GN-07:2024-2(E)

Medical Device Administrative Control System (MDACS)

Guidance Notes for

Listing of Importers of Medical Devices

Guidance Notes: GN-07

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

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1. Purpose

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

1.2 Recognising the importance of importers in the medical device supply chain and vigilance system, the Medical Device Division (MDD) maintains a List of Importers under the MDACS.

2. Scope

2.1 Importers of medical devices may apply to be included on the List of Importers if they import and supply medical devices to Hong Kong.

2.2 Application for listing as an importer is entirely on a voluntary basis.

3. Definitions

3.1 The following definition and those given in other Guidance Notes issued by the MDD are applicable:

3.1.1 Importer: means a legal person who brings or causes to be brought into Hong Kong any medical devices falling within the scope of the MDACS for supply in Hong Kong but does not include:

(a) Any person who is employed or engaged by such person to carry such products into Hong Kong; or

(b) Any person who imports medical devices for his/her personal use.

4. Application procedures

4.1 Submission of applications

4.1.1 An application for listing of importer must be made with the Application Form MD-IP+D through the online Medical Device Information System (MDIS) (https://mdis.mdd.gov.hk/).

4.2 Acknowledgement of application

4.2.1 On receiving an application, the MDIS will send an acknowledgement receipt to the applicant's registered email. If an applicant does not receive any acknowledgement receipt within two (2) weeks after submitting an application, he/she may contact the

MDD to check if the submission has been received by the MDD.

5. Requirements for listing of importer

5.1 Establishment of procedures

5.1.1 For the purpose of fulfilling the requirements of a listed importer, the listed importer must have a properly manned office in Hong Kong where business operations for the import of medical device(s) 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. The content of these procedures shall cover the key elements specified in Appendix I. Records (including, but not limited to, those listed in Appendix I) shall be established and maintained to provide evidence of conformity to the requirements and the effective implementation of the procedures. The listed importer shall document the procedures to define the controls needed for the identification, storage, security and integrity, retention time and disposition of records. The listed importer shall also retain the records for a period of time not less than the projected service life of the medical device as defined by the manufacturer, or seven (7) years after the date on which the MD is supplied to another person, whichever is longer.

5.1.1.1 Ensuring the standard of medical devices imported

(a) The listed importer shall establish a documented procedure in ensuring the medical devices that are imported and supplied are in quality and originated from a qualified manufacturer. The procedure shall include, but not limited to the following key activities:

(i) Ensure the medical device manufacturer maintains a quality management system, which includes but not limited to the handling of adverse incidents and implementing corrective and preventive actions for safety alerts/recalls; and

(ii) Ensure the safety, efficacy/ performance and quality of the medical devices to be imported.

5.1.1.2 Keeping of supply records

(a) The listed importer shall establish a documented procedure in maintaining the supply records of the medical devices he/she imports and supplies. The supply records should include the manufacturer, model, batch number, serial number, quantity of medical devices, as appropriate. Such records shall contain

sufficient information to trace the imported medical device(s) and to permit prompt and complete withdrawal of the device(s) from the market when needed. For specific medical devices requiring tracking indicated in Guidance Notes GN-01 (Overview of the Medical Device Administrative Control System), the additional information stipulated in Clause 5.1.1.7 shall also be kept.

5.1.1.3 Handling, storage and delivery of medical devices

(a) The listed importer shall establish a documented procedure in handling, storage and delivery of medical devices to fulfill 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 nonconforming, returned or recalled medical devices to prevent them from being inadvertently sold/issued;

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

(vii) 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.

(b) The importer shall also make reference to the “Requirements on storage of pharmaceutical products” from the website of Drug Office, Department of Health (website: https://www.drugoffice.gov.hk/) where applicable for storage of medical devices containing pharmaceutical products and for those having 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.

5.1.1.4 Management of safety alerts, field safety notices and recalls

(a) The listed importer shall establish a documented procedure in managing safety alerts, field safety notices and recalls affecting any of the imported medical devices, which may be issued by the manufacturers, LRPs or other regulatory authorities from time to time.

5.1.1.5 Managing reportable adverse events in Hong Kong

(a) The listed importer shall establish a documented procedure in managing reportable or potentially 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 listed importer. The listed importer is required to 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 importer should ask the reporting party to report the adverse event directly to the LRP, the manufacturer or the MDD.

(b) 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 importer 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 is found on the supply records.

5.1.1.6 Complaints handling

(a) The listed importer 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:

(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 corrective or preventive actions on the basis of risk; and

(vi) Defining requirements for complaint records.

5.1.1.7 Tracking of specific medical devices

(a) The listed importer shall establish a documented procedure to track the high-risk devices specified in 'List of Medical Devices Requiring Tracking' in Guidance Notes GN-01 down to patient or user-facility level and pass all necessary information to the LRP.

