Medical Device Administrative Control System (MDACS)

Guidance Notes for

Listing of Distributors of Medical Devices

Guidance Notes: GN-09

中華人民共和國
香港特別行政區政府衞生署

Department of Health
The Government of the Hong Kong Special Administrative Region
The People's Republic of China

Revision History

Edition Number	Date of Revision	Summary of Revision	Reference Number
0	30 April 2015	First issue of GN-09	GN-09:2015(E)
1.0	19 April 2021	● Revised Clause 1 - Introduction. ● Added Clause 2 - Scope ● Revised the definition of Distributor and Documented Procedure in Clause 3 - Definition ● Merged Clause 4 and 6 in Edition Number 0 into Clause 4 – Application procedures ● Revised the requirements for premises in Clause 5 – Requirements for listing of distributors ● Added Appendix I for the guidance on requirements for listing of distributors	GN-09:2021 (E)

Table of Contents

1. Introduction

1.1 This document provides general guidance to applicants applying for listing as distributors under the Medical Device Administrative Control System (MDACS).

1.2 Recognising the importance of distributors in the medical device supply chain and medical device post-market phase, the Medical Device Division (MDD) maintains a List of Distributors under the MDACS.

1.3 Application for listing as a distributor is entirely on a voluntary basis.

2. Scope

2.1 Distributors of medical devices may apply to be included on the List of Distributors if they distribute any of the medical devices in Hong Kong.

3. Definitions

3.1 For the purposes of this document, the following definitions and those given in the Guidance Notes issued by the Medical Device Division (MDD) are applicable:

3.1.1 Distributor means any legal person (other than a manufacturer, an importer or a retailer) in the supply chain who carries on business of distributing medical devices in Hong Kong either on his own behalf or to another distributor.

Notes: The following are exempted from the scope of listing as distributors:

(a) A person who purchases or receives medical device(s) exclusively for one's own personal use;

(b) Retailer who supplies a medical device, or provides a service utilising a medical device, solely and directly to the end user;

(c) Health care facility or provider that provides diagnostic or therapeutic services to patient(s) or individual(s);

(d) A business party which purchases or receives medical device(s) solely for use by its employees during work activities (e.g. first aid kits and disposable gloves) or for incidental emergency use as long as one is not in the business of offering healthcare service(s) to employees or

other individuals; and

(e) A person in the supply chain involves in activities such as storage and transport of medical devices on behalf of the manufacturer, importer, distributor or Local Responsible Person (LRP).

3.2 Documented procedure means standard operating procedure (SOP) that requires to be established, implemented and maintained.

4. Application procedures

4.1 The applicants for listing as distributors are required to complete the application form MD-IP+D and send it to the MDD together with the following documents:

4.1.1 A copy of business registration certificate in Hong Kong; and

4.1.2 A copy of documented procedures as specified in Clauses 5.3 - 5.9; or a copy of ISO 13485 or ISO 9001 certificate for their business covering the documented procedures as specific in Clauses 5.3 - 5.9 and a copy of the quality manual.

4.2 The application form MD-IP+D for listing of distributors under the MDACS can be obtained from the MDD or downloaded from the MDD website. Applicants may use this application form to apply for listing of importers concurrently. The Guidance Notes GN-07 (Guidance Notes for Listing of Importers of Medical Devices) provides details about requirements for listing of importers.

4.3 Submission of applications (by hard copies)

4.3.1 An application for listing of distributor must be made with the application form. The completed form in original copy shall be submitted together with a submission folder containing copies of all the required documents indexed in accordance with the order of the documents as given in the “Enclosure” column shown in the application form. The originals of these documents are only required for validation upon request by the MDD and they shall not be submitted together with the application form or enclosed in the submission folder. The application form and all documents submitted, including enclosures in the submission folder, will not be returned to the applicant regardless of whether the application is successful. The submission shall be

made by hand or by registered mail to the MDD.

4.4 Submission of application (by soft copies)

4.4.1 The applicants are encouraged to use soft copies for submission of applications as far as possible. If a submission is made using soft copies, only the duly signed application form (original copy) has to be submitted in paper format. The signed application forms, together with a portable storage device (PSD) containing soft copy of other required documents, shall be submitted by hand or by recorded delivery mail to the MDD. Alternatively, an applicant with Hongkong Post e-Cert may submit an application entirely by soft copies (i.e. both the completed application form and the other documents in soft copies) to the email address mdd_app@dh.gov.hk of the MDD.

