) *The documentation can be in any form or type of medium.*

4.2.2) *Master file*

The establishment shall establish and maintain a master file that includes:

- (i) the scope of the GDPMD implemented, including details of, and justification for any exclusion and/or non-application;
- (ii) the documented procedures established for the GDPMD, or reference to them; and
- (iii) information regarding the premises where activities are conducted.

4.2.3) *Control of documents*

The establishment shall:

- (i) control the documents required by GDPMD; and
- (ii) establish a documented procedure for the control of documents.

All documents shall be prepared, approved, signed and dated by an appropriate authorised person(s) and any change in person(s) permitted to carry out this task requires authorisation.

All documents shall be reviewed regularly and kept up-to-date. When a document has been revised, the control system shall be established to prevent the unintended use of the superseded version.

4.2.4) *Control of records*

The establishment shall:

- (i) establish and maintain records of GDPMD 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.

5) MANAGEMENT RESPONSIBILITY

5.1) Responsibility and authority

The management shall:

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

5.2) Management representative

The management shall appoint a management representative who, shall have the defined responsibility and authority that includes:

- (i) ensuring that processes needed for the GDPMD are established, implemented and maintained;
- (ii) reporting to top management on the performance of the GDPMD and any need for improvement; and
- (iii) ensuring the promotion of awareness of ~~customer requirements~~the decision made by top management throughout the establishment.

NOTE: The responsibility of a management representative can include liaising with external parties on matters relating to the GDPMD and regulatory affairs.

5.3) Management review

The management shall:

- (i) review its quality management system at planned intervals, to ensure its continuing suitability, adequacy and effectiveness;
- (ii) ensure the review includes assessment of opportunities for improvement and the need for changes to the quality management system; and
- (iii) maintain records of management reviews.

5.4) Review input

The input for management review shall include:

- (i) results of audits;

- (ii) customer feedback;
- (iii) process performance and product conformity;
- (iv) status of preventive and corrective actions;
- (v) follow-up actions from previous management reviews;
- (vi) changes that could affect the quality management system; and
- (vii) recommendations for improvements.

5.5) Review output

The output from the management review shall include any decisions and actions related to:

- (i) improvement of the effectiveness of the quality management system and its processes;
- (ii) improvement of medical device related to customer requirements; and
- (iii) resource needs.

6) RESOURCE MANAGEMENT

6.1) Personnel

Key personnel in charge of managing the import, distribution and post-market operations including technical support shall be competent and possesses appropriate professional knowledge, education, training, skills and experience.

Skills of personnel providing post market technical support for active medical devices shall conform to the requirements of Malaysian Standard MS 2058:2009 Code of Practice for Good Engineering Maintenance of Active Medical Devices.

6.2) Training, competency and awareness

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.

6.3) Infrastructure

The establishment shall determine, provide and maintain the infrastructure needed to

achieve conformity to GDPMD requirements which includes, as applicable:

- (i) buildings, workspace, workshop (if required) and associated utilities,
- (ii) measuring and test equipment (both hardware and software), and
- (iii) supporting services (such as transport or communication).

The establishment shall, as applicable:

- (i) ensure that the premises and equipment used are suitable and adequate to ensure proper conservation and distribution of medical devices;
- (ii) establish documented requirements for maintenance activities, including their frequency, ~~when such activities or lack thereof can affect medical device GDPMD~~; and
- (iii) maintain records of such maintenance.

6.4) Work environment

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 for work environment conditions 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.

6.5) Cleanliness

The establishment shall:

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

6.6) Pest control

The establishment shall:

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

7) SUPPLY CHAIN AND DEVICE SPECIFIC

7.1) Authorisation

The establishment shall:

- (i) obtain appropriate authorisation from the relevant party to become LAR, importer or distributor of medical devices; and
- (ii) establish and maintain written agreement with the relevant party pertaining to regulatory matters relating to medical devices it deals with.

7.2) Communication channels

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 the users, public and Authority on pre-market and post-market matters of the corresponding medical devices;
- (iii) as appropriate, 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) as appropriate, establish feedback mechanisms for collecting comments and complaints from the users and public, to be forwarded to the relevant party;
- (v) as applicable, establish mechanisms to provide maintenance services, including calibration, provision of spare parts and other services, to the users.

7.3) Receipt of stock

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.