5.1.1.8 Maintenance and services arrangements

(a) The listed importer 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.

5.2 Submission of documented procedures

5.2.1 The documented procedures described under Clauses 5.1.1 shall be submitted together with the completed application form. These procedures are considered essential for the evaluation of an application. A sample procedure could be found in Appendix II. The listed importer 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.

5.3 Requirements for inspections

5.3.1 Upon request by the MDD during the application stage or after the application is approved, the applicant/listed importer 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 importer's premises where business operations are carried out as well as any related storage and/or transportation facilities. The applicant/listed importer must make provision for such inspections and provide all the necessary assistance to the MDD to facilitate the conduction of the inspections.

5.4 Requirements in respect of advertisement, promotional materials, etc.

5.4.1 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 importer is a listed importer, or that the importer is in compliance with the MDACS requirements on listed importers, it shall at the same time include a statement to the effect that:

(a) The listing of an importer 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.

5.4.2 Where the representation that the importer is a listed importer, or that the importer is in compliance with the MDACS requirements on listed importers, is in writing, then the statements required by 5.4.1(a) and 5.4.1(b) above shall be in the same format (in terms of font size, colour, etc.) as the aforesaid representation.

6. Other requirements

6.1 Notification of changes

6.1.1 The listed importer 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 importer particulars. The MDD has the discretion to request the listed importer to produce documentary evidence of the change within two (2) weeks.

6.2 List of medical devices imported

6.2.1 In addition to the application form and documents stipulated above, the applicant shall also submit a list of medical devices being imported by him/her. The list shall contain key information of each medical device including manufacturer, model, device description and device's listing number (if applicable).

7. Processing, approval and rejection of applications

7.1 Each application for listing as an importer will be subject to processing and vetting by the MDD before it is considered by the Importer Listing Approval Board. The Board will decide whether to approve or reject the application or remit the application for further processing.

7.2 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. Where necessary, the MDD may request the

applicant to provide supplementary information or additional documents in support of its application.

7.3 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.

7.4 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.

8. Administrative provisions

8.1 Validity of approval

8.1.1 If an application for inclusion on the list of importers is approved, subject to Clause 8.4 below, the applicant will be included on the List for three (3) years unless otherwise specified.

8.2 Renewal of listing

8.2.1 The listed importer may apply for renewal of the current inclusion on the List of Importers (current listing) not less than 12 weeks before the expiry date 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.

8.3 Fees

8.3.1 No fee will be charged by the Government for the application or in relation to the inclusion of an importer's name on the List of Importers.

8.4 Undertaking by applicant

8.4.1 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.

8.5 Delisting of importers

8.5.1 An importer on the List of Importers may be delisted from the List if any of the following circumstances arise:

(a) The listed importer has been wound up, dissolved or otherwise has ceased to exist;

(b) The delisting is requested by the listed importer;

(c) The listed importer fails to comply with the MDACS requirements including, but not limited to, those stipulated in Clauses 5 and 6; or

(d) The listed importer 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 public health or public safety concern.

8.6 The List of Importers

8.6.1 For each listed importer the entries on the List may include:

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

(b) The Listed Importer Number assigned to the importer.

8.6.2 The List of Importers will be publicly accessible.

8.7 Appeal

8.7.1 The importer may appeal against a decision of the Importer Listing Approval Board to reject an application, or to remove a listed importer from the List of Importers within fourteen (14) working days of being notified of the decision.

8.7.2 To appeal, the importer shall write to the Secretary to Medical Device Administration Appeal Committee, c/o Medical Device Division, stating its grounds of appeal.

8.7.3 The lodging of an appeal against a decision of MDD does not suspend the decision unless MDD decides otherwise.

8.7.4 An appeal lodged after the time limit specified in clause 8.7.1 will not be considered.

8.7.5 The importer will be notified of the outcome of the appeal application within four (4) weeks following the submission of the appeal application and all the required supporting information (if applicable). The decision of the Medical Device

Administration Appeal Committee shall be final.