4.5 Acknowledgement of application

4.5.1 On receiving an application, the MDD will send an acknowledgement receipt if no obvious problem or outstanding item has been identified after an initial checking of the application. If an applicant does not receive any acknowledgement receipt or any notification within two (2) weeks after submitting an application, he/she may contact the MDD to check if the submission has reached the MDD.

4.6 Submission of documented procedures

4.6.1 The documented procedures stipulated in Clauses 5.3 - 5.9 shall be submitted together with the completed application form. These procedures are considered essential for the evaluation of an application. The listed distributor should establish its own procedures taking account of the workflow, operations, nature of medical devices, reporting and follow up requirements, organisation structure and needs of its own organisation. If necessary, the applicant may be requested to provide documentary evidence such as relevant documents/agreements signed with the LRPs/manufacturers/importers on the role and arrangement for the establishment and implementation of such documented procedures.

4.7 Each application for listing as a distributor will be subject to processing and vetting by the MDD before it is considered by the Distributor Listing Approval Board. The

Board will decide whether to approve or reject the application or remit the application for further processing.

4.8 The processing of an application will include, but not limited to, the checking of the submitted application for adequacy and accuracy of the information and supporting documents provided by the applicant. Where necessary, the MDD may request the applicant to provide supplementary information or additional documents in support of its application.

4.9 The MDD will only proceed with the application if, and only if, the "Undertaking by Applicant" in the application form has been duly completed and signed by or on behalf of the applicant.

4.10 The processing and approval of an application will normally be completed within twelve (12) weeks, provided that a properly completed application form (which must include inter alia a duly completed and signed "Undertaking by Applicant"), together with all the necessary supporting documents, have reached the MDD.

5. Requirements for listing of distributors

5.1 Premises and equipment

5.1.1 The distributors shall have properly manned premise(s) in Hong Kong where distribution of medical device(s) are carried out. Where appropriate, premises should include, but not limited to, office, receiving area, storeroom, medical device maintenance area (if any) and dispatching area.

5.1.2 Actions should be taken to prevent unauthorized persons from entering the premise(s).

5.1.3 Storeroom should be of sufficient capacity to allow the orderly storage of the various categories of medical devices.

5.1.4 Storeroom should be clean, and free from accumulated waste and vermin. Cleaning records should be kept. There should be pest control measures to prevent pest infestation. Records of any pest control measures taken shall be kept. There should be appropriate programme for the clean-up of any spillage to ensure complete removal of any risk of contamination.

5.1.5 Storage conditions for medical devices should be in compliance with the instructions on the label.

5.1.6 Recorded temperature and appropriate humidity monitoring data should be available for review and inspection. The equipment used for monitoring should be checked at suitable predetermined intervals and the results of such checks should be recorded and retained.

5.1.7 Equipment used for monitoring of storage conditions or measuring equipment used for determining of product quality should be calibrated and maintained at defined intervals. Relevant records should be kept.

5.2 Establishment, implementation and maintenance of procedures

5.2.1 The distributors are required to have documented procedures to cope with distribution and post-market activities. Distributors are encouraged to implement quality management systems covering the full scope of their operations that are related to the MDACS. The documented procedure should be in conjunction with the respective Local Responsible Persons (LRPs), or manufacturers if there is no LRP.

5.2.2 Records shall be established and maintained to provide evidence of conformity to the requirements and the effective implementation of the procedures. The listed distributor shall document the procedures to define the controls needed for the identification, storage, security and integrity, retention time and disposition of records. The listed distributor shall also retain the records for a period of time not less than the lifetime of the medical device as defined by the manufacturer, or seven (7) years from the date of product distribution, whichever is longer.

5.2.3 All operation procedures and records related to the handling and control of medical devices shall be reviewed regularly and documented. In the event of irregularities and/or deficiencies found in the operation procedures and record keeping, the causes of irregularities and/or deficiencies shall be investigated and corrective and/or preventive actions shall be taken and documented.