7.4) Storage and stock handling

The establishment shall:

- (i) identify storage measures for specific medical devices and stored in accordance with the specified 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;

7.5) Stock rotation

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 labelled as “Not for Sale” or other similar phrases/words; and
- (iii) dispose the expired medical devices in accordance to Clause [97.8](#).

7.6) Delivery to customers

The establishment shall:

- (i) verify that the medical device bears the conformity marking, that it is accompanied by the required documents and by instructions for use in languages required by the regulatory requirements;
- (ii) ensure that the medical device bears a type, batch or serial number or other elements of identification as well as name, trade name and address of the manufacturer and/or distributor organisation;
- (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 regulation by obtaining the proof of such authority prior to the distribution of medical devices to such person;
- (iv) enclose documentation of all medical devices supplied to customers to ascertain the date, the name of the medical device, the quantity supplied, the batch and/or 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 from the manufacturer and communicate to those responsible for the storage and transportation of medical devices;
- (vii) those responsible for the storage and transportation of medical devices should ensure adherence to the conditions specified by the manufacturer throughout transportation and at any intermediate store stages;
- (viii) establish adequate methods of transportation to achieve safe and secure delivery of medical device from the point of collection to the point of delivery;
- (ix) establish safe medical devices transportation mechanisms prior to delivery;
- (x) establish appropriate transportation or specialised means for medical devices requiring controlled temperature storage or other special control conditions; and
- (xi) ensure transportation and storage of bulk medical devices carrying highly dangerous and/or otherwise hazardous substances presenting 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 applicable international agreements and national legislation.

7.7) Return of medical devices

The establishment shall:

- (i) establish documented procedures for handling of returned medical devices and shall be treated as a non-conforming product;
- (ii) ensure that non-conforming product is accepted by concession only if regulatory requirements are met;
- (iii) maintain records of the identity of the person(s) authorising the concession;
- (iv) maintain records of the nature of non-conformities and any subsequent actions taken, including concessions obtained;
- (v) ensure, when non-conforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements;
- (vi) take appropriate action for nonconforming medical device that is detected after delivery or use has started, to the effects, or potential effects, of the non-conformity;
- (vii) segregate all returned medical devices from saleable stock to prevent redistribution until a decision has been reached regarding their disposal;
- (viii) document the criteria for re-evaluation of the returned medical devices; and
- (ix) maintain records of the re-evaluation and any subsequent actions taken.

7.8) Disposal of medical devices

The establishment shall:

- (i) establish a documented procedure for the disposal of medical devices;
- (ii) ensure, if the medical device have not been immediately sent for disposal, they shall be kept in a clearly segregated area and identified so that they will not be sold inadvertently or contaminate other medical devices; and
- (iii) maintain records of the disposal.

7.9) Traceability*7.9.1) General*

The establishment shall:

- (i) maintain an updated records providing traceability of medical devices being dealt with, which include the make, model, batch number, serial number, and quantity of devices, as appropriate; and
- (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 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.

7.9.2) Tracking of specific medical devices

The establishment shall track 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.

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:

- (i) to track the medical devices down to the user-facility level; and
- (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 device, the date it was explanted.

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

The Authority reserves the right to revise the submission schedule as it sees appropriate, and in case of the Authority conducts such revision, the establishment will be notified accordingly.

7.10) Specific requirements for active medical devices

7.10.1) Technical support office and workshop

The establishment shall, as appropriate:

- (i) establish a technical support office and appropriate engineering workshop for medical devices requiring post-market technical support;
- (ii) establish mechanisms to provide technical support, if applicable, to the users;
- (iii) be responsible for compliance to the GDPMD should such services are outsourced; and
- (iv) ensure the technical support service for active medical devices conform to the requirements of Malaysian Standard MS 2058:2009 - Code of Practice for Good Engineering Maintenance Management of Active Medical Devices.

The technical support shall include maintenance services, calibration, stock of spare parts, workshop setup and management.

7.10.2) Installation, testing and commissioning

The establishment shall:

- (i) establish installation qualification and maintain adequate installation and inspection instructions for medical devices requiring specified installation requirement, and where appropriate, test procedures;
- (ii) ensure proper installation and any required testing in accordance with the instructions and procedures are carried out; and
- (iii) maintain testing and commissioning records, including test results, to demonstrate proper and satisfactory installation.

