

# MEDICAL DEVICE TECHNICAL SPECIFICATION

01 SEPTEMBER 2012

TS-01: Good Distribution Practice for Medical Devices -  
Requirements

Revision 2.1

**PREFACE**

This document sets out the requirements for the Good Distribution Practice for Medical Devices (GDPMDS).

In the event of any contradiction between the contents of this document and any written law, the latter shall take precedence.

## **1. INTRODUCTION**

### **1.1. Purpose**

This document specifies the requirements for the Good Distribution Practice for Medical Devices, including secondary assembly activity.

### **1.2. Background**

The storage, trade and distribution of medical devices are carried out by various organisations. The nature of the risks involved may be the same as those in the manufacturing environment, e.g. mix-ups and contamination. Hence, certain aspects of a quality system for manufacturing (e.g. storage, transportation, documentation and record-keeping practices) are applicable to the distribution of medical devices.

The quality of medical devices can be adversely affected by a lack of adequate control over the activities that occur during the storage and distribution processes.

The need for establishment, development, maintenance and control over the activities involved in the distribution process has, hitherto, generally not been well-emphasised. The objective of Good Distribution Practice for Medical Devices (GDPMDS) is to assist in ensuring the quality and integrity of medical devices throughout the distribution process.

The International Medical Products Anti-Counterfeiting Taskforce (IMPACT) of the World Health Organisation (WHO) has also recommended that operators of the distribution chain should comply with an official Good Practice Guideline, such as the Good Distribution Practice, as part of the global effort to combat counterfeit medical products.<sup>1</sup>

GDPMDS specifies requirements for a quality system used by an organisation

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

for the handling, storage, delivery, installation, servicing and secondary assembly, with respect to the medical devices they deal in.

GDPMDS requires the organisation to demonstrate its ability to maintain the quality of medical devices throughout the supply chain.

GDPMDS is to be used by both internal and external parties, including certification bodies, to audit an organisation's ability to meet the requirements specified within.

The certification to GDPMDS is to be conducted by certification bodies accredited by the Singapore Accreditation Council (SAC) and recognised by the Health Sciences Authority (HSA).

The design and implementation of GDPMDS by an organisation is influenced by the size and structure of the organisation, the processes employed, and the type of medical devices it deals with. It is not the intent of GDPMDS to imply uniformity in the structure of the quality systems or uniformity of documentation.

*NOTE* Conformance to GDPMDS does not imply compliance to any written laws. It is the responsibility of the organisation to ensure that they are in compliance with all applicable laws in force.

*NOTE* In the event of any contradiction between the requirements of this document and any written law, the latter shall take precedence.

### **1.3. Scope**

GDPMDS is applicable to all organisations that import and supply by wholesale medical devices in Singapore.

For organisations that had been certified to *ISO 9001 Quality management systems – Requirements*, various requirements of GDPMDS are covered

under *ISO 9001*. As certain clauses of GDPMDS are covered under *ISO 9001*, the audit time for companies that have obtained certification to *ISO 9001* from Certification Bodies should be reduced in accordance to *CT 04: SAC Criteria for Certification Bodies (Good Distribution Practice for Medical Devices)*.

*NOTE* *ISO 9001 is not equivalent to GDPMDS. The ISO 9001 Certification shall not be accepted in lieu of GDPMDS Certification for the purpose of obtaining Importer's and Wholesaler's Licence(s) from HSA.*

#### **1.4. Application**

All requirements of GDPMDS are specific to organisations providing medical devices, regardless of the type or size of the organisation.

If any requirement in Clause 4 of GDPMDS is deemed to not be applicable based on the characteristics of the medical device(s), the organisation does not need to implement such a requirement. If an organisation identifies any requirement in Clause 4 that does not apply to the range of medical devices they deal in, a justification has to be provided for their exclusion from fulfilment of that particular requirement.