5.3 Keeping of supply records

5.3.1 The distributor shall have documented procedures for keeping of supply records and maintain an updated list of all the medical devices distributed. The supply records should include the make, model, batch number, serial number, quantity of medical devices, as appropriate. Such records should

contain sufficient information to trace the distributed medical device(s) and to permit a prompt and complete withdrawal of the device(s) from the market when needed.

5.4 Handling, storage and delivery of medical devices

5.4.1 The distributor shall have documented procedures in handling, storage and delivery of medical devices to fulfill the following requirements:

(a) Protection from environmental conditions that may affect the safety or performance of medical devices;

(b) Identification and appropriate storage, handling and delivery of medical devices that require special storage or transport conditions, for instance IVD medical device that requiring cold chain management;

(c) Stock rotation (first-expiry first-out) for medical devices that have a limited shelf-life or expiry date;

(d) Proper handling of medical devices to prevent damage, deterioration or contamination;

(e) Identification, segregation and control of nonconforming, returned or recalled medical devices to prevent them from being inadvertently sold/issued;

(f) Adequate and sufficient incoming and outgoing inspection to ascertain the safety, performance and quality of the medical devices received and to be issued;

(g) Periodic stock reconciliation should be performed by comparing the actual and recorded stocks, all significant stock discrepancies should be investigated to checked that there have been no advertent mix-ups, incorrect issue and/or misappropriation of medical devices; and

(h) Delivery procedures, including verification of orders and physical inspection of label description, type and quantity of medical devices to avoid incorrect medical devices from being delivered/received.

5.5 Management of product recalls and field safety notices

5.5.1 The distributor shall have documented procedures to manage product recalls and field safety notices (that including field safety corrective actions, product recall, product modification, etc.). The procedure should describe how the distributor manages or assists in managing product safety alerts

that issued by MDD or other overseas authorities, and field safety notices/advisory notices that issued by the manufacturers, importers or LRPs.

5.6 Managing reportable adverse events in Hong Kong

5.6.1 The distributor shall have documented procedures to manage reportable or potential reportable adverse events as defined in Guidance Notes GN-00 (Definitions and Abbreviations for Medical Device Administrative Control System) involving any of the medical devices which have come to the attention of the distributor. The listed distributor should seek the consent of the reporting party for referring the reportable adverse event to the LRP (the manufacturer and the MDD if there is no LRP). If the reporting party does not consent, the listed distributor should ask the reporting party to report the adverse event directly to the LRP (or the manufacturer and the MDD if there is no LRP).

5.6.2 The Guidance Notes GN-03 (Guidance Notes for Adverse Event Reporting by Local Responsible Persons) provides details about reporting adverse events. Where applicable, the listed distributor shall work closely with the LRP (the manufacturer and the MDD if there is no LRP) and render all necessary assistance to the LRP and/or manufacturer in reporting any reportable adverse event related to a medical device particularly if the device in found on the supply records.

5.7 Complaints handling

5.7.1 The distributor shall establish a documented procedure in handling complaints related to any of the imported medical devices. The procedure shall include, but not limited to, the following key activities

(a) Receiving and evaluating information to determine if the feedback constitutes a complaint;

(b) Investigating complaints;

(c) Reporting to regulatory authorities as appropriate;

(d) Handling of complaint related devices;

(e) Determining and initiating corrections and/or preventive actions on the basis of risk; and

(f) Defining requirements for complaint records.

5.8 Tracking of specific medical devices

5.8.1 The distributor shall have documented procedures to track the high-risk devices specified in 'List of Medical Devices Requiring Tracking' in Guidance Notes GN-01 (Overview of the Medical Device Administrative Control System) down to patient or user-facility level and pass all necessary information to the LRP.

5.9 Maintenance and services arrangements

5.9.1 The distributor shall establish a documented procedure in providing preventive and corrective maintenance services to the medical devices, including calibration, provision of spare parts and other maintenance services.

5.10 List of medical device distributed

5.10.1 In addition to the application form and documented procedures stipulated above, the applicant shall also submit a list of medical devices being distributed by him/her. The list shall contain key information of each medical device including make, model, device description, storage conditions, and MDACS listing number (if applicable).

