HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

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MEDICAL DEVICE GUIDANCE

GN-33: Guidance on the Application of Singapore Standard Good Distribution Practice for Medical Devices

Revision 1.2

HSA
Health Sciences Authority

CONTENTS

PREFACE

This document is intended to provide general guidance to SS 620: 2016 Singapore Standard for Good Distribution Practice for Medical Devices – Requirements. Although we have tried to ensure that the information contained here is accurate, we do not, however, warrant its accuracy or completeness. The Health Sciences Authority (HSA) accepts no liability for any errors or omissions in this document, or for any action/decision taken or not taken as a result of using this document. If you need specific legal or professional advice, you should consult your own legal or other relevant professional advisers.

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

REVISION HISTORY

Guidance Version (Publish Date) *[3 latest revisions]*	Revision
GN-33: Revision 1 (October 2017)	R1
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**Where applicable, changes and updates made in each document revision are annotated with or within the arrow symbol "►". Deletions may not be shown.*

0. INTRODUCTION

This document provides guidance for the application of the SS 620: 2016 Singapore Standard for Good Distribution Practice for Medical Devices – Requirements (SS GDPMDS).

It illustrates some approaches which an organisation may follow in order to implement and maintain a quality management system that conforms to the requirements of SS GDPMDS. It does not add to or change the requirements of SS GDPMDS.

It also provides useful information to certification bodies and the Singapore Accreditation Council.

Conformance to SS GDPMDS does not imply compliance to any written law; it is the responsibility of the organisation to ensure that they are in compliance with all applicable laws in force.

The following sections correspond to the various clauses in the SS GDPMDS. Refer to SS GDPMDS for the content of the respective clauses.

1. SCOPE

1.1 General

The company should develop a quality management system that conforms to the requirements of SS GDPMDS and demonstrate its ability to maintain the quality and integrity of medical devices throughout the supply chain.

1.2 Application

SS GDPMDS is applicable to importers, wholesalers and outsourced service providers dealing with medical devices in Singapore. For more information on the scope of SS GDPMDS certification, please refer to Annex A and Annex B of this document.

2. NORMATIVE REFERENCES

Refer to SS GDPMDS.

3. TERMS AND DEFINITIONS

Refer to SS GDPMDS.

4. QUALITY MANAGEMENT SYSTEM

4.1 General requirements

The quality management system established should be sufficiently robust to meet external and internal considerations such as changes in regulatory requirements, customer feedback, changes to key personnel, facilities, etc.

4.2 Documentation requirements

4.2.1 General

It is important to recognise that the structure and level of detail required in the procedures should be tailored to the needs of the organisation. It is also dependent on the methodology or approach taken to implement the SS GDPMDS requirements, and the skills and qualifications of the personnel involved in the activities.

Procedures or instructions may be presented in any form (text, graphic or audio-visual) or medium.

4.2.2 Site master file

Refer to the HSA medical devices regulatory guidance GN-03: Guidance on Preparation of a Site Master File for Licensing which is published on the HSA website.

4.2.3 Control of documents

There should be suitable control to ensure accuracy, availability, legibility and traceability of documents.

4.2.4 Control of records

The organisation should maintain all records required to illustrate their compliance to the various relevant clauses in the SS GDPMDS.

Where an electronic records system is used in place of a paper-based system, the system utilised should have built-in checks and balances to ensure the integrity of the records and to protect against unauthorised entries. The system should also incorporate audit trails for tracking changes.

Examples of records to be maintained and their expected retention periods:

SS GDPMDS clauses	Examples of records	Expected retention periods
5.3 Management review	Attendance and minutes of management review	3 years; in line with audit cycle and should be available at point of audit
6 Resource management	Training records; attendance and training effectiveness checks	At least for the period of employment and should be available at point of audit
7 Premises and facilities	Records of receipt / verification of stock	Projected useful life* of the medical device or 2 years from date of supply; whichever is longer
	Records of installation, commissioning and any test results to demonstrate proper installation	Projected useful life* of the medical device or 2 years from date of installation; whichever is longer
	Records of servicing activities	Projected useful life* of the medical device or 2 years from date of servicing; whichever is longer
8 Secondary assembly	Records for each batch of medical devices that provide traceability	Projected useful life* of the medical device or 2 years from date of assembly; whichever is longer

	Batch assembly records should be kept for each batch or part of the batch assembled	Projected useful life* of the medical device or 2 years from date of assembly; whichever is longer
9 Traceability	Delivery orders, distribution or sales records, returns and disposal records, etc.	Projected useful life* of the medical device or 2 years from date of supply and/or disposal; whichever is longer
11 Complaint handling	Records of the complaint, investigation and any subsequent actions taken	At least 5 years after the expiry of the projected useful life* of the medical device
12 Field safety corrective action (FSCA)	Records of all actions taken in connection with the FSCA and their approval by the company and regulatory authority	Projected useful life* of the medical device or 2 years from date of completion of the FSCA; whichever is longer
13 Internal audit	Records of the internal audit and the verifications of actions taken	3 years; in line with audit cycle and should be available at point of audit

* The projected useful life for medical device is determined by the product owner.

For all other types of records required by SS GDPMDS, the expected retention period should be defined by the organisation based on the type of medical device or nature of activities conducted.

5. MANAGEMENT RESPONSIBILITY

5.1 Responsibility and authority

The organisation should document job descriptions, including key responsibilities and authorities, within the Quality Management System, e.g. in the Site Master File.

5.2 Management representative

The appointment of the management representative should be documented, e.g. in the Site Master File or on an official appointment letter. Only one member of management is to be authorised as the organisation's management representative. A deputy may be appointed in the absence of the management representative.

There should be no conflict of interest between the other responsibilities and functions that the management representative performs and those relating to the quality management system.