When the terms “where appropriate” are used to qualify a requirement in the GDPMDS, it is deemed to be “appropriate” unless the organisation can document a justification otherwise.

Clause 7 (Field Safety Corrective Action) of GDPMDS may be excluded for suppliers of storage, warehousing, secondary assembly and distribution services.

Clause 14 shall only be applicable to organisations who perform secondary assembly.

The applicable scope of GDPMDS is defined in Annex 1. The categories of

medical devices are defined in Annex 2.

### 1.5. Definitions

The terms used to describe the supply chain is in line with ISO 13485:2003 Medical devices – Quality management systems – Requirements for regulatory purposes.

supplier -----> organisation -----> customer

The following definitions should be regarded as generic, as definitions provided in written law can differ slightly and take precedence.

**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.

**CERTIFICATION BODIES:** for the purposes of this technical specification, means certification bodies accredited by the Singapore Accreditation Council (SAC) and recognised by the Health Sciences Authority (HSA).

**CUSTOMER COMPLAINT:** is 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.

*NOTE* This definition is adopted from ISO 13485:2003 Medical devices – Quality management systems – Requirements for regulatory purposes (Terms and definitions 3.4)

**DISTRIBUTION:** for the purposes of this technical specification, means the release, delivery and post-delivery activities conducted by the company.

**EXPORT:** with its grammatical variations and cognate expressions, means to take or cause to be taken out of Singapore by land, sea or air.

**FIELD SAFETY CORRECTIVE ACTION (FSCA):** any action taken to reduce the risk of death or serious deterioration in the state of health of a person associated with the use of a medical device, including —

- the return of the medical device to its product owner;
- the replacement or destruction of the medical device;
- any action regarding the use of the medical device that is taken in accordance with the advice of its product owner;
- the clinical management of any patient who has used the medical device;
- the modification of the medical device;
- the retrofitting of the medical device in accordance with any modification to it or any change to its design by its product owner;
- the making of any permanent or temporary change to the labelling or instructions for use of the medical device; or
- any upgrade to any software used with the medical device, including any such upgrade carried out by remote access;

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):** a communication sent out by a product owner 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 Singapore by land, sea or air.

**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 product owner 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.

**PREMISES:** for the purposes of this technical specification, 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:** Element of the packaging system that maintains the sterility and/or integrity of the medical device.

**SECONDARY ASSEMBLY:** the process of repackaging a medical device from its original packaging into another packaging, without breach of the primary

package, before the medical device is supplied.

**WHOLESALE:** for the purposes of this technical specification, in relation to a medical device, means any one or more of the following:-

- supplying the medical device to a person who obtains the medical device for the purposes of supplying it again to some other person;
- supplying the medical device to a person as a commercial sample in the normal course of a lawful trade;
- supplying the medical device to a Government department or statutory body which requires the medical device for the purposes of the public service or use in connection with the exercise of any statutory power;
- supplying the medical device to a person or an institution concerned with scientific education or research which requires the medical device for the purpose of education or research;
- supplying the medical device to a person who requires the medical device for the purpose of enabling him to comply with any requirements made by, or in pursuance of, any written law with respect to the medical treatment of persons employed by that person in any business or trade carried out by that person;
- supplying the medical device to a person who requires to use the medical device, other than by way of administration to one or more persons, for the purpose of his business or trade;
- supplying the medical device by export to a party outside Singapore.

## **2. QUALITY MANAGEMENT SYSTEM**

### **2.1. General Requirements**

The organisation shall establish, document, implement and maintain a quality management system and maintain its effectiveness in accordance to the requirements of GDPMDS.

Where an organisation chooses to outsource any activities that may affect the quality of medical devices, the organisation shall ensure control over such processes.

### **2.2. Documentation Requirements**

#### **2.2.1. General**

The documentation shall include:

- a site master file,
- documented procedures required by the GDPMDS,
- documents needed by the organisation to ensure the effective planning, operation and control of its processes,
- records required by the GDPMDS, and
- any other documentation specified by the regulatory authorities.