9. Point to note

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

10. Enquiries

10.1 Enquiries concerning this document 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

11. References

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

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

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

11.4 Department of Health. Guidance Notes for Listing of Local Manufacturers of Medical Devices. Guidance Notes GN-08.

11.5 Department of Health. Guidance Notes for Listing of Distributors of Medical Devices. Guidance Notes GN-09.

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

Appendix I

1. Documented procedures required for the listing of importer

1.1 The procedures described in Clause 5.1 of this guidance document and tabulated below shall be established and maintained, 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)	Ensuring the standard of medical devices imported	• Records in ensuring the device manufacturer has implemented a Quality Management System including supporting documents • Records of the devices to be imported demonstrating their safety, efficacy/ performance or quality e.g. testing reports, evaluation reports.
(b)	Keeping of supply records	• Supply records of devices including manufacturer, model, country of origin, batch/serial number, quantity, manufacturing date, expiry date, factory, vendor, customer, and delivery details • For devices required tracking, also see (g) below
(c)	Handling, storage and delivery of medical devices	• Receipts and issues of medical devices according to batch/serial numbers • Records of incoming medical devices inspection • Records of outgoing medical devices inspection • Records of segregated medical devices • 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)
(d)	Management of safety alerts, field safety notices and recalls	• Reports and records related to safety alerts, field safety notices and recalls
(e)	Managing reportable adverse events in Hong Kong	• Reports and records for reportable adverse events in Hong Kong
(f)	Complaints handling	• Reports and records for complaints • Reports for any corrective and preventive actions resulting from the complaint handling process
(g)	Tracking of specific medical devices	• Records in passing the LRP the details of the device and parties supplied to
(h)	Maintenance and services arrangements	• Records for arrangement of preventive and corrective maintenance services for the device, including calibration, provision of spare parts and other services

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

1.2.1 Purpose of the procedure

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

1.2.3 Definitions /abbreviations of terms used / references (if applicable)

1.2.4 Roles and responsibilities of persons taking part in the procedure

1.2.5 Detailed procedures

(a) A detailed description of the procedure including:

(i) Source of information and how the received information are handled;

(ii) Reporting requirements to the MDD with timing, if applicable (including notification, progress reports and final report to the MDD until completion); and

(iii) Actions required (including any corrective and preventive actions needed), persons responsible and timing of each key step.

1.2.6 Records

(a) Records related to each of the procedures as summarised in Clause 1.1 above shall be maintained and kept; and

(b) Means of identification, storage, security and integrity, retention time and disposition of records shall be specified.

1.2.7 Supplementary information (if applicable)

(a) Information necessary for completeness or useful for understanding of the procedure.

Appendix II

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

1. Purpose

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

2. Scope

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

(a) Procedure for ensuring the standard of medical devices imported;

(b) Procedure for keeping of supply records; and

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

2.2 According to the 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 management of safety alerts, field safety notices and recalls;

(b) Procedure for managing reportable adverse events 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. Importer 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

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

(a) Annex I – List of medical devices imported

(b) Annex II – Contact information of manufacturers, distributors, LRPs and maintenance agents for the medical devices imported

(c) Annex III – Contact information of staff involved in the import of the medical devices

4. References

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

5. Procedures

5.1 Procedure for ensuring the standard of medical devices imported

5.1.1 Purpose

(a) To set out procedures for ensuring of the standard of imported medical devices.

5.1.2 Scope

(a) It applies to the procedure and documents related to the import of the medical devices.

5.1.3 Reference documents

(a) The procurement handbook of accounts department.

5.1.4 Definitions and abbreviations

(a) Follows the definitions and abbreviations given under the procurement handbook.

5.1.5 Roles and responsibilities of persons

Person	Responsibility
Quality Control Manager (QCM) (including his/her designate)	• To ensure that the manufacturer(s) of imported medical devices has/have established appropriate quality system • To ensure that the imported medical devices meeting the safety, efficacy/ performance and quality requirement

5.1.6 Procedure

(a) The QCM shall review the quality system of the manufacturer to ensure that their manufacturing procedures and quality control system have consistently met applicable requirements and specifications. The ISO 13485 certificates of the manufacturers shall be kept.

(b) The QCM shall review the safety, efficacy/ performance and quality of the medical device to be imported including the history of recalls and adverse incidents.

5.1.7 Record

(a) Manufacturer evaluation form

(b) Certificate of manufacturer's quality system

(c) Product evaluation form

5.2 Procedures for keeping of supply records

5.2.1 Purpose

(a) To set out procedures for keeping of import, and associated supply records for medical devices on the import list of this Company

5.2.2 Scope

(a) It applies to the procedure and documents related to the import of the medical devices

5.2.3 Reference documents

(a) The procurement handbook of accounts department

5.2.4 Definitions and abbreviations

(a) Follows the definitions and abbreviations given under the procurement handbook

5.2.5 Roles and responsibilities of persons

Person	Responsibility
Accounts and Administration Manager (AAM) (including his/her designate)	• To ensure that import and associated supply records are kept and maintained for the period of time specified • To ensure that such records contain the information specified

5.2.6 Procedure

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

(b) Records for the medical devices imported into Hong Kong shall be kept using the Import Record Form (Form A) in addition to the in-house medical device database system (mdDBsys). Records for the medical devices supplied to distributors shall be kept using the Distribution Record Form (Form B). The forms and mdDBsys shall include information on manufacturer, model, batch/serial number, quantity, manufacturing date (if applicable), expiry date (if applicable), customer, factory/vendors, delivery details of the medical devices.