5.11 Reporting changes

5.11.1 The listed distributor shall notify the MDD as soon as possible but no later than four (4) weeks after changes made to the information submitted such as contact details and distributor particulars. The MDD has the discretion to request the listed distributor to produce documentary evidence of the change within two (2) weeks.

5.12 Requirements for inspections

5.12.1 Upon request by the MDD during the application stage or after the application is approved, the applicant / listed distributor shall:

(a) Make available to the MDD for inspections, as soon as possible, the supply records, documented procedures and other requested documents maintained by them; and

(b) Allow the MDD to perform inspections of the applicant's / listed

distributor's premises where distribution operations are carried out as well as any related storage and/or transportation facilities. The applicant / listed distributor must make provision for such inspections and provide all the necessary assistance to the MDD to facilitate the conduction of the inspections.

5.13 Responsibilities in respect of advertisements

5.13.1 The distributor shall not publish or cause to be published any advertisements or other commercial promotional materials that contravene applicable ordinances such as the Undesirable Medical Advertisement Ordinance (Cap. 231).

5.13.2 Where any document, statement, information, claim, advertisement, promotional material (or any other communication by any means) published to the public, customers or potential customers includes any representation that the distributor is a listed Distributor, or that the distributor is in compliance with the MDACS requirements on listed Distributor, it shall at the same time include a statement to the effect that:

(a) The listing of a Distributor carries no implication that its medical devices are listed; and

(b) Clearly state whether any of the medical devices presented in the same article are listed under the MDACS or not.

5.13.3 Where the representation that the distributor is a listed Distributor, or that the distributor is in compliance with the MDACS requirements on listed Distributors, is in writing, then the statements required by 5.13.2 (a) and 5.13.2 (b) above shall be in the same format (in terms of font size, colour, etc.) as the aforesaid representation.

5.13.4 All advertised claims of a listed medical device shall align with the indications and instructions for use as listed with the MDD. Information that has not been listed or which may potentially or indirectly extend the usage of a listed medical device must not be included in advertisements. This is to ensure information provided in the advertisement falls within the scope of the listed uses of the medical device.

6. Administrative Provisions

6.1 Validity of approval

6.1.1 If an application for inclusion on the List of Distributors is approved, the applicant will be included on the List for three (3) years. The listed Distributor should apply for renewal of its current inclusion on the List of Distributor (current listing) not less than three (3) months before its expiry through the submission of a renewal application form and requisite documents as specified by the MDD. If the current listing expires prior to a decision of its application for renewal is made by the MDD, its current listing shall remain in effect until there is a decision.

6.2 Fees

6.2.1 No fee will be charged by the Government for the application or in relation to the inclusion of a distributor on the List of Distributors.

6.3 Undertaking by Applicant

6.3.1 The applicant shall, on the terms set out in the “Undertaking by Applicant” in the Application Form, undertake inter alia to indemnify the Government of the Hong Kong Special Administrative Region against any loss or claim that flows from any of the following:

(a) Any act or default of the applicant;

(b) Any defective design of the medical devices of the applicant;

(c) Any defect in such medical devices; and

(d) Any information supplied by the applicant to the Government.

6.4 Delisting of Distributors

6.4.1 A distributor on the List of Distributors may be delisted or removed from the List if any of the following circumstances arises:

(a) The listed distributor fails to comply with the MDACS requirements including, but not limited to, those stipulated in Clause 5 of this Document;

(b) The listed distributor fails to address or adequately address a situation that gives rise or that might give rise to a hazard of its medical devices or to a public health or public safety concern; or

(c) The listed distributor has been wound up, dissolved or has ceased to exist;

(d) the MDD considers the delisting necessary for public health or safety considerations; or

(e) The delisting is requested by the listed Distributor.

6.5 The List of Distributors

6.5.1 For each listed Distributor, the entries on the List may include:

(a) The name, telephone number and address of the distributor; and

(b) The Listed Distributor Number assigned to the Distributor.

6.5.2 The List of Distributors will be publicly accessible.

6.6 Appeal against rejection of an application or decision to delist a listed distributor

6.6.1 A rejection of an application or decision to delist a Listed Distributor may be appealed against by the distributor within fourteen (14) calendar days of being notified of the decision.