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

#### **2.2.2. Site Master File**

The organisation shall establish and maintain a site master file that includes:

- the scope of the GDPMDS implemented, including the details of, and justification for any exclusion and/or non-application,
- the documented procedures established for the GDPMDS, or reference to them, and
- information regarding the premises where activities are conducted.

### **2.2.3. Control Of Documents**

Documents required by GDPMDS shall be controlled.

A documented procedure shall be established 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.

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

### **2.2.4. Control Of Records**

Records shall be established and maintained to provide evidence of conformity to requirements of GDPMDS. Records shall be legible, readily identifiable and retrievable.

A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

The organisation shall 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 organisation,

whichever is the longest.

### **3. RESOURCE MANAGEMENT**

#### **3.1. Personnel**

##### **3.1.1. General**

Key personnel in charge of warehousing operations shall possess the necessary competence in terms of education, training, skills and experience, prior to performing their work.

##### **3.1.2. Training**

The organisation shall

- determine the necessary competence for the key personnel,
- provide training to satisfy these needs,
- evaluate the effectiveness of the training, and
- maintain training records.

##### **3.1.3. Responsibility And Authority**

The organisation shall ensure that responsibilities and authorities are defined, documented and communicated within the organisation. The organisation shall establish the interrelation between all personnel who manage, perform and verify work that affects quality, and shall ensure the independence and authority to perform these tasks.

##### **3.1.4. Management Representative**

The organisation shall appoint a member of the management who, irrespective of other responsibilities, shall have the ultimate responsibility of:

- ensuring that processes needed for the quality management system are established, implemented and maintained,
- reporting to top management on the performance of the quality management system and any need for improvement, and
- ensuring the promotion of awareness of regulatory and customer requirements throughout the organisation.

*NOTE*            *The responsibility of a management representative can include liaising with external parties on matters relating to the quality management system.*

## **3.2. Premises And Facilities**

### **3.2.1. General**

The organisation shall ensure that the premises and equipment used are suitable and adequate to ensure proper conservation and distribution of medical devices.

### **3.2.2. Cleanliness**

The organisation shall establish documented requirements for cleaning of premises, including frequency and methods.

Records of cleaning shall be maintained.

### **3.2.3. Pest Control**

The organisation shall establish a pest control programme to identify and prevent pest infestation.

Records of pest control programme shall be maintained.

## **4. STORAGE AND STOCK HANDLING**

The organisation shall provide suitable and adequate storage to ensure proper conservation of the medical devices.

### **4.1. Receipt Of Stock**

The organisation shall establish and implement inspection or other activities necessary to ensure that medical devices received meet specified requirements.

Medical devices subject to specific storage measures shall be immediately identified and stored in accordance with the specified instruction(s).

Records of the verification shall be maintained.

## **4.2. Calibration**

Equipment used to ensure proper conservation and distribution of medical devices shall be calibrated or verified at specific intervals, or prior to use, against measurement standards traceable to international or national standards.

## **4.3. Storage**

### **4.3.1. Storage Condition**

Medical devices shall be stored under conditions specified to prevent deterioration by light, moisture, temperature or other conditions. Storage conditions shall be monitored and recorded periodically, where appropriate.

Records of the storage conditions shall be maintained.

### **4.3.2. Stock Rotation**

The organisation shall establish a system to ensure stock rotation.

Medical devices beyond their expiry date or shelf life shall be segregated from usable stock. They shall be clearly labelled as “Not for Sale” or in other similar phrases/words. The expired medical devices shall be disposed of in accordance to Clause 9.

## **4.4. Delivery To Customers**

The organisation shall establish adequate methods of transportation to achieve safe and secure delivery of all medical devices from their point of

collection to their point of delivery.