5.3 Management review

5.3.1 General

The top management should review the quality management system on a regular basis, at least once a year to ensure that the quality management system remains effective.

5.3.2 Review input

Please refer to the sub-clause of SS GDPMDS for input to management review.

5.3.3 Review output

Management records may be in any form that suits the organisation. These include formal meeting minutes or meeting notes, which should be produced, distributed and stored on paper or electronically.

Records of the management review should include the identity of those taking part in the review, date(s) of the review and all the review input and output aspects listed in the SS GDPMDS. This includes description of any corrective or preventive action to be taken. For any action determined, the responsibility for such actions, the resources, target dates for completion, etc. should be identified.

6. RESOURCE MANAGEMENT

6.1 Personnel

The organisation should consider the experience, qualifications, capabilities and abilities of personnel who are involved in the distribution of medical devices.

Personnel working within the quality system require a certain level of competence or training (internal or external) before they can perform the tasks properly. Training may take the form of on-the-job training/coaching by supervisors, instructional briefings, courses, workshops, etc.

Special training may be necessary for personnel dealing with certain categories of substances/materials such as chemicals, biological, radiation emitting or energy source components or products, and those requiring cold chain management.

6.2 Training

Training for personnel should be tailored to the person's roles and responsibilities. Typical training and education should cover:

- nature of business;
- functions of the personnel;
- relevant policies, procedures and instructions; and
- health, safety, environmental and any other applicable regulations.

Effectiveness of the training should be evaluated to ensure competency. Evaluation may consist of assessing the trainee's feedback on the training, evaluating the work performed by the trainee after training, etc.

Records should be maintained to show the competencies that a person possesses. Examples of such records are results of training assessments and certifications.

7. PREMISES AND FACILITIES

7.1 Storage, warehousing and stock handling

7.1.1 Receipt of stock

The receiving areas should protect deliveries from damage by the external environment (e.g. rain) during unloading. The receiving area should be separated from the storage area.

7.1.2 Storage conditions

Premises used for storage, warehousing and stock handling should have sufficient security to prevent unauthorised access and misappropriation of the medical devices. Premises should protect medical devices from contamination and deterioration, including protection from excessive heat or undue exposure to direct sunlight. The storage areas should have adequate lighting and ventilation. Smoking, eating and drinking should not be permitted.

There should be adequate storage areas, and where applicable, physically separated zones for the orderly segregation of medical devices. There should be designated areas for quarantined, saleable stock, expired, rejected/damaged, recalled and returned medical devices. Alternative means of segregation may be considered if proven, to prevent mix-up.

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The storage temperature as appropriate for the medical device should be based on the manufacturer's recommendation. Where there are special storage requirements, these are typically indicated on the labels of the medical device. ◄

Temperature of the storage areas should be measured at suitable predetermined intervals to show the maximum and minimum temperatures for the day and recorded. Where applicable, humidity measurements should also be performed. Temperature monitors should be located in areas that are most likely to show fluctuations.

Medical devices requiring special storage conditions (i.e. storage conditions of 8°C and below) would require cold chain management. For more information on cold chain management of medical devices, please refer to Annex C.

Appropriate and suitable storage conditions should be provided for hazardous, sensitive and dangerous materials such as combustible liquids and solids, pressurised gases, highly toxic and radioactive substances. As there may be other applicable laws and their regulations, please check with the relevant controlling agencies to comply with the specific requirement.

7.1.3 Cleanliness

Storage areas should be kept clean and waste should be removed at regular intervals. Medical devices should be stored off the ground and suitably spaced to permit cleaning and inspection. Pallets should be well maintained and kept in a good state of cleanliness. Adequate precautions should be taken against spillage or breakage, contamination and cross-contamination.

7.1.4 Pest control

Storage areas should be set up to prevent the entry of insects, rodents and other pests/animals.

Examples of records to retain include service reports issued by third party pest control companies, records of in-house bait replacement, pest type and count.

7.1.5 Stock rotation

All records of incoming and outgoing medical devices according to batch/lot/serial number or equivalent should be maintained

Periodic stock reconciliation of medical devices should be performed by comparing the physical stock quantity against the recorded stock quantity. All

significant stock discrepancies should be subjected to investigation to check for inadvertent mix-ups and supply errors.

The expiry of the projected useful life of medical devices should be monitored to ensure that they are only supplied within their projected useful lives. Medical devices should not be received or supplied near or after the expiry date.

A system should be in place to ensure medical devices due for expiry first are sold and/or distributed first (First-Expiry-First Out, FEFO). For cases where no expiry date exists for the medical devices, FIFO (First-In-First-Out) should be applied.

All labels and containers of medical devices should not be altered, tampered or changed. Medical devices with broken seals, damaged packaging or suspected tampering/contamination should not be sold or supplied.

To prevent any inadvertent mix-up with usable stock, damaged or expired medical devices should be clearly segregated, labelled as not for use, and disposed accordingly to documented procedure.

7.2 Delivery of medical devices

Procedures should be in place to achieve safe and secure delivery of all medical devices from their point of release to their point of delivery.

Due consideration should be given to ensure adequate security and proper storage conditions during transportation of the medical devices. The transport process should not affect the integrity and quality of the medical devices. Vehicles should not be used as a storage facility for medical devices.

Medical devices should be supplied to the designated party only. Deliveries should be made only to licensed wholesalers or distributors / persons authorised to supply medical devices.

For more information on delivery of medical devices requiring cold chain management, please refer to Annex C.

7.3 Installation and servicing

7.3.1 Installation activities

Instructions and procedures for performing and verifying that the installation meets the specified requirements should be established. Only appropriately trained and qualified personnel should conduct installation of medical devices.

7.3.2 Servicing activities

Instructions and procedures for performing and verifying that the servicing (including repair and maintenance) meets the specified requirements should be established. Only appropriately trained and qualified personnel should conduct servicing of medical devices.

