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醫療儀器的規管

Regulation of Medical Devices

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
of the People's Republic of China

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1. Introduction

1.1 The purpose of this booklet is to provide 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 vigilance system, the Medical Device Control Office (MDCO) maintains a List of Distributors under the MDACS.

1.3 Distributors of medical devices may apply to be included on the List of Distributors if they distribute any of the medical devices listed under the MDACS. This requirement does not apply to distributors distributing only Class I medical devices as they are currently excluded from the scope of listing.

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

1.5 Among others, it is essential that a listed distributor shall establish, maintain and implement a set of specified documented procedures for the medical devices it distributes.

2. Definitions

2.1 For the purpose of this booklet, the following definitions and those given in the Guidance Notes issued by the MDCO are applicable:

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 falling within the scope of the MDACS by sale for use in Hong Kong either on his own behalf or to another distributor.

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

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

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

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

(iv) 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

(v) 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).

End user is an individual who purchases or receives a medical device for one's own personal use or receives treatment or diagnosis with a medical device from a health care facility or provider.

3. Application Procedures

3.1 Application form

Application form for listing of distributors under the MDACS can be obtained from the MDCO or downloaded from the website http://www.mdco.gov.hk.

3.2 Submission of applications (by hardcopies)

An application for listing of distributor must be made with the Application Form MD-TREG. 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 MDCO 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 recorded delivery mail to the MDCO.

3.3 Submission of application (by softcopies)

The applicants are encouraged to use softcopies in CD-ROM/DVD-ROM format for making the application submission as far as possible. If a submission is

made using softcopies, only the duly signed Application Form MD-TREG (original copy) has to be submitted in paper format. The signed application form, together with duplicated softcopies of other required documents recorded in two separate CD-ROMs/DVD-ROMs, shall be submitted by hand or by recorded delivery mail to the MDCO. Alternatively, an applicant with Hongkong Post e-Cert may submit an application entirely by softcopies (i.e. both the completed application form and the other documents in softcopies) to the email address mdco_app@dh.gov.hk of the MDCO, provided that the total file size of these softcopies is less than 5MB.

3.4 Acknowledgement of application

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

4. Requirements for Listing of Distributor

4.1 Establishment of Procedures

For the purpose of fulfilling the requirements of a listed distributor, the listed distributor must have a properly manned office in Hong Kong where business operations for the distribution are carried out. It shall establish, implement and maintain the following procedures in conjunction with the respective Local Responsible Persons (LRPs), or manufacturers if there is no LRP. While some of these procedures are dependent on the agreement among the manufacturer, the LRP and the distributor, the procedures described under Sections 4.1.1 and 4.1.2 are mandatory. Content of these procedures shall cover the key elements specified in Appendix 1. Records (including, but not limited to, those listed in Appendix 1) 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 years from the date of product distribution, whichever is longer.

4.1.1 Keeping of distribution records

The listed distributor shall maintain the distribution records for the medical devices it distributes. Such records shall 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. For specific medical devices requiring tracking, the additional information stipulated in Section 4.1.6 shall also be kept.

4.1.2 Handling, storage and delivery of medical devices

The listed distributor shall also establish a documented procedure for handling, storage and delivery of medical devices to fulfil the following requirements:

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

(ii) identification and appropriate storage, handling and delivery of medical devices that require special storage or transport conditions;

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

(iv) proper handling of medical devices to prevent damage, deterioration or contamination;

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

(vi) 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.

The distributor shall also make reference to the “Requirements on storage of Pharmaceutical Medical devices” from the website of Drug Office, Department of Health (web site: https://www.drugoffice.gov.hk) where applicable for storage of the medical devices which contain

pharmaceutical products and for those which have specific storage requirements of temperature and humidity. In general, there must be adequate storage facilities with appropriate measures in monitoring the storage temperature and humidity.

4.1.3 Managing product alerts, modifications and recalls

This procedure, if applicable, shall describe how the listed distributor manages or assists in managing field safety advisory notices (product recalls, alerts and modifications, etc.) affecting any of the distributed medical devices, which may be issued by the manufacturers, LRPs or other regulatory authorities from time to time.