Medical devices shall be transported in such a way that:-

- their identification is not lost;
- they do not contaminate, and are not contaminated by, other medical devices or materials/substances;
- adequate precautions are taken against spillage, breakage or theft;
- they are secure and not subjected to unacceptable degrees of heat, cold, light, moisture or other adverse influence, or to attack by microorganisms and pests.

Medical devices requiring controlled temperature storage or other special control and conditions shall be transported by appropriate or specialised means.

## **4.5. Installation And Servicing**

### **4.5.1. Installation**

Where the installation of a medical device is a specified requirement, the organisation shall establish and maintain adequate installation and inspection instructions, and where appropriate, test procedures.

Instructions and procedures shall include directions for ensuring proper installation so that the medical device will perform as intended after installation. Installation, inspection and any required testing are to be performed in accordance with the instructions and procedures.

The records of inspection and any test results to demonstrate proper installation shall be maintained.

### **4.5.2. Servicing**

Where servicing is a specified requirement, the organisation shall establish

and maintain instructions and procedures for performing and verifying that the servicing meets the specified requirements.

Records of servicing shall be maintained.

## **5. TRACEABILITY**

Records providing traceability of medical devices from the supplier and to the customers shall be maintained.

The organisation shall 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 organisation,
- whichever is the longest.

## **6. MEDICAL DEVICE COMPLAINTS**

The organisation shall establish a documented procedure for handling of complaints regarding medical devices.

Any reports of adverse event that meets the regulatory reporting criteria received by the organisation shall be reported to the regulatory authority.

*NOTE Reporting criteria and specific timelines for reporting of adverse events are stipulated in the Health Products (Medical Devices) Regulations.*

Records of the complaint, investigation and any subsequent actions taken shall be maintained.

## **7. FIELD SAFETY CORRECTIVE ACTION (FSCA)**

The organisation shall establish documented procedures for handling of FSCA. The responsibilities for planning, conducting, reporting of the corrective action shall be defined in the documented procedure.

The regulatory authority shall be informed prior to execution of the FSCA. If the medical devices are exported, the overseas counterparts shall be informed of the FSCA.

Records of all actions taken in connection with the FSCA and their approval by the company and regulatory authority shall be maintained.

## **8. RETURN OF MEDICAL DEVICES**

The organisation shall establish documented procedures for handling of returned medical devices.

All returned medical devices shall be segregated apart from saleable stock to prevent redistribution until a decision has been reached regarding their disposal.

The criteria for re-evaluation of the returned medical devices shall be documented. Records of the re-evaluation and any subsequent actions taken shall be maintained.

## **9. DISPOSAL OF MEDICAL DEVICES**

The organisation shall establish a documented procedure for the disposal of medical devices.

If the medical devices 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.

Records of the disposal shall be maintained.

## **10. COUNTERFEIT, ADULTERATED, UNWHOLESOME OR TAMPERED MEDICAL DEVICES**

Any counterfeit, adulterated, unwholesome or tampered medical devices found in the distribution network shall be physically segregated from other medical devices to avoid any confusion. They shall be clearly labelled as “Not for Sale” or in other similar phrases/words.

The organisation shall inform the regulatory authority, registrant and product owner immediately.

## **11. INTERNAL AUDITS**

The organisation shall conduct internal audits at planned intervals to monitor the implementation of and compliance with the requirements of GDPMDS.

The organisation shall 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.

Actions to eliminate detected nonconformities and their causes shall be taken without undue delay. Verification of the actions taken and the reporting of verification results shall be recorded.

## **12. MANAGEMENT REVIEW**

The top management shall review its quality management system at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system.

Records from management reviews shall be maintained.

### **12.1. Review input**

The input to management review shall include information on

- results of audits,
- customer feedback,
- process performance and medical device conformity,
- status of preventive and corrective actions,
- follow-up actions from previous management reviews,
- changes that could affect the quality management system,
- recommendations for improvement, and
- new or revised regulatory requirements.