7.4 Calibration

The instruments used for measuring and monitoring (e.g. temperature, humidity, and electrical current) should be calibrated or verified for accuracy regularly and the results of such calibrations or verifications should be recorded and retained. Calibration should be performed by competent personnel or party.

7.5 Return of medical devices

Any product returned to the organisation should be treated as a nonconforming product until the assessment of disposition has been determined.

The returned medical devices should only be formally released as saleable stock, following a satisfactory quality re-evaluation by authorised personnel. This assessment should take into account the nature of the medical device,

any special storage conditions required, and the time that has elapsed since it was distributed. Advice should be sought from the product owner as necessary. In addition, the following should be considered:

- medical devices are in their original unopened containers and in good condition;
- medical devices have been stored and handled under proper conditions; and
- remaining projected useful life of the medical devices is acceptable to the customer.

Products that have been deemed suitable for release to saleable stock should be subject to the stock rotation system.

7.6 Disposal of medical devices

Medical devices that no longer meet specifications (for example, expired, contaminated, damaged, defective, etc.) should be disposed of properly.

Control should be established to ensure that the medical devices meant for disposal are not made available for re-supply and they are disposed off in accordance with the procedure and in line with the manufacturer's instructions, if any.

Methods of disposal may include but not limited to incineration, return to product owner, etc.

8. SECONDARY ASSEMBLY

Please refer to Annex D of this document for information on manufacturing activities that fall within the purview of secondary assembly. Manufacturing activities such as sterilisation do not fall within the definition of secondary assembly.

The Quality Management System (QMS) Requirements for all other manufacturing activities other than secondary assembly is *ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes.*

8.1 General requirements

The size of assembly area should reflect the volume of assembly. The adequacy of the working space should permit the orderly and logical positioning of equipment and materials so as to avoid confusion and to minimize the risk of mix-up between different medical devices or their components. Segregated areas should be provided for the storage of approved, quarantined, rejected, recalled and returned materials or products.

Assembly areas should be well-lit and effectively ventilated, with air handling system (including temperature, humidity and filtration controls) where appropriate. Smoking, eating and drinking should not be permitted in the assembly area.

In considering which controlled conditions are applicable for a given process, a due consideration an organisation should make is if in the absence of the control, whether there could be an adverse or potentially adverse effect on the quality of the medical device. If yes, then control is necessary.

The amount of control and level of detail should be commensurate with the degree of criticality (e.g. based on the output of risk management activities) of the process in achieving the requirements for quality and the degree of

training of personnel involved in the secondary assembly line.

8.2 Assembly documents

Any secondary assembly work instructions should include:

- name of medical device;
- description of the applicable medical devices for assembly and pack size;
- complete list of all the packaging materials required for a standard batch size, including quantities, sizes and types, with the code or reference number relating to the specifications of each packaging material;
- where appropriate, an example or reproduction of the relevant printed packaging materials, and specimens indicating where to apply batch number references, and expiry date of the medical device;
- special precautions to be observed, e.g. a careful examination of the area and equipment in order to ascertain the line clearance before operations begin;
- description of the packaging operation, including any significant subsidiary operations, and equipment to be used; and
- details of any in-process controls with instructions for sampling and acceptance limits, if applicable.

Records that facilitate traceability and review of the secondary assembly of a batch of medical device, derived during the secondary assembly of that batch, should be contained in a batch record, and frequently collated in a single file. Such files may be referred to as a “Device History Record”, “Batch Assembly Record”, “Lot History Record” or “Lot Record”.

If it is not practical to include all the relevant documents in the batch record, then the record should list the titles of those documents and their location(s).

During secondary assembly, relevant information should be entered into the batch record. Such information should include:

- quantity of raw materials, components and intermediate products, and their batch number, if appropriate,
- date of start and completion of different stages of secondary assembly;
- quantity of medical device assembled;
- signed results of all inspections and tests;
- designation of the product line used; and
- deviation from the secondary assembly specifications, if applicable.

Data may be recorded by electronic data processing systems, photographic or other reliable means, but detailed procedures relating to the system in use should be available and the accuracy of the records should be checked.

If documentation is handled by electronic data processing methods, only authorised personnel should be able to enter or modify data in the computer and there should be a record of changes and deletion; access should be restricted by passwords or other means and the result of entry of critical data should be independently checked.

Batch records electronically stored should be protected by back-up transfer on magnetic tape, microfilm, paper or other means. It is particularly important that the records are readily available and to ensure their integrity throughout the period of retention.

Records of batch/lot numbers and identities of all individual medical devices that are re-packaged or assembled during the secondary assembly process should be recorded and maintained to allow for traceability. Distribution records should be maintained for each batch of medical device in order to facilitate the recall of the batch if necessary.

8.3 Materials control

8.3.1 Medical devices to be repacked

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Medical devices should only be purchased from approved suppliers and, where possible, directly from the manufacturer. A batch certificate of analysis or equivalent document with key information on the specifications of the medical device being re-packed should be obtained from the supplier for each batch of medical device to be re-packed. Inspection of breached primary packages should be performed. Any breached packages should be disposed of and should not be re-processed and returned to the secondary assembly line. ◄

Reference materials may be physical or visual, such as product examples indicating permissible colour variation, or visual such as photos of known non-conformities. Reference materials should be available at the point of use. An individual procedure may be in the form of a simple flowchart, or a processing sequence, combined with a checklist.

8.3.2 Packaging materials

Particular attention should be paid to printed materials. They should be stored in adequately secure conditions so as to exclude unauthorised access. Cut labels and other loose printed materials should be stored and transported in separate closed containers so as to avoid mix-ups.

Packaging materials should be issued for used only by authorised personnel following an approved and documented procedure. Each delivery or batch of printed or packaging materials should be given a specific reference number or identification mark.