7.10.3) Calibration and Maintenance service

The establishment shall:

- (i) ensure equipment used for proper conservation and operation of medical devices is calibrated or verified at specific intervals, or prior to use, against measurement standards traceable to international or national standards;
- (ii) establish and maintain instructions and procedures to perform and verify medical device maintenance service meets the specified requirements;
- (iii) ensure for active medical devices, the maintenance service shall conform to Malaysian Standard MS 2058:2009 - Code of Practice for Good Engineering Maintenance Management of Active Medical Devices; and
- (iv) maintain calibration and maintenance service records.

7.11) Outsourced activities

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; and
- (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 that covers the scope of the outsourced activities.

7.12) Counterfeit, adulterated, unwholesome and tampered medical devices

The establishment shall:

- (i) ensure that any counterfeit, adulterated, unwholesome and tampered medical devices found in the distribution network shall be physically segregated from other medical devices to avoid any confusion;
- (ii) clearly label any counterfeit, adulterated, unwholesome and tampered medical devices found in the distribution network as "Not for Sale" or other similar phrases/words; and
- (iii) inform the Authority and product owner immediately.

7.13) Secondary assembly

7.13.1) General requirements

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.

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.

7.13.2) Assembly documents

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 regulation; 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.

7.13.3) Materials control

The establishment shall ensure:

- (i) for each delivery, the incoming medical devices are checked for integrity of package and seal, for correspondence between the delivery note and the supplier's labels, and for compliance with medical device quality specification.:-

- (ii) medical devices with breached primary package are not used for secondary assembly;
- (iii) medical devices in the storage area ~~shall bear~~ appropriately labelled;
- (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 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 authorised personnel in accordance with the documented procedure;
- (xi) when setting up a programme for the packaging operations, particular attention is given to minimise 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.

7.13.4) Labelling

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

7.13.5) Good assembly practices

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.

7.13.6) Quality control

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 the Essential Principles of Safety and Performance.

8) VIGILANCE AND CORRECTIVE ACTION

8.1) Medical device complaints

The establishment shall:

- (i) establish and implement a documented procedure for handling complaints regarding medical devices;
- (ii) provide mechanism for collecting comments and complaints from the users and public;
- (iii) report to the Authority on any adverse event that meets the regulatory reporting criteria; and
- (iv) maintain records of the complaint, investigation and any subsequent actions taken.

8.2) Field safety corrective action (FSCA)

The establishment shall:

- (i) establish documented procedures for handling of FSCA;
- (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 the FSCA;
- (v) inform all customers to whom the medical device was distributed with the appropriate degree of urgency;
- (vi) inform the overseas counterparts on the FSCA if the medical devices are exported
- (vii) request that the recalled 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 FSCA and their approval by the manufacturer and the Authority.

8.3) Internal audits

The establishment shall:

- (i) conduct internal audits at planned intervals to monitor the implementation of and compliance with the requirements of GDPMD;
- (ii) define in a documented procedure, the responsibilities and requirements for planning and conducting audits and reporting of the results and maintenance of the audit records;
- (iii) take actions to eliminate detected nonconformities and their causes without undue delay; and
- (iv) record the verification of actions taken and reporting of verification results.

ANNEX 1**(Normative)****Scope of Certification**

- 1) The scope of the certificate shall specify the following:
 - (i) activities performed by the establishment + categories of medical devices handled by the establishment;
 - (ii) activities (storage, warehousing, secondary assembly and distribution) that are outsourced, if applicable; and
 - (iii) storage and handling conditions.
- 2) Applicable activities for establishment include;
 - (i) import;
 - (ii) storage;
 - (iii) distribution (includes transportation);
 - (iv) installation;
 - (v) servicing (includes repair and maintenance); and
 - (vi) secondary assembly.

Note: For establishment that are suppliers of outsourced storage, warehousing, secondary assembly and distribution services should only have the following activities listed in the scope of their certification:

 - (i) storage;
 - (ii) distribution (includes transportation); and/or
 - (iii) secondary assembly.
- 3) The certification shall also cover any special storage and handling conditions, such as chill room or cold room for cold chain management. Examples of statements can include (non-exhaustive list):
 - (i) there are no special storage and handling conditions;
 - (ii) cold-chain management for *in vitro* diagnostic (IVD) medical devices; and
 - (iii) chill room, freezer (to indicate temperature range).

Note: If special storage and handling conditions are not applicable, the scope of the certificate must indicate that there are no special storage and handling conditions.
- 4) The following information shall be indicated in the certification:
 - (i) address(es) of all premises of ~~registered company~~ the establishment, including storage facilities, and activities performed at those premises; and
 - (ii) address(es) of the supplier of outsourced activities and activities performed by that supplier.