### **12.2. Review output**

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

- improvement of the effectiveness of the quality management system and its processes,
- improvement of medical device related to customer requirements, and
- resource needs.

## **13. OUTSOURCED ACTIVITIES**

Where the organisation outsources any process within the scope of the GDPMDS, the organisation shall ensure control over such processes.

The organisation shall establish requirements to ensure that the outsourced activities conform to specified requirements.

The type and extent of control applied to the supplier shall be dependent on the impact on meeting the requirements of GDPMDS.

The supplier shall be audited as part of the internal audit if the supplier has not been certified to GDPMDS.

For outsourced activities under Clause 4 of GDPMDS, the supplier of outsourced storage, warehousing, secondary assembly and distribution services shall be audited by the certification body as part of the organisation's system, unless the supplier is already certified to GDPMDS. The scope of the supplier's certification shall cover the scope of the organisation.

## **14. SECONDARY ASSEMBLY**

### **14.1. General requirements**

The organisation shall plan and carry out secondary assembly of medical devices under controlled conditions.

Controlled conditions shall include, as applicable

- the availability of information that describes the characteristics of the medical device,
- the availability of documented procedures, documented requirements, work instructions, and reference materials and reference measurement procedures as necessary,
- the use of suitable equipment,
- the availability and use of monitoring and measuring devices,
- the implementation of monitoring and measurement activities,
- the implementation of release of medical devices, their delivery and post-delivery activities, and
- the implementation of defined operations for labelling and packaging of medical devices.

The organisation shall establish and maintain a record for each batch of medical devices that provides traceability (see clause 5) and identifies the amount assembled and the amount approved for distribution. The batch record shall be verified and approved by qualified personnel.

### **14.2. Assembly documents**

A batch assembly record shall be kept for each batch or part batch assembled. The record shall carry the batch number and the quantity of bulk medical devices to be packed.

The assembly shall be made or completed at the time each action is taken and in such a way that all significant activities concerning the assembly of

medical device are traceable.

These records shall be retained 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 organisation,

whichever is the longest.

### **14.3. Materials control**

#### **14.3.1. Medical devices to be re-packed**

For each delivery, the incoming medical devices shall be 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.

Medical devices with breached primary package shall not be used for secondary assembly.

Medical devices in the storage area shall be appropriately labelled. There shall be appropriate procedures or measures to assure the identity of the contents of each packaging of the medical devices. Bulk containers from which quantities of the medical devices have been drawn shall be clearly identified.

Medical devices requiring special storage conditions shall be placed in separate areas constructed and equipped to provide the desired conditions. The storage conditions shall be continuously monitored and recorded.

As far as possible, the actual storage temperature shall be expressed quantitatively. Where the storage temperature is not expressed quantitatively or stated (in terms of a range) on the labels of the registered medical device,

the definitions in Annex 1 of *GN-01 Guidance on the Application of Good Distribution Practice for Medical Devices (GDPMDS)* shall apply.

#### **14.3.2. Packaging materials**

The purchase, handling and control of all packaging materials shall be accorded attention similar to that given to starting materials.

When setting up a programme for the packaging operations, particular attention shall be given to minimising the risk of mix-ups or substitutions. Different medical devices shall not be packaged in close proximity unless there is physical segregation.

#### **14.3.3. Medical device labelling**

All original labelling (including instructions for use, label and any other informational sheet or leaflet, etc) and all original labelling information shall accompany the repackaged medical device when it is supplied. Additional secondary package labelling is permitted in accordance to Annex 3.

### **14.4. Good assembly practices**

#### **14.4.1. Special considerations**

All medical devices and materials used for assembly shall be checked before use by a designated person for quantity, identity and conformity with the packaging instructions. Line clearance shall be performed prior to commencement of the assembly operation.

The correct performance of any printing operation which is carried out separately or in the course of the packaging shall be checked and recorded.