6.6.2 To appeal, the distributor must write to the Secretary to Medical Device Administration Appeal Committee, c/o Medical Device Division, stating its grounds for appeal.

6.6.3 The lodging of an appeal against a decision of the MDD to delist a distributor does not suspend the decision unless the MDD decides otherwise.

6.6.4 An appeal lodged after the specified time limit specified in Clause 6.6.1 will not be considered.

7. Points to Note

7.1 The inclusion of an individual, person, company or partnership on the List of Distributors is not an endorsement in support or any recommendation whatsoever of that individual, person, company or partnership as a distributor of medical devices by the Department of Health. Nor does the inclusion imply that the distribution of medical devices by that individual, person, company or partnership is in compliance with the applicable laws or has the necessary regulatory approvals. The responsibility for ensuring the legality of the distribution rests with the distributor.

8. Enquiries

8.1 Enquiries concerning this booklet and the MDACS should be directed to:

Medical Device Division,
Department of Health.
Telephone number: 3107 8484
Facsimile number: 3157 1286
Email address: mdd@dh.gov.hk
Website: www.mdd.gov.hk

9. References

9.1 Department of Health. Guidance Notes for Definitions and Abbreviations for Medical Device Administrative Control System. Guidance Notes GN-00.

9.2 Department of Health. Overview of the Medical Device Administrative Control System. Guidance Notes GN-01.

9.3 Department of Health. Guidance Notes for Adverse Event Reporting by Local Responsible Persons. Guidance Notes GN-03.

9.4 Global Harmonization Task Force: Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer. Final Document SG1-N055:2009.

Appendix I – Guidance on requirements for listing of distributors

This appendix provides additional information and examples in the form of guidance on Clause 5 of this document. The guidance listed in this appendix is only for referencing during the establishment and maintaining of the required procedures, the distributor should establish and maintain its own procedures taking account of the workflow, operations, nature of medical devices, reporting and follow up requirements, organisation structure and needs of its own organisation.

Clause	Requirement	Guidance
5.1.1	Zones in the premises	- A layout that showing all the operating zones is recommended. - Each zone should be clearly segregated and indicated ■ Example: Goods Receiving Area is segregated by blue-color tape on the floor and clear wording “Goods Receiving Area” posted on the wall of this area; ■ Example: Rejected Goods Area is physically isolated in plastic box that with red-color label and clear wording “Rejected Goods” adhered outside the plastic box. - Zones where handling of medical devices should be physically segregated from other zones such as general office, toilet, zones for storing non-medical products unless it is justified.
5.1.2	Actions for access control	- Possible access control can include, but not limited to, ■ Key-lock control by designated persons; ■ Authorized list posted at the entrance of the storeroom; ■ Electronic access control system; ■ Logbook for guest visitor. - Storeroom should be restricted from any personnel who are not carrying their activities inside the storeroom such as general administrative personnel.
5.1.3	Sufficient storage capacity	There should be sufficient space for routine activities such as putting-away, sorting, pick-packing, cleaning, etc.

<table>
<tr><td>5.1.4</td><td>Sanitation</td><td>A sanitation program is recommended
Examples:<table><tr><td>Daily</td><td>Sweeping floor, cleaning-up trash bin</td></tr><tr><td>Weekly</td><td>Vacuum cleaning</td></tr><tr><td>Monthly</td><td>Wiping walls</td></tr><tr><td>Annually</td><td>Sweeping Ceiling</td></tr><tr><td>All the time</td><td>Eating, drinking, chewing or smoking, or the storage of food, drink, smoking materials or personal medication in the storeroom should be prohibited</td></tr></table></td></tr>
<tr><td>5.1.4</td><td>Pest control</td><td>A programme and pest control layout that showing all the pest control location is recommended.
Examples: Electric fly-killing device, rodent trap, insect bait, etc.</td></tr>
<tr><td>5.1.4</td><td>Spillage handling programme</td><td>Where distributor is handling medical devices in liquid form, such as IVD reagent and contact lens solutions, the distributor should establish a procedure for handling of spillage to prevent medical devices being contaminated.
Examples: cleaning process and usage of spillage kit, etc.</td></tr>
<tr><td>5.1.5</td><td>Storage conditions</td><td>Distributor can make reference from the standards listed in Clause 2.5 of Recognized Standards RS-01 (List of Recognised Standards for Medical Devices) or seek clarification from the manufacturer for the meanings of the symbols shown on the labels for determining the requirements of storage conditions.</td></tr>
<tr><td>5.1.6</td><td>Temperature and humidity monitoring</td><td>- Monitoring of temperature or humidity are only required when there are temperature or humidity storage requirements on the handled medical devices.
- The monitoring of temperature and humidity can be conducted manually or by automatic data logger.
- The intervals for checking and recording the temperature or humidity should be determined in according to, but not limited to,</td></tr>
</table>