Outdated or obsolete packaging material or printed packaging material should be destroyed and the disposal should be recorded.

8.3.3 Medical device labelling

The appropriate marketing authorisation of the medical device to be assembled and the labelling and other requirements imposed by the regulatory authority on these products as part of the marketing authorisation, should be complied with, and where necessary, the approval of the marketing authorisation holder and/or regulatory authority should be sought.

The risk of labelling and packaging errors may be minimised by the introduction of appropriate controls such as:

- segregation of secondary assembly (e.g. packaging and labelling) operations from other operations;
- avoidance of packaging and labelling products of similar appearance in close proximity;
- secondary assembly line identification;
- application of line clearance procedures;
- destruction of unused batch-coded materials on completion of packaging and labelling;
- use of roll-feed labels;
- use of a known number of labels and reconciliation of usage;
- on-line printing, including batch coding;
- use of electronic code encoders/readers and label counters;
- use of labels designed to provide clear product differentiation;
- inspection of label content before use; and
- proper storage of labels in areas of restricted access.

8.4 Good assembly practices

8.4.1 Special considerations

On-line control of the product during packaging should include checking of the following:

- general appearance of packages;
- completeness of packages;

- correctness of products and packaging materials used; and
- correctness of over-printing, e.g. batch number, shelf life/expiry date.

Upon completion of a packaging operation, any unused batch-coded packaging materials should be destroyed and the destruction recorded. Any significant or unusual discrepancy observed during reconciliation of the amount of bulk product and printed packaging materials and the number of units produced should be investigated and satisfactorily accounted for before release. A documented procedure should be followed if uncoded printed materials are returned to stock.

Where any packaging process validation applies, the study should be carried out in accordance with pre-defined and authorised protocols.

8.4.2 Assembly equipment

Suitable equipment should be designed and selected so that process and product specifications are met. It should be verified that new and/or significantly modified equipment meets purchasing/design specifications and is capable of operating within its defined limits and process operating limits.

Before any assembly begins, line clearance should be carried out. There should be recorded checks that the equipment and work station are clear of previous products, documents or materials not required for the planned process, and that equipment is clean and suitable for use.

Each batch of medical device produced should be assigned a unique batch number. Normally, packing and sealing should be followed as quickly as possible by labelling. If it is not the case, appropriate procedures should be applied to ensure that no mix-ups or mislabelling can occur.

The performance of the printing operation should be checked and recorded. Attention should be paid to printing by hand which should be re-checked at

regular intervals. Printed and embossed information on packaging materials should be distinct and resistant to fading or erasing.

8.5 Product release

There should be authorised and independent personnel in charge of product release. If sampling of the final finished pack is performed, the samples taken should be done in accordance with approved written procedures that describe:

- method of sampling;
- equipment to be used;
- quantity of samples to be taken;
- special storage condition for the samples taken, if applicable; and
- recording of the results of in-process control.

9. TRACEABILITY

Traceability of medical devices in the distribution chain is important as it is necessary to track medical devices to the customer (e.g. clinics or hospitals) in the event of a field safety corrective action (FSCA). Traceability allows for investigation of quality-related problems and identification of other possible nonconforming medical devices. Identification of medical device by batch/lot/serial number permits end-to-end traceability, i.e. upstream to the manufacturer and downstream to the customers/disposal.

Records providing traceability may include delivery orders from the supplier, distribution or sales records, returns and disposal records, etc. To facilitate traceability, the records should include the date, lot/batch/serial number, quantity, name of medical device, address of the supplier and customer. For more information on distribution records, please refer to GN-06: Guidance on Distribution Records for Medical Devices which is published on the HSA website.

10. COUNTERFEIT, ADULTERATED, UNWHOLESOME OR TAMPERED MEDICAL DEVICES

Reporting should be performed using the Medical Device Post-Market Information Report Form once the organisation becomes aware of possible counterfeit, adulterated, unwholesome or tampered medical devices. Key information (i.e. brand, place and period of purchase) should be provided in the form, to assist in the detection of counterfeit medical devices supplied in Singapore.

Appropriate measures should be undertaken for identified counterfeit, adulterated, unwholesome or tampered medical devices, which include, but are not limited to the following:

- reporting to the regulatory authority;
- segregation/quarantine of the affected medical devices, labelling them “Not for Use” or with other similar phrases/words;
- investigation of supply chain breach; and
- communication to all affected wholesalers / distributors / retailers / consignees possibly supplied with the affected medical devices (prior notification to the regulatory authority is required for such communication)

11. COMPLAINT HANDLING

A procedure describing the handling of all written and oral complaints regarding a medical device should be available. The procedure for handling complaints should ensure that the complaints received are investigated, followed through, and that corrective and preventive actions are taken. For more information on complaint handling, please refer to the GN-07: Guidance on Complaint Handling of Medical Devices which is published on the HSA website.

A person within the company should be authorised to handle complaints and initiate investigations. All investigations should be documented in writing. Complaint investigation should take into consideration the condition and circumstances under which the medical device was distributed, stored and used. An investigation report should be prepared.

All applicable corrective and preventive actions should be clearly stated. If a medical device defect is detected or suspected, a review of all potentially affected batches should be considered. Where a decision is made to recall the medical device, the details of the recall should be documented. For more information on medical device recalls, please refer to the GN-04: Guidance on Medical Device Recall which is published on the HSA website. When the complaint is an adverse event related to a medical device, the regulatory authority must be notified promptly in accordance to GN-05: Guidance on Reporting of Adverse Events for Medical Devices which is published on the HSA website.

Individual complaint records should be maintained. Complaints records should be trended and reviewed regularly for any indication of specific or recurring problems requiring attention.

12. FIELD SAFETY CORRECTIVE ACTION (FSCA)

Once the product owner initiates the FSCA and affected medical devices have been supplied in Singapore, the implementation of the FSCA should not be delayed.