#### **14.4.2. Assembly equipment**

The organisation shall ensure that the assembly equipment used are suitable and adequate to ensure proper secondary assembly of medical devices.

The parts that come into contact with the medical devices must not affect the quality of the medical devices and present any hazard.

Control equipment shall be calibrated and checked at defined intervals by appropriate methods. Adequate records of such tests shall be maintained.

#### **14.5. Quality control**

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.

The process of secondary assembly shall not compromise the medical device's conformance to the Essential Principles of Safety and Performance. Details of the essential principles of safety and performance can be found at *GN-16: Guidance on Essential Principles for Safety and Performance of Medical Devices*.

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

The scope of the certificate shall specify the following:

- Activities performed by the organisation + categories of medical devices handled by the organisation
- Activities (storage, warehousing, secondary assembly and distribution) that are outsourced, if applicable.
- Storage and handling conditions

*NOTE* See Annex 2 for categories of medical devices.

Applicable activities for organisation include:

- Import
- Storage
- Distribution (includes transportation)
- Installation
- Servicing (includes repair and maintenance)
- Secondary assembly

*NOTE* For organisations that are suppliers of out-sourced storage, warehousing, secondary assembly and distribution services should only have the following activities listed in the scope of their certification:

- Storage;
- Distribution (includes transportation); and/or
- Secondary assembly

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):-

- There are no special storage and handling conditions
- Cold-chain management for *in vitro* diagnostic (IVD) medical devices
- Chiller room, freezer (to indicate temperature range)

*NOTE Special storage conditions would involve special handling because devices that are stored in special conditions require special handling.*

*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.*

Following information shall be indicated in the certification:

- Address(es) of all premises of registered company, including storage facilities, and activities performed at those premises.
- Address(es) of third-party warehouse used and activities performed at that warehouse.

[R2.1 ► \[Removal – conditional certification option\] ◀ R2.1](#)

**ANNEX 2****(Normative)****Medical device categories for inclusion in scope of certification**

The certification is specific for categories of medical devices that are covered under the audit. Some replication may exist when it comes to classifying the device. For example, a device may be classified as dental device and single use device. Therefore, the category selected should be the one that is most appropriate for that medical device.

*NOTE*            *Category 11: Single-use devices is a generic category that shall be used only if all other categories do not apply to the medical device in question.*

<b>S/N</b>	<b>Term Name</b>	<b>Term definition</b>
1	Active implantable devices	<p>A category that includes devices relying on a source of power other than that directly generated by the human body or by gravity and intended to be totally or partially introduced, surgically or medically, into the human body, or by medical intervention into a natural orifice, and which is intended to remain there after the procedure.</p> <p>Examples of devices in this category are: pacemakers, implantable infusion pumps, cochlear implants.</p>
2	Anaesthetic and respiratory devices	<p>A category that includes devices and accessory devices used for supplying, conditioning, monitoring, dispensing and delivering respiratory, medical and anaesthetic gases and vapours to provide and/or controlling respiration and/or anaesthesia.</p> <p>Examples of devices in this category are: anaesthetic workstations, respiratory circuits, ventilators.</p>

S/N	Term Name	Term definition
3	Dental devices	<p>A category that includes devices for use in the diagnosis, prevention, monitoring, treatment or alleviation of oral, maxillo-facial and dental disease or disorders.</p> <p>Examples of devices in this category are: dental hand instruments, impression materials, dental amalgam, dental tools.</p>
4	Diagnostic and therapeutic radiation devices	<p>A category that includes devices which are diagnostic and/or therapeutic and use such modalities as X-rays, magnetic resonance imaging, ultrasound imaging, in vivo isotope imaging and linear accelerators.</p> <p>Examples of devices in this category are: X-ray equipment, computed tomography scanners, ultrasonic imaging devices.</p>
5	Electro mechanical medical devices	<p>A category that includes devices where the operation depends upon a source of electrical energy (electromedical), or source of energy other than that directly generated by the patient's body or gravity and which uses this energy to produce its effect or action (mechanical).</p> <p>Examples of devices in this category are: EEG, infusion pumps, monitors for haemodialysis, monitors for ECG, spring driven and elastomeric pumps.</p>
6	Hospital Hardware	<p>A category that includes devices which are not directly used in diagnosis or examinations, nor has direct influence on the clinical evaluation of the patient's condition, test results or further treatment.</p> <p>Examples of devices in this category are: sterilisers, patient transfer equipment, disinfectants.</p>