4.1.4 Managing reportable adverse incidents in Hong Kong

This procedure, if applicable, shall outline how the listed distributor manages or assists in managing reportable or potentially reportable adverse incidents 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 listed distributor. The listed distributor is required to seek the consent of the reporting party for referring the reportable adverse incident to the LRP (or the manufacturer and the MDCO if there is no LRP). If the reporting party does not consent, the listed distributor should ask the reporting party to report the adverse incident directly to the LRP (or the manufacturer and the MDCO if there is no LRP).

The Guidance Notes GN-03 (Adverse Incident Reporting by Local Responsible Persons) provides details about reporting adverse incidents. Where applicable, the listed distributor shall work closely with the LRP (or the manufacturer and the MDCO if there is no LRP) in providing all necessary assistance to the LRP and/or manufacturer in reporting any field safety notice and reportable adverse incident related to a medical device particularly if the device is found on the distribution records.

4.1.5 Complaints handling

This procedure, if applicable, shall depict how the listed distributor handles complaints related to any of the distributed medical devices. The procedure shall include, but not limited to, the following key activities:

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

(ii) investigating complaints;

(iii) reporting to regulatory authorities as appropriate;

(iv) handling of complaint related devices;

(v) determining and initiating corrections and/or preventive actions on the basis of risk; and

(vi) defining requirements for complaint records.

4.1.6 Tracking of specific medical devices

The distributor shall, if applicable, have in place a tracking system that tracks those high-risk devices specified in Appendix 4 of GN-01 down to patient level. Where this tracking is not possible for any individual devices (e.g. the tracking does not have the patient's consent), the system is still required

(i) to track the devices down to the user-facility level (so that, if a need to recall these devices arises, the recall can still be effected through the assistance of these user facilities) and

(ii) for each of these devices, to keep track of the following:

(a) the date the device was put into service or (for an implantable device) implanted into a patient, and

(b) (if tracking of the device is possible) the date the device permanently retired from use or (for an implanted device) the date it was explanted.

4.1.7 Maintenance and services arrangements

If applicable, the distributor shall offer or arrange other parties to provide preventive and corrective maintenance services for the distributed medical devices, including calibration, provision of spare parts and other services to the users when requested.

4.2 Submission of Documented Procedures

The documented procedures described under Sections 4.1.1 and 4.1.2 together with other applicable procedures mentioned in Sections 4.1.3 to 4.1.7 shall be submitted together with the completed application form. These procedures are considered essential for the evaluation of an application. A sample procedure is also given in Appendix 2 for illustration purpose only. The listed distributor must 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 on the role and arrangement for the establishment and implementation of such documented procedures.

4.3 Requirements for Inspections

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

4.3.1 make available to the MDCO for inspections, as soon as possible, the distribution records, updated documented procedures and other requested documents maintained by them; and

4.3.2 allow the MDCO 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 MDCO to facilitate the conduction of the inspections.

4.4 Requirements in Respect of Advertisement, Promotional Materials, etc.

4.4.1 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 distributors, it shall at the same time include a statement to the effect that

(i) the listing of a distributor carries no implication that its medical devices are listed, and

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

4.4.2 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 4.4.1(i) and (ii) above shall be in the same format (in terms of font size, colour, etc.) as the aforesaid representation.

5. Other Requirements

5.1 Notification of changes

Both during the application process and after the application is approved, the applicant/listed distributor shall notify the MDCO as soon as possible but no later than four weeks after changes made to the information submitted such as contact details and distributor particulars. The MDCO has the discretion to request the applicant/listed distributor to produce documentary evidence of the change so notified within two weeks.

5.2 List of medical devices distributed

In addition to the application form and documents 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 and MDACS listing number (if applicable).

6. Processing, Approval and Rejection of Applications

6.1 Each application for listing as a distributor will be subject to processing and vetting by the MDCO 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.