Prior to the initiation of the FSCA in Singapore, it is a requirement that the FSCA is notified to the regulatory authority. After the notification, the dealer may proceed to initiate the FSCA or conduct stock recovery unless otherwise instructed by the regulatory authority. Dissemination of the product owner's Field Safety Notice (FSN) and implementation of the corrective actions listed in the FSN are some measures (but not limited to) that constitute initiation of the FSCA.

Where the FSCA affects a particular batch, consideration should also be given to determine whether other batches/materials are also affected.

Upon completion of each FSCA, a final report should be provided to the regulatory authority. Reconciliation should be made between delivered and recovered quantities of medical devices. More information on FSCA is available in GN-10: Guidance on Medical Device Field Safety Corrective Action which is published on the HSA website.

13. INTERNAL AUDIT

Internal audits should be conducted on a regular basis, at least once a year, and recorded in order to monitor the implementation and conformance with the requirements of the SS GDPMDS.

The results of the audits are usually stated in a written report indicating the nonconformities found. Timely action should be taken to correct/eliminate the nonconformities and their root causes. The audit results and the status of the

nonconformities should be communicated to management for review and be monitored till effective closure is achieved.

The organisation should identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system.

14. OUTSOURCED ACTIVITIES

All service provider of outsourced activities should be audited by the certification body unless they are already certified to this standard. Certification bodies will normally conduct an on-site audit for service providers of storage and secondary assembly.

The organisation should control and review the outsourced activities as part of its internal audit. The organisation is ultimately responsible to put in place processes to assure the control of outsourced activities.

Prior to outsourcing activities, the organisation is responsible for assessing the suitability and the competence of the service provider to carry out the outsourced activities. When monitoring the performance of the service provider, the organisation should consider compliance trends and conformance history. The performance of the service provider should be monitored on a regular basis.

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Certain activities relating to cleaning, pest control, installation and servicing, calibration and transportation may be outsourced to third party service providers. The service provider shall be audited as part of the internal audit of the organisation if they have not been certified to this standard.

For outsourced activities relating to storage, warehousing, stock handling and secondary assembly, the service provider of outsourced activities shall be

audited by the certification body as part of organisation's system unless they are already certified to this standard. ◄

For outsourced activities covered under Clause 7 (Premises and facilities) and Clause 8 (Secondary assembly) of the SS GDPMDS, there should be a written contract to define the roles and responsibilities of each party, technical specification and contractual agreements to avoid any misunderstandings which could result in a product or work of unsatisfactory quality. Technical specification may include any special storage and handling conditions for storage or transportation, or packing configuration of medical devices to be assembled.

REFERENCES

1. Guidance Notes on Good Distribution Practice, Health Sciences Authority, August 2015.
2. Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products, World Health Organization Technical Report Series No. 961, 2011.
3. PIC/S Guide to Good Distribution Practice for Medicinal Products, 1 June 2014.
4. Singapore Standard Good distribution practice for medical devices – Requirements, Spring Singapore, SS 620: 2016.
5. US Pharmacopeia <1118> Monitoring Devices – Time, Temperature and Humidity.

ANNEX A

The scope of SS GDPMDS certification shall specify the following:

(A) Activities performed + categories of medical devices handled by the organisation

- Applicable activities for organisation include:
  - Import
  - Storage
  - Distribution
  - Installation
  - Servicing
  - Secondary assembly

- Refer to Annex B for categories of medical devices.

(B) Activities that are outsourced

The name and address(es) of outsourced service providers for storage, distribution and secondary assembly.

(C) Any special storage and handling conditions

For organisations with facilities to handle medical devices requiring cold chain management (storage conditions of 8°C and below), the following statement shall be provided:

- There are special storage and handling conditions.

For organisations without facilities to handle medical devices requiring cold chain management, the following statement shall be provided:

- There are no special storage and handling conditions.

ANNEX B

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 medical device. For example, a medical 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.

Name	Definition
01 Active implantable devices	Devices that operate with an integral power source (i.e., independent of energy from the human body or gravity), that are totally or partially introduced, surgically or medically, into the human body or body-orifice, where they are intended to remain temporarily or permanently. Examples of devices in this category include cochlear implants, implantable defibrillators, implantable infusion pumps, implantable stimulators, pacemakers, and their accessories.
02 Anaesthetic and respiratory devices	Devices used to supply, condition, monitor, dispense, or deliver respiratory or anaesthetic gases, vapours or other substances to provide and/or control respiration and/or anaesthesia. Examples of devices in this category include airways, anaesthesia systems, breathing circuits, humidifiers, tracheal tubes, ventilators, and their accessories.
03 Dental devices	Devices used to diagnose, prevent, monitor, treat, or alleviate oral, maxillo-facial, and dental disease/disorders. Examples of devices in this category include dental amalgam, dental cements, dental hand instruments, dental implants, dental materials, dental tools/laboratory devices, and their accessories.
04 Electro mechanical medical devices	Devices that operate on electrical energy (electromedical) and/or through some integrated physical mechanism or machinery (mechanical). Examples of devices in this category include specialized beds, defibrillators, dialysis systems, electrocardiographs (ECG), electroencephalographs (EEG), endoscopes, infusion pumps, lasers, operation/examination tables/lights, suction systems, and their accessories.
05 Hospital hardware	Treatment-related devices that typically are not directly or actively involved in the diagnosis or treatment of patients, but that support or facilitate such activities. Examples of devices in this category include disinfectants for medical devices, patient beds, patient transfer equipment, sterilisers, and their accessories.