S/N	Term Name	Term definition
7	<i>In vitro</i> diagnostic devices	<p>A category that includes devices which are used for in vitro examination of samples from the human body for the purpose of determining physiological or pathological conditions.</p> <p>Examples of devices in this category are: blood glucose monitors, bilirubinometers, microbial sensitivity systems.</p>
8	Non-active implantable devices	<p>A category that includes devices other than active implantable devices which are implanted for longer than thirty days.</p> <p>Examples of devices in this category are: intra-uterine devices, heart valves, bone prostheses.</p>
9	Ophthalmic and optical devices	<p>A category that includes devices for use in the diagnosis, prevention, monitoring, treatment, correction or alleviation of eye diseases and optical malfunctions.</p> <p>Examples of devices in this category are: tonometers, intraocular lenses, slit lamps.</p>
10	Reusable instruments	<p>A category that includes devices which are used in surgery or elsewhere and are intended to be cleaned and sterilised for reuse.</p> <p>Examples of devices in this category are: retractors, haemostats, drills, saws</p>
11	Single-use devices	<p>A category that includes devices which are intended to be used only once and then disposed.</p> <p>NOTE: This also includes devices that are used more than once upon the same patient during the same procedure and then disposed.</p> <p>Examples of devices in this category are: intravenous infusion sets, condoms, laparotomy sponges, internal tissue stapling devices.</p>

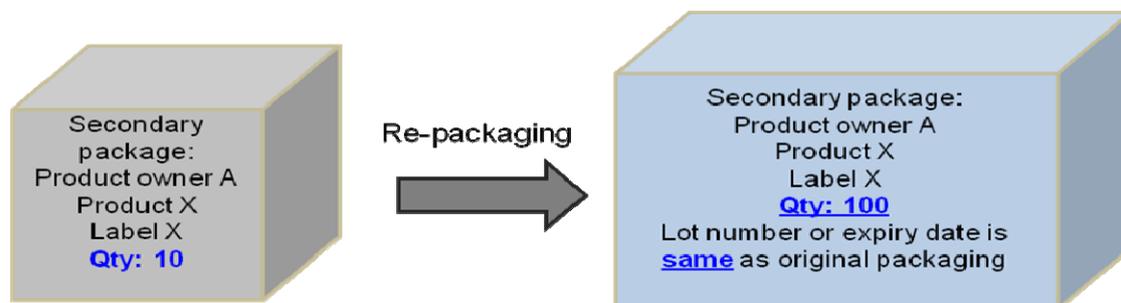
<b>S/N</b>	<b>Term Name</b>	<b>Term definition</b>
12	Technical aids for disabled persons	<p>A category that includes devices specially produced or generally available which compensate for, relieve, prevent, or neutralise an impairment, disability or handicap.</p> <p>Examples of devices in this category are: crutches, artificial limb, hearing aids, wheelchairs.</p>