6.2 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. It is highly preferred that applicants should have at least one of the medical devices distributed by them listed under the MDACS. However, applicants distribute only Class I medical devices are exempted from this requirement. Where necessary, the MDCO may request the applicant to provide supplementary information or additional documents in support of its application.

6.3 The MDCO will only proceed with the processing of 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.

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

7. Administrative Provisions

7.1 Validity of Approval

If an application for inclusion on the List of Distributors is approved, subject to Section 7.4 below, the applicant will be included on the List for three years unless otherwise specified.

7.2 Renewal of Listing

The listed distributor may apply for renewal of the current inclusion on the List of Distributors (current listing) not less than six months before the expiry date through the submission of a renewal application form and requisite documents as specified by the MDCO. If the current listing expires prior to a decision of its application for renewal is made by the MDCO, its current listing shall remain in effect until there is a decision.

7.3 Fees

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

7.4 Undertaking by Applicant

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:

(i) any act or default of the applicant,

(ii) any defective design of the medical devices of the applicant,

(iii) any defect in such medical devices, and

(iv) any information supplied by the applicant to the Government.

7.5 Delisting of Distributors

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

(i) the listed distributor has been wound up, dissolved or otherwise has ceased to exist;

(ii) the delisting is requested by the listed distributor;

(iii) the listed distributor fails to comply with the MDACS requirements including, but not limited to, those stipulated in Sections 4 and 5;

(iv) the listed distributor does not 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

(v) the MDCO considers the delisting necessary for public health or safety considerations.

7.6 The List of Distributors

For each listed distributor the entries on the List may include:

(i) the name, telephone number and address of the distributor, and

(ii) the Listed Distributor Number assigned to the distributor.

The List of Distributors will be publicly accessible.

7.7 Appeal against Rejection of an Application or Decision to Delist a Listed Distributor

Any appeal against a decision to reject an application for inclusion or renewal of inclusion on the List of Distributors or to delist a listed distributor must be lodged by the applicant/listed distributor within four weeks of receiving the notification of decision. To lodge the appeal the applicant/listed distributor must write to the Secretary to Medical Device Administration Appeal Committee, c/o Medical Device Control Office, stating its grounds of appeal. An appeal lodged after the specified time limit will not be considered.

8. Points to Note

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.

9. Enquiries

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

Medical Device Control Office,
Department of Health.
Telephone number: 3107 8484
Facsimile number: 3157 1286
E-mail address: mdco@dh.gov.hk
Website: www.mdco.gov.hk

10. References

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

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

[3] Department of Health. Guidance Notes for Adverse Incident Reporting by Local Responsible Persons. Guidance Notes GN-03.

[4] Department of Health. Guidance Notes for Listing of Importers of Medical Devices. Guidance Notes GN-07.
[5] Department of Health. Guidance Notes for Listing of Local Manufacturers. Guidance Notes GN-08.
[6] Global Harmonization Task Force: Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer. Final Document SG1-N055:2009.

Appendix 1

Documented Procedures Required for the Listing of Distributor

1. The procedures described in Section 4.1 of this guidance document and tabulated below shall be established, where applicable, and a set of these procedures shall be submitted together with the listing application. The records for each of the procedures shown in table 1 below shall be established and maintained to provide evidence of conformity to the requirements and the effective implementation of the procedures:

Table 1: Titles of documented procedures and records required

	Documented procedure	**Records**
(a)	Keeping of distribution records	• Distribution records of devices including make, model, batch/serial number, quantity, expiry date, customer/delivery details • For devices required tracking, see also (f) below
(b)	Handling, storage and delivery of medical devices	• Receipts and issues of medical devices according to batch/serial numbers • Records for cleaning and pest control programme • Calibration and measurement results of instrument(s) used in storage facility for monitoring temperature / relative humidity (if applicable)
(c)	Managing product alerts, modifications and recalls (if applicable)	• Reports and records related to product recalls, alerts and modifications.
(d)	Managing reportable adverse incidents in Hong Kong (if applicable)	• Reports and records for reportable adverse incidents in Hong Kong
(e)	Complaints handling (if applicable)	• Reports and records for complaints • Reports for any corrective and preventive actions resulting from the complaint handling process
(f)	Tracking of specific medical devices (if applicable)	• Records for tracking of the devices down to end user or user-facility level (so that, if a need to recall these devices arises, the recall can still be effected through the assistance of these user facilities) • the date the device was put into service or (for an implantable device) implanted into a patient