		■ The classification or risk of the medical devices; ■ The availability of resources; ■ The ranges of the temperature or humidity requirements; ■ The stability of the storage environment; and ■ The activities will be carried out such as secondary packaging. - The number and locations of the monitoring sensors should be depending to the size and layout of the storeroom. - The checked results can be retained in the format of hard copy or in electronic means.
5.1.7	Calibration	- Examples of equipment include, but not limited to: ■ Thermometer; ■ Data logger; ■ Hygrometer; ■ Electronic balance. - The calibration methods should be appropriate to the use of the equipment, for example: ■ The calibration of a 2°C ~ 8°C cold chain used data logger should include 2°C ~ 8°C.
5.2.1	Quality management system	If the quality management system of the distributor has been certifying by certification body accredited for quality management system by a member of the International Accreditation Forum (IAF) and the scope of the quality management system are covering all the documented procedures stipulated in Clause 5, the distributor can submit a valid certificate and the quality manual of the quality management system instead of submitting the required documented procedures. Examples of quality management system are ISO 13485 or ISO 9001.
5.2.1	Documented procedures	The contents of each procedure should at least cover the following sections:

<table>
<tr><td></td><td></td><td><table>
<tr><td>Title</td><td>Name and identification of the procedure</td></tr>
<tr><td>Version history</td><td>Summary of each update on the procedure</td></tr>
<tr><td>Purpose</td><td>Purpose of the procedure</td></tr>
<tr><td>Scope</td><td>Types of medical device and circumstances to which the procedure applies</td></tr>
<tr><td>Definitions/ Abbreviations/ References</td><td>Definitions and abbreviations of terms used
Referencing documents of the procedure</td></tr>
<tr><td>Roles and Responsibilities</td><td>Roles of responsibilities of the personnel taking part in the procedure</td></tr>
<tr><td>Procedures</td><td>Detailed and step-by-step descriptions of the control processes</td></tr>
<tr><td>Records</td><td>List of records related to the procedure</td></tr>
</table></td></tr>
<tr><td>5.2.2</td><td>Record retention</td><td>Records can be retained in the format of hard copy or in electronic means provided that the integrity of the data in the records is maintained.</td></tr>
<tr><td>5.2.3</td><td>Regular review of procedures</td><td>- All the operation procedures should be reviewed from time to time (e.g. annually) to ensure the effectiveness of the procedures. For example, adding of maintenance service may need to update the maintenance procedure.
- The outcome of the review, that may lead to update or no change of the procedures, should be documented.</td></tr>
<tr><td>5.2.3</td><td>Corrective and preventive actions (CAPA)</td><td>- Corrective actions are actions to be taken to eliminate the cause of a detected non-conformity or other undesirable situation and to prevent recurrence.
- Preventive actions are actions to be taken to eliminate the cause of a potential non-conformity or other undesirable potential situation.</td></tr>
<tr><td>5.3.1</td><td>Supply records</td><td>- Supply records should include appropriate information</td></tr>
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<td>to ensure the traceability of medical devices.
- Traceability of medical devices can be achieved using medical devices' unique identifier such as model number with batch number, serial number, unique device identifier, etc.
- Examples of supply records
■ Purchasing order from customer
■ Documents associated with incoming medical devices
■ Incoming quality check reports/records
■ Storage records
■ Cycle count/ stock take records
■ Secondary packaging records
■ Picking and packing records
■ Delivery notes
■ Medical device return records
■ Medical device recall records
- Supply records should be retained for a period of time not less than the lifetime of the medical device as defined by the manufacturer, or seven years from the date of product distributions, whichever is longer.</td>
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<tr>
<td>5.4</td>
<td>Scope of handling, storage and delivery of medical devices</td>
<td>- The distributor should identify the scope, where they are responsible for handling of medical devices, among the whole supply chain.
- The scope should be based on the contractual requirement(s) that agreed between the distributor and other related traders in the medical device supply chain.
- The distributor shall comply with all the requirements in this Guidance Note within the defined scope
- Examples:
<table>
<tr><th>Cases</th><th>Starting point</th><th>Completed point</th></tr>
<tr><td>1</td><td>Receiving area of distributor</td><td>Dispatching area of distributor</td></tr>
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		2	Dispatching area of importer	Receiving area of retail shop
		3	Importing bay of cargo terminal	Receiving area of clinic
		4	Dispatching area of upstream distributor	Receiving area of downstream distributor
5.4	Operation flow and corresponding records	Example:		