06	In vitro diagnostic devices	Devices used to examine clinical samples taken from the human body to evaluate physiological or pathological conditions. Examples of devices in this category include analysers, blood glucose monitoring devices, in vitro diagnostic (IVD) test kits/calibrators/controls, dedicated laboratory equipment, microbial sensitivity systems, and their accessories.
07	Non-active implantable devices	Devices without an integral power source that are totally or partially introduced, surgically or medically, into the human body or body-orifice, where they are intended to remain for longer than 30 days. Examples of devices in this category include cardiovascular clips, embolization implants, orthopaedic fixation systems, intrauterine devices, heart valves, bone prostheses, and their accessories.
08	Ophthalmic and optical devices	Devices used to diagnose, prevent, monitor, treat, correct, or alleviate diseases or disorders related to the eye. Examples of devices in this category include contact lenses, keratomes, intraocular lenses, slit lamps, ophthalmic test instruments, phacoemulsification systems, tonometers, and their accessories.
09	Reusable devices	Devices that can be used for more than one application period, often involving cleaning and/or sterilisation between the periods (excluding capital equipment). Examples of devices in this category include drills, elastic bandages, haemostats, medicine administration kits, saws, scar management garments, reusable surgical instruments (chisels, scissors, retractors, scalpels), and their accessories.
10	Single-use devices [#]	Devices intended to be used only once, or for only one patient during one medical procedure or short term, and then discarded if not already rapidly absorbed. Examples of devices in this category include adhesive tapes, bandages, blood collection devices, catheters, condoms, dressings, electrodes, kits/sets (biopsy, intravenous infusion), needles, single-use surgical instruments/products (cannulae, scalpels, absorbents), and disposable bedding.
11	Assistive products for persons with disability	Devices specially produced or adapted which compensate for, relieve, prevent, or neutralize an impairment, disability, or handicap. Examples of devices in this category include artificial limbs, audiometers, crutches, hearing aids, patient lifts, wheelchairs, and their accessories.
12	Diagnostic and therapeutic radiation devices	Devices that use radiation energy including in vivo isotopes, excited particle energy, magnetic resonance imaging, nuclear energy, ultrasound, and x-ray for the purpose of providing diagnostic imaging and/or therapeutic radiation treatment. Examples of devices in this category include accelerator systems, bone absorptiometric systems, computed tomography (CT) systems, magnetic resonance imaging (MRI) systems, positron emission tomography (PET) systems, X-ray systems, and their accessories. Radiant warming and phototherapy devices are excluded.

13	Medical software	Computer programs and related data designed for use in a parent medical device, or as a stand-alone medical device, intended to provide a variety of functions such as: to help drive and/or influence a process or procedure, manage [data manipulation (e.g., calculations)], assist in analysis of data. It is typically supplied pre-installed in a parent device, or as an update, or is installed on an electronic medium for installation into an existing computer(s)/network or Internet-based software. Examples of devices in this category include application program software, diagnostic digital imaging systems, IVD software, and web-based software.

[#] *Category 10: 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.*

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ANNEX C

Cold Chain Management

(1) Introduction

This annex is meant to provide guidance on the cold chain management of medical devices in relation to the SS GDPMDS.

Cold chain medical devices refer to those which require special storage and handling conditions of 8°C and below (e.g. refrigeration at 2°C to 8°C, deep freeze at below -15°C). The storage condition requirements are usually described on the product label.

(2) Documentation requirements

Procedures for receiving, storage and delivery should include instructions on the special storage and handling of medical devices requiring cold chain management.

There should be a written procedure for investigation and handling temperature excursions that may occur during receiving, storage and delivery. All records should be readily retrievable to enable early detection of temperature excursions. Temperature excursions or any possible product damage should be reported to the distributor and recipient of the affected medical devices.

(3) Personnel and Training

Specific training in cold chain management should be provided to all personnel, including delivery drivers, who are involved in operations that may affect the quality of cold chain medical devices. The training procedure should describe the training program required for personnel involved with cold chain management, and training records for relevant personnel should be retained.

(4) Receipt of stock

a) Immediate identification of cold chain medical devices:
- A list of cold chain medical devices handled by the company should be available for reference by the personnel involved in receiving goods and other relevant store personnel.
- Cold chain medical devices should be prioritised and transferred to the appropriate storage facilities immediately upon receipt.

b) Appropriate handling of cold chain medical devices:
- Products transported in insulated boxes with cool-packs should be unpacked before storage in the cold room as internal temperature of such insulated boxes can drop below its minimum temperature allowable if kept in the cold room for extended periods.
- Checks on incoming goods for signs of tampering, damage and non-compliance with cold chain storage condition, as well as other relevant information against the purchase order should be carried out under the storage conditions as recommended on the product label unless otherwise justified.
- If temperature loggers are used to monitor the temperature of the medical devices during transportation, the temperature profile provided by the temperature loggers should be kept as records to show that the medical devices were transported under the required storage conditions. Any excursions should be investigated and the impact on the quality of the medical devices assessed.
- Records of all checks performed should be kept.

(5) Storage conditions

a) Storage facilities:
Storage facilities for cold chain management include refrigerator, freezer and walk-in cold room. The facility should be able to provide adequate temperature controls for all areas used for storing products, as determined by a temperature mapping exercise. The storage conditions should be monitored and recorded continuously and installed with an alarm system to alert the relevant personnel to any temperature excursions.

A maintenance program should be in place to ensure the functioning of the facility and in case of power failure, backup power supply or alternative storage solutions should provide means to maintain the storage conditions.

b) Temperature mapping:
An initial temperature mapping exercise should be carried out on the facility under representative conditions. The mapping exercise should be repeated for significant changes according to the results of a risk assessment exercise. Temperature monitoring and recording instruments should be placed in various locations within the facility and monitored for a representative period of time, usually under the worst-case scenarios, e.g., areas that experience extreme fluctuations in temperature or the hottest time of the year. The results should be analysed to determine if all parts of the facility are able to meet the storage requirements and to identify the hottest and coldest spots, and other suitable locations for routine temperature monitoring.

c) Temperature monitoring and recording:
Acceptable temperature ranges for the storage conditions should be established based on the storage requirements of the medical devices. The routine monitoring should be taken from suitable locations identified from the temperature mapping exercise, unless otherwise justified.