## ANNEX 3

### Secondary assembly activities

1. Repackaging/assembly of medical devices (change in quantity only)

#### Example



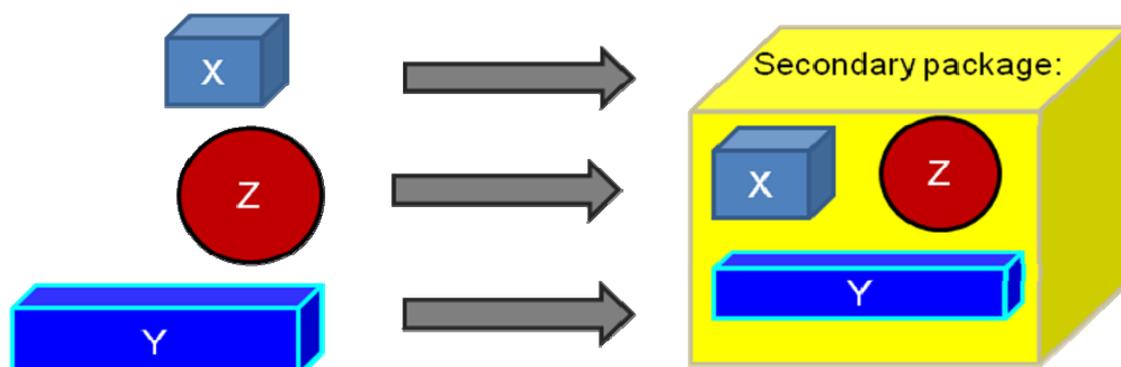
#### Restrictions

- No assignment of new expiry date, NEW product name and NEW product owner name to medical device
- No assignment of new primary label (Original primary label shall remain with individual medical devices)

*NOTE: Any expiry date indicated shall reflect the shortest expiry date in the package.*

2. Packaging/assembly of different medical devices

#### Example



#### Restrictions

- No assignment/addition of new product owner name/logo or proprietary brand name to secondary package

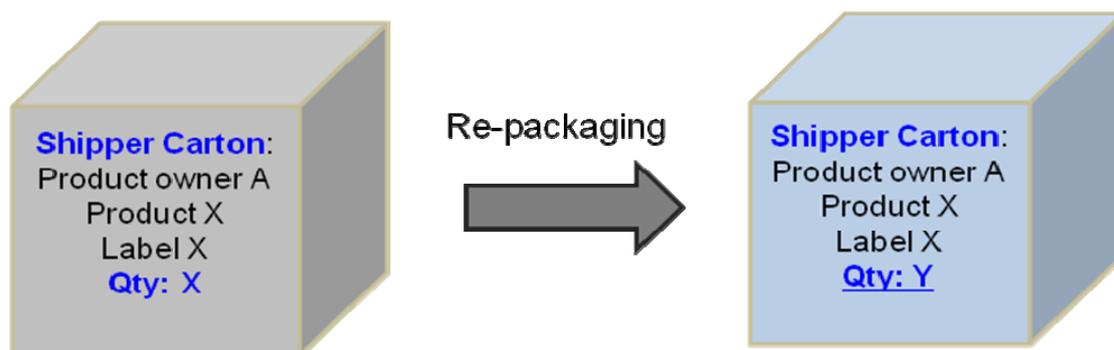
- No assignment of new primary label (Original primary label shall remain with individual medical devices)
- Secondary package label shall only contain the following:-
  - List of items in secondary package;
  - Expiry date of secondary package, based on component with shortest expiry date; and
  - Optional inclusion of statement, "Packed for <customer name>".
  - Product identifier code for secondary package.

**Manufacturing activities not deemed to be secondary assembly activities (non-exhaustive list):-**

- Assignment of new expiry date to medical device(s);
- Assignment of new brand name and/or new product owner name to medical device(s);
- Assignment of new primary label to medical device(s); or
- Sterilisation of medical device(s).

*NOTE: The change/addition of brand name and/or new product owner name constitutes a change in product owner.*

Change in quantity for shipper cartons (example provided below), intended for shipping and transportation only, is not considered a secondary assembly activity. It is not deemed a manufacturing activity in the first place.



# HEALTH SCIENCES AUTHORITY

Health Products Regulation Group  
Blood Services Group  
Applied Sciences Group

[www.hsa.gov.sg](http://www.hsa.gov.sg)

## Contact Information:

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