Steps	Locations	Examples of records
Inbounding	Receiving area	- Shipping documents such as packing list, delivery notes or invoice issued from the manufacturer - Product final inspection report / certificate - Certificate of Conformity (CoC) - Temperature record (cold chain product)
Incoming inspection		- Incoming inspection records / checklists
Putting away / segregation	Released / Quarantine / Rejected good area	- Stock entry records
Storage		- Stock take records - Cycle count records - Investigation report (in case of significant stock discrepancy)
Secondary packaging	Secondary packaging area	- Label printing records - Secondary packaging batch records
Picking	Released good area	- Picking list

<table>
<tr><td></td><td></td><td>
<table>
<tr><td>Packaging</td><td>Dispatching area</td><td>- Packing list</td></tr>
<tr><td>Transportation</td><td>Outdoor</td><td>- Delivery notes
- Invoice
- Temperature record (cold chain product)</td></tr>
<tr><td>Receipt</td><td>Clinic</td><td>- Signed delivery note or delivery note with chop from clinic</td></tr>
<tr><td>Return and recall</td><td>Returned or recalled area</td><td>- Good returned notice and form</td></tr>
</table>
</td></tr>
<tr><td>5.4.1 (a)</td><td>Environmental conditions</td><td>Examples:
- External weather such as raining or heat wave;
- Internal facility such as toilet built inside the warehouse;
- Cleanliness and hygiene of the warehouse.</td></tr>
<tr><td>5.4.1 (b)</td><td>Special storage or transport conditions</td><td>- It is recommended to review the storage requirements and symbols shown on labels of medical devices to determine the storage and transport conditions.
- Examples:
■ Temperature such as ambient temperature, < 30 ˚C, 15˚C ~ 25˚C, 2˚C ~ 8˚C, -25˚C ~ -15˚C
■ Relative humidity such as < 65%
■ Atmospheric pressure</td></tr>
<tr><td>5.4.1 (c)</td><td>Expired medical devices</td><td>- The distributor should ensure that medical devices with the earliest expired date are sold and/or distributed first.
- Unless specifically requested, the distributor is not recommended to sell and/or distribute short-expired medical devices (such as 1-month shelf-life).</td></tr>
<tr><td>5.4.1 (d)</td><td>Proper handling of medical devices</td><td>Examples:
- Medical devices should be stored off the floor and suitably spaced to permit cleaning and inspection;</td></tr>
</table>

		- There should be regular checks to ensure the storage area is free of waste and contamination; - Light sensitive medical device should be placing away from light source.
5.4.1 (e)	Returned and recalled medical devices	- Each returned or recalled medical devices should be clearly labeled and segregated, appropriate access control to returned or recalled devices should be applied.
5.4.1 (f)	Incoming inspection	- When receiving a medical device. It is recommended to have a checklist where lists all the necessary items to be inspected, for example: ■ Correctness of the information shown on the labels such as model name, model code, batch number / serial number (S/N), quantity, expired date, special listing information (if any), etc.; ■ Integrity of the packaging; ■ Documents associated with the medical device such as Certificate of Conformity (CoC) or Temperature record (cold chain product).
5.4.1 (f)	Outgoing inspection	- Before product delivery, it is recommended to verify the following items: ■ Model name, model code, batch number / serial number (S/N), quantity, expired date, special listing information (if any), etc.; ■ Integrity of the packaging; ■ Required shipping condition and associated equipment (such as cold box and data logger for cold chain product).
5.4.1 (g)	Stock reconciliation	- The interval for conducting stock reconciliation should be depending on the following factors: ■ Risks of medical devices; ■ Variety of medical devices; ■ Size of the storeroom; ■ Number of personnel involved;