The temperature conditions of the storage facility should be monitored and recorded continuously using temperature monitoring and recording instruments. As far as possible, the actual storage temperature recorded should be expressed quantitatively. Temperature monitoring records should be checked and independently reviewed regularly.

d) Alarm system:
The storage facility should be installed with an alarm system to notify relevant personnel of any temperature excursions so that appropriate corrective or preventive actions can be initiated in a timely manner. Action and alert limits should be established based on the pre-defined storage conditions. The correct function of the alarm system should be subject to periodic testing.

e) Backup power:
Backup power should be available for the storage facility to ensure that storage temperature conditions can be maintained and temperature monitoring and recording instruments will continue to function in the event of a power failure. Any backup generators used should be subject to periodic testing. Alternative backup plans that provide equivalent storage temperature conditions and monitoring system may be considered in the absence of backup generator.

f) Maintenance program:
A regular maintenance programme should be established and carried out for the air-conditioning system of the storage facility. For storage facilities with auto-defrost function, precautionary steps should be taken to ensure that the storage temperature is not affected during the defrost cycles.

(6) Delivery of medical devices

Medical devices requiring special storage conditions should be transported by appropriate and suitable means to ensure that the required temperature conditions are maintained throughout delivery. Transportation providers should be informed of the special storage requirements for cold chain medical devices. The planning of the delivery route should be taken into consideration in the procedure for the delivery of cold chain medical devices. Where the transportation route includes unloading and reloading or transit storage at a transportation hub, particular attention should be paid to temperature monitoring, cleanliness and the security of any intermediate storage facilities.

a) Thermal packaging and insulated boxes:
- Insulated boxes should be accompanied with temperature loggers which can monitor and record the temperature within each box throughout the delivery. Alternatively, if temperature loggers are not used, the delivery conditions using insulated boxes should be validated by simulating the possible worst-case scenarios during transportation to show that the desired temperature can be maintained under those conditions.

- Based on the validation study, there should be written procedures to describe the packing materials, packing configuration of the insulated boxes, labelling on the product that clearly identifies the required special storage/transport conditions and acceptable delivery time required for the cold chain medical devices.

- The packing operation for the cold chain medical devices should be recorded and there should be an independent check to ensure that the packing operation is carried out in accordance with the written procedure. The records for check should be kept.

- If cool-packs are used in insulated boxes, they should be located such that the product does not come into direct contact with them. There should be a system in place to control the reuse of cool packs to ensure that incompletely cooled packs are not used in error. There should be adequate physical segregation between frozen and chilled cool-packs.

- Special care should be exercised when using dry ice during transportation. Products should not come into direct contact with dry ice as this may cause freezing of the product.

b) Temperature-controlled vehicles or transportation containers:
- If refrigerated vehicles or transportation containers provide the primary means for environmental control, temperature mapping under representative conditions should be carried out. The storage conditions within the refrigerated vehicles or transportation containers used for cold chain medical devices should be monitored and recorded with calibrated temperature monitoring and recording instruments.

(7) Calibration

Key equipment in cold chain management include cold rooms, air handling units, alarm system, refrigerators, temperature monitoring and recording instruments etc. Adequate records of repair, maintenance and calibration activities for key equipment should be maintained.

Temperature monitoring and recording instruments should be calibrated regularly to show that they are operating correctly. The frequency of calibration should be determined based on a risk assessment. A minimum of three-point calibration to cover the operating range and carried out annually is preferred. Certificates of calibration should be traceable to national or international standards and are reviewed and maintained.

(8) Return of medical devices

There should be procedures established to describe how return of cold chain medical devices should be handled. Return of cold chain medical devices to saleable stock is not advisable unless there is sufficient evidence to demonstrate that the cold chain and quality of the medical devices has not been compromised.

Records of evaluation should include documentation of the complete trail of the medical devices, including but not limited to the delivery to customer, opening of the package by customer, delivery back to the distributor and receipt of returned medical devices by the distributor.

(9) Secondary assembly of cold chain medical devices

The secondary assembly of cold chain medical devices should be carried out under the storage conditions as recommended on the product label unless otherwise justified by stability studies that such operations can be performed outside the recommended storage condition within an established timeframe do not compromise the quality of the medical devices.

(10) Outsourced activities

Written contract(s) should be established to describe arrangements and responsibilities between the company and the outsourced service provider with respect to contract warehousing, secondary assembly and transportation of cold chain medical devices. The contract should provide all the necessary information and define the conditions required for the contracted operations to be carried out.

ANNEX D

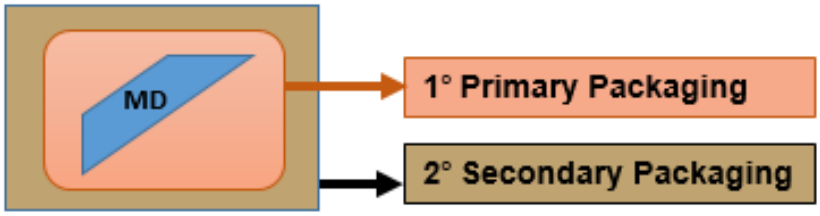
R1.1 ►

Secondary assembly:

‘‘secondary assembly’’ means enclosing the medical device(s) in its primary packaging, into another container or packaging material in which it is to be sold or supplied, without any breach of the primary packaging.