		• (if tracking of device is possible) the date the device permanently retired from use or (for an implanted device) the date it was explanted.
(g)	Maintenance and services arrangements (if applicable)	• Records for arrangement of preventive and corrective maintenance services for the device, including calibration, provision of spare parts and other services

2. The content of each procedure should essentially cover the following sections:

(a) Purpose

- Purpose of the procedure

(b) Scope/Coverage

- Types of medical devices and circumstances to which the procedure applies

(c) Definitions/Abbreviations/References (if applicable)

- Definitions and abbreviations of terms used

(d) Roles and responsibilities of persons

- Roles and responsibilities of persons taking part in the procedure

(e) Detailed procedure

A detailed description of the procedure including

- Basic information (such as source of information and how the received information are handled)
- Reporting requirements to the MDCO with timing, if applicable (including notification, progress reports and final report to the MDCO until completion)
- Actions required (including any corrective and preventive actions needed), persons responsible and timing of each key step

(f) Records

- Records related to each of the procedures as summarised in section 1 above shall be maintained and kept
- Means of identification, storage, security and integrity, retention time and disposition of records shall be specified.

(g) Supplementary information (if applicable)

- Information necessary for completeness or useful for understanding of the procedure.

Appendix 2

Sample documented procedures of a medical device distributor XYZ Co. Ltd.

1. Purpose

This set of documented procedures describes the essential procedures established by this Company for the distribution of medical devices.

2. Scope

2.1 This set of procedures applies to all the medical devices distributed by this Company, which includes:

(a) Procedure for keeping of distribution records; and

(b) Procedure for handling, storage and delivery of medical devices.

2.2 According to the distribution agreements signed with the manufacturers and Local Responsible Persons (LRPs), the following procedures are established and implemented by the LRPs in conjunction with the manufacturers as part of the agreements. While this Company shall render all necessary assistance to the manufacturers and LRPs promptly in implementing the procedures below, they shall be specified and carried out by the LRPs.

(a) Procedure for managing product alerts, modifications and recalls;

(b) Procedure for managing reportable adverse incidents in Hong Kong;

(c) Procedure for complaints handling;

(d) Procedure for tracking of specific medical devices; and

(e) Procedure for maintenance and services arrangements.

(Note: This is just a sample procedure for illustration purpose. Distributor may assume a more dominating role in the above procedures depending on the agreement and arrangement with the manufacturer and the LRP.)

3. Related Information

The following annexes are useful information related to this set of procedures:

3.1 Annex 1 – Table showing all the medical devices distributed by this Company

3.2 Annex 2 – Contact details of the manufacturers, importers and LRPs for the medical devices distributed by this Company

3.3 Annex 3 – Contact details of staff involved in the distribution of the medical devices

4. Reference Documents

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

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

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

4.4 Department of Health. Guidance Notes for Listing of Importers of Medical Devices. Guidance Notes GN-07.

4.5 Department of Health. Guidance Notes for Listing of Local Manufacturers. Guidance Notes GN-08.

5. Procedures

5.1 Procedures for keeping of distribution records

(a) Purpose

To set out procedures for keeping of distribution and associated records for medical devices on the distribution list of this Company.

(b) Scope

It applies to the procedure and documents related to the distribution of the medical devices.

(c) Reference Documents

N/A

(d) Definitions and Abbreviations

N/A

(e) Roles and Responsibilities of Persons

Person	Responsibility
Accounts and Administration Manager (AAM) (including his/her designate)	- To ensure that distribution and associated records are kept and maintained for the period of time specified in section (f) of this procedure. - To ensure that such records contain the information specified in section (f) below.