		■ Complexity of operations. - Example: Annually, quarterly, monthly, etc.
5.5.1	Management of product recalls and field safety notices	General procedures for Management of product recalls and field safety notices: - Receiving of safety alerts and field safety notice (FSN); - Determining the nature of the safety alerts or FSN; ■ Field safety corrective actions; ■ Product recalls; ■ Product modifications; - Determining the need for the following actions: ■ Notification to MDD or other regulatory authorities; ■ Notification to manufacturers, LRPs, importer, etc.; ■ Notification to the users with regard to the modifications; ■ Investigations and reporting to relevant parties including MDD; ■ Product recalls; ■ Returning of product to manufacturers; - All the received safety alerts, FSN and follow-up records should be kept.
5.7.1	Complaints	- Complaints can occur by telephone, fax, email, letter or in person, etc. - All types of complaints should be recorded. - It is recommended to have a complaint master list or complaint logbook. - If complaints are not investigated or handled, justification should be recorded. - Any correction, corrective action or preventive actions resulting from the complaint should be recorded.
5.10	List of medical device distributed	Refer to Appendix II for a sample of list of medical device distributed.

Appendix II – Sample list of medical devices

List of Medical Devices

Item	Make	Model	Device Description	Listed device (Y with no. / N)?	Class	Manufacturer	Importer	LRP	Storage Environment	Other information
1	SCTCB	CTCB-SCAN	Scanning Systems, Computed Tomography, Cone-Beam	Yes (Listing No.: 120777)	III	SCTCB Co. Ltd.	ABC Co. Ltd.	ABC Co. Ltd.	10~40℃	
2	SCTCB	CTCB-SCANR	Scanning Systems, Computed Tomography, Cone-Beam	No	III	SCTCB Co. Ltd.	BCD Co. Ltd.	N/A	10~40℃	
3	NEO IRU	WIR-111	Incubator / Radiant Warming Units, Infant, Mobile	Yes (Listing No.: 130666)	III	NEO IRU Inc.	BCD Co. Ltd.	CDE Co. Ltd.	0~40℃	
4	NEO IRU	WIR-333	Incubator / Radiant Warming Units, Infant, Mobile	No	III	NEO IRU Inc.	BCD Co. Ltd.	N/A	0~35℃	
5	MD	SurIn A	Insufflators, Endoscopic	Yes (Listing No.: 159999)	II	MD GmbH	EFG Co. Ltd.	CDE Co. Ltd.	0~40℃	
6	MD	MD Chair	Insufflators, Endoscopic	No	I	MD GmbH	EFG Co. Ltd.	N/A	0~40℃	
7	MD	MD Bed – General	Beds, Electric	No	I	MD GmbH	EFG Co. Ltd.	N/A	0~40℃	
8	MD	MD bed - Birth	Beds, Electric, Birthing	No	I	MD GmbH	EFG Co. Ltd.	N/A	0~40℃	
9	DIAGNO	DIAGNO reagent 123	IVD Test Reagent/Kits, Serology, Virus, Retrovirus, HIV-1/2	Yes	D	DIAGNO Co.	ABC Co. Ltd.	ABC Co. Ltd.	-15~-25 ℃	Need for secondary packaging
10	DIAGNO	DIAGNO BG 456	Blood Glucose Monitors, Portable	Yes (Listing No.: 140888)	C	DIAGNO Co.	ABC Co. Ltd.	ABC Co. Ltd.	0 ~ 25 ℃	
11	DIAGNO	DIAGNO reagent 789	Reagents, Pregnancy Testing	No	B	DIAGNO Co.	ABC Co. Ltd.	ABC Co. Ltd.	2 ~ 8 ℃	Need for secondary packaging
12	DIAGNO	DIAGNO S000	Receptacles, Hospital Grade	Yes (Listing No.: 170444)	A	DIAGNO Co.	ABC Co. Ltd.	ABC Co. Ltd.	0~40℃	