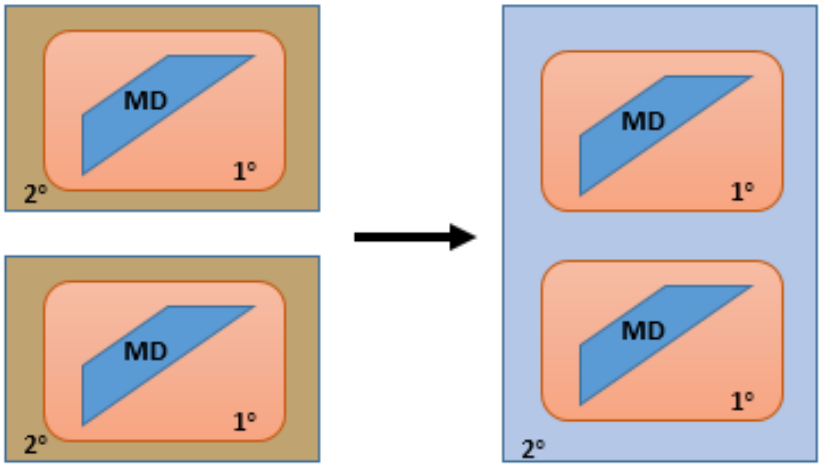
Any labelling information on the secondary packaging, where applicable, shall be aligned to the labelling on the primary packaging and as approved by the regulatory authority for the medical device.

‘‘primary packaging’’, in relation to a medical device, means packaging that maintains the sterility or integrity of the medical device. This maintains the wholesomeness of the medical device. Typically the appropriate packaging for a medical device is determined and validated by its manufacturer to ensure that it is effective in maintaining the sterility and wholesomeness of the medical device throughout its shelf life.

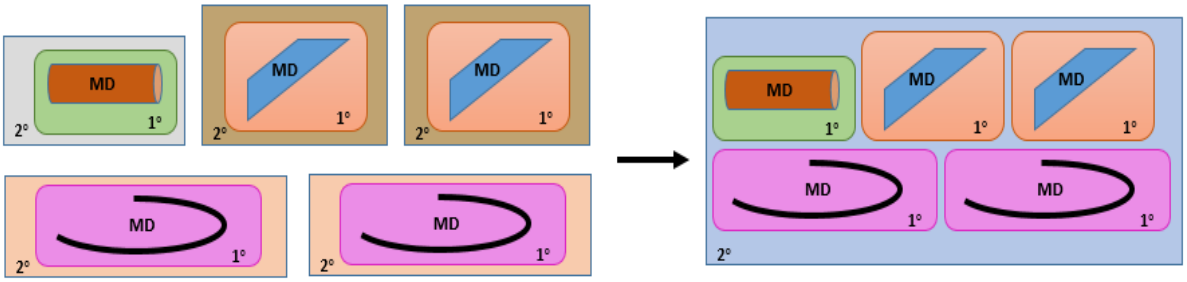


Examples of secondary assembly

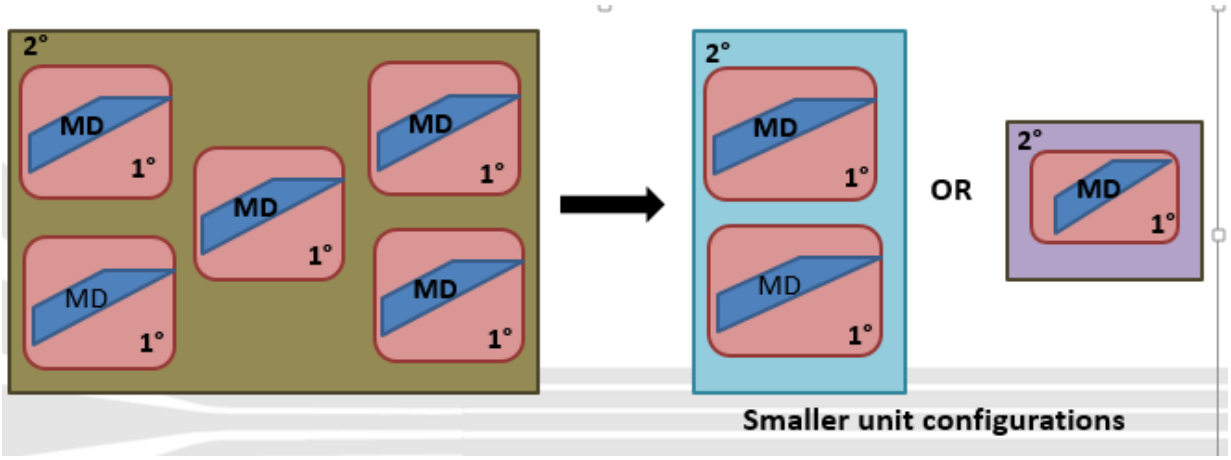
1. **Repackaging of single units of single type medical device into multiple unit configuration.**



2. **Repackaging of single units of different medical devices into multiple unit configuration.**



3. Break-pack of multiple unit configuration of medical devices into smaller unit configurations.



Break-pack and repackaging as reduced number of medical device units or as single medical device units typically to meet local user demand for cost-effectiveness or usability.

Points to Note:

- No breach of the original primary packaging of the individual medical devices and no assignment of new primary label (original primary label shall remain with individual medical devices).
- All information on the label of the new secondary packaging, where applicable, shall be aligned to the labelling on the primary packaging and as approved by the regulatory authority for the medical device.
- No assignment of new expiry date, new product name, new product owner name or any other new information related to the identity or use of the medical device on the new repackaged format of the medical device.
- Any expiry date indicated on the repackaged unit containing different medical devices shall reflect the shortest expiry date based on the expiry dates of the individual medical devices in it.

What is not secondary assembly:

1. **Repackaging of medical device units enclosed within original intact/sealed packaging into additional cartons intended for shipping and transportation purposes only.**

2. **Manufacturing activities which are 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)

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HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

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