(f) Procedure

(i) Source of supply and the associated contact details in the supply chain for each device on the distribution list shall be kept and maintained using Annex 1 to facilitate tracking when needed.

(ii) Records for the medical devices distributed in Hong Kong shall be kept using the Distribution Record Form (form D) in addition to the in-house medical device database system (mdDBsys). It shall include information on make, model, batch/serial number, quantity, expiry date (if applicable), customer/delivery details of the distributed medical devices.

(iii) The above records shall 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 distribution, whichever is longer.

(g) Record
Distribution Record Form (Form D)

(h) Supplementary information
Responsible staff shall be familiar with this procedure and the in-house medical device database system (mdDBsys).

5.2 Procedure for handling, storage and delivery of medical devices

(a) Purpose
To set out the procedures for handling, storage and delivery of medical devices on the distribution list.

(b) Scope
It covers the procedures and all documents related to the handling, storage and delivery of medical devices distributed by this Company.

(c) Reference Documents
(i) Guideline on the assignment of item code for medical device (G-CodeAssignment)
(ii) Guideline on handling product delivery (G-ProductDelivery)
(iii) Guideline on preparation of invoice for delivered products (G-PrepareInvoice)

(d) Roles and Responsibilities of Persons

Person	Responsibility
Accounts and Administration Manager (AAM) (including his/her designate)	- to update stock record in the Stock Record Form (Form SHD_S) - to assign each of the received medical devices with an item code according to G-CodeAssignment - to prepare invoice for delivered devices as per G-PrepareInvoice
Logistics Department Manager (LDM) (including his/her designate)	- to check the stock record regularly to ensure correctness and completeness - to supervise and perform spot check of the storage area to ensure that the devices are stored properly - to prepare delivery note for devices to be delivered according to G-ProductDelivery - to ensure proper storage conditions during transportation

(e) Procedure

(i) For each received medical device, the AAM shall assign an item code to the device in accordance with the Guideline on the assignment of item code for medical device (G-CodeAssignment).

(ii) All incoming and outgoing records for the medical devices shall be kept using the Stock Record Form (Form SHD_S) in addition to in-house medical device database system (mdDBsys).

(iii) The LDM shall perform weekly stock checks by comparing the actual and recorded stocks. Any stock discrepancies shall be investigated, with the help of AAM, to identify the causes of discrepancies for taking any necessary corrective and preventive actions.

(iv) Before storing any newly received medical devices in the storage area (store room 123), the LDM shall check to ensure that the storage conditions of the store room are suitable for the product.

(v) The store room shall be normally locked to prevent unauthorised entry. The room keys shall be kept by the LDM.

(vi) Cleaning and pest control for the store room shall be carried out regularly. The cleaning and pest control records shall be reviewed regularly by the LDM. Medical devices shall be stored off the floor and suitably spaced to permit cleaning and inspection. The LDM shall conduct regular checks to ensure the storage area is free of waste and contamination.

(vii) The area allocated for keeping quarantine goods must be clearly marked with access restricted to authorised personnel only. Any system introduced to replace physical quarantine shall reach an equivalent security level.

(viii) Drawers (nos. 101-110) in the store room are assigned for the storage of rejected, expired, recalled, or returned products. Labels (rejected, expired, recalled and returned) are affixed to the Drawers for clear identification.

(ix) To prevent the distribution of expired products, the LDM shall ensure that medical devices with the earliest expiry date are sold and/or distributed first.

(x) Temperature and humidity monitoring data of the store room obtained from the installed digital thermometers and hygrometers shall be checked twice daily and the measurement results shall be recorded and retained. All monitoring records should be kept for at least the shelf-life of the stored medical device plus one year.

(xi) Digital thermometers and hygrometers installed in the store room shall be calibrated annually. Relevant calibration records shall be kept by the LDM for at least seven years.

(xii) The LDM shall ensure that vehicles and equipment used to distribute, store or handle medical devices shall be suitable for the purpose and properly equipped to prevent exposure of the devices to conditions that could affect their quality and packaging integrity, and to prevent contamination of any kind. Where special storage conditions (e.g. temperature and/or relative humidity) are required during transportation, the LDM shall ensure that the

vehicles and containers are equipped in compliance with the recommendations of the manufacturers.

(xiii) The LDM is responsible for confirming the delivery and prepare the Delivery Note according to the Guideline on Product Delivery (G-ProductDelivery). AAM shall liaise with the LDM on the issuing of Invoice in accordance with the Guideline on Preparing Invoice (G-PreparingInvoice).

(xiv) All records (including information of the Delivery Notes and Invoices) shall be kept using the Delivery Form (Form SHD_D) in addition to the in-house medical device database system (mdDBsys). The LDM shall ensure that the following information are included in the delivery records

— date of dispatch
— complete business name and address of the addressee
— make, model, serial number/batch number
— quantity and expiry date (if applicable) of the medical devices
— information on Delivery Note and Invoice

(f) Records

(i) Stock Record Form (Form SHD_S)
(ii) Delivery Note (Form SHD_D)

(g) Supplementary information

Responsible staff shall be familiar with this procedure, the in-house medical device database system and storage requirements of the medical devices.

Annex 1

List of Medical Devices Distributed

Item	Make	Model	Device Description	Listed device (Y with no. / N)?	Manufacturer	Importer	LRP	Other information
1	SCTCB	CTCB-SCAN	Scanning Systems, Computed Tomography, Cone-Beam	Yes (Listing No.: 120120)	SCTCB Co. Ltd.	ABC Co. Ltd.	ABC Co. Ltd.	Class IIb (Rule 10) under EU's classification of medical device
2	SCTCB	CTCB-SCANR	Scanning Systems, Computed Tomography, Cone-Beam	No	SCTCB Co. Ltd.	BCD Co. Ltd.	---	Class IIb (Rule 10) under EU's classification of medical device
3	NEO IRU	WIR-111	Incubator / Radiant Warming Units, Infant, Mobile	Yes (Listing No.: 1301310)	NEO IRU Inc.	BCD Co. Ltd.	CDE Co. Ltd.	Class IIb (Rule 9) under EU's classification of medical device
4	NEO IRU	WIR-333	Incubator / Radiant Warming Units, Infant, Mobile	No	NEO IRU Inc.	---	---	Class IIb (Rule 9) under EU's classification of medical device

Annex 2

Contact Information of Manufacturers, Importer and LRP

Company	**Manufacturer(M)/ Importer(I)/LRP(L)**	**Contact Information**
SCTCB Inc.	M	Mr. James Williams, QA Manager. 123-123th Avenue, Seattle, WA 99999, USA. Tel: +1 999 888 7777 Fax: +1 777 888 9999 e-mail: james.williams@sctcb.com
NEO IRU Inc.	M	Mr. John Miller, Regulatory Affairs Manager. 888 Sample Street, Mansfield, MA 33333, USA. Tel: +1 777 666 5555 Fax: +1 555 444 3333 e-mail: john.miller@neo-iru.com
ABC Co. Ltd.	I, L	Miss M.Y. Liu, President. Room 338, Cheerful Building, 3 Happy Road, Central, Hong Kong. Tel: +852 5555 4444 Fax: +852 4444 5555 e-mail: my.liu@abc.com
BCD Co. Ltd.	I	Miss S.W. Wong, Logistics In-charge. Room 388, Joyful Mansion, 8 Amazing Street, Tsim Shai Tsui, Kowloon, Hong Kong. Tel: +852 6666 5555 Fax: +852 5555 6666 e-mail: sw.wong@bcd.com
CDE Co. Ltd.	L	Mr. Bates Wong, Regulatory Affairs Manager. Room 148, Blessing Commercial Centre, 38 Wonderful Road, San Po Kong, Kowloon, Hong Kong. Tel: +852 7777 5555 Fax: +852 5555 7777 e-mail: bates.wong@cde.com

Annex 3

Contact details of staff involved in the distribution of the medical devices (XYZ Co. Ltd.)

Staff	Post title	Main Duties	Contact information
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