(c) The above records shall be retained for a period of time not less than the projected service life of the medical device as defined by the manufacturer, or seven (7) years from the date of product imported, whichever is longer.

5.2.7 Record

(a) Import Record Form (Form A)

(b) Distribution Record Form (Form B)

5.2.8 Supplementary information

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

5.3 Procedure for handling, storage and delivery of medical devices

5.3.1 Purpose

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

5.3.2 Scope

(a) It covers the procedures and all documents related to the handling, storage and delivery of medical devices imported by this Company

5.3.3 References

(a) 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)

5.3.4 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 C) • To assign each of the incoming 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 inspect the incoming medical devices • 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 inspect the outgoing medical devices to be delivered • To ensure proper storage conditions during transportation

5.3.5 Procedure

(a) For each incoming 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).

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

(c) The LDM shall perform an incoming inspection to ensure the received medical devices conform to required safety, performance, quality and other ordering requirement before storage. He/she shall record any discrepancy found in the inspection record (Form D).

(d) 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.

(e) 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.

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

(g) 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.

(h) 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.

(i) 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) shall be affixed to the Drawers for clear identification.

(j) 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 (1) year.

(k) 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 (7) years.

(l) 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.

(m) 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).

(n) The LDM shall perform an outgoing inspection and to ensure that the medical devices to be delivered conform to required safety, performance, quality and other ordering requirement prior delivery. Expired or nonconforming medical devices are identified, segregated and not inadvertently delivered to customers. Relevant inspection record (Form E) shall be kept.

(o) All records (including information of the delivery notes and invoices) shall be kept using the Delivery Form (Form F) 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:

(i) Date of dispatch

(ii) Complete business name and address of the addressee

(iii) Manufacturer, model, serial number/batch number

(iv) Quantity and expiry date (if applicable) of the medical devices

(v) Information on Delivery Note and Invoice

(p) The maintenance, service arrangement of medical devices would be carried out by the respective manufacturers and contractors (Annex I).

(q) Tracking of specific medical devices would be carried out by the respective LRPs (Annex I).

5.3.6 Records

(a) Stock Record Form (Form C)

(b) Incoming product inspection record (Form D)

(c) Outgoing product inspection record (Form E)

(d) Delivery Form (Form F)

(e) Temperature and humidity monitoring record

(f) Thermometers and hygrometers calibration record

(g) Cleaning and pest control record

5.3.7 Supplementary information

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

Annex I

List of medical devices imported

Item	Manufacturer	Model	Device Description	Listed Device (Y with no. / N)?	LRP	Other Information
1	SCTCB Co. Ltd.	CTCB-SCAN	Scanning Systems, Computed Tomography, Cone-Beam	Yes (Listing No.: 120120)	ABC Co. Ltd.	Class IIb (Rule 10) under EU's classification of medical device; Maintenance agent: contractor EFG Co.
2	SCTCB Co. Ltd.	CTCB-SCANR	Scanning Systems, Computed Tomography, Cone-Beam	No	---	Class IIb (Rule 10) under EU's classification of medical device; Maintenance agent: contractor EFG Co.
3	NEO IRU Inc.	WIR-111	Incubator / Radiant Warming Units, Infant, Mobile	Yes (Listing No.: 130130)	CDE Co. Ltd.	Class IIb (Rule 9) under EU's classification of medical device; Maintenance agent: manufacturer NEO IRU Inc.
4	NEO IRU Inc.	WIR-333	Incubator / Radiant Warming Units, Infant, Mobile	No	---	Class IIb (Rule 9) under EU's classification of medical device; Maintenance agent: manufacturer NEO IRU Inc.
5	Advance Ltd.	Heartbeat	Defibrillator/ Cardioverter/ Pacemakers, Implantable	Yes (Listing No.: 140140)	LMN Co. Ltd.	Class IV (Rule 8) under EU's classification of medical device; Device tracking by LMN Co. Ltd.

Annex II

Contact information of manufacturers, distributors, LRPs and maintenance agents for the medical devices imported

Company	Manufacturer(M)/ Distributor(D)/LRP(L)/ Maintenance Agent (A)	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 email: 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 email: john.miller@neo-iru.com
ABC Co. Ltd.	D, L	Miss M.Y. Liu, President Room 338, Cheerful Building, 3 Happy Road, Central, Hong Kong Tel: +852 5555 4444 Fax: +852 4444 5555 email: my.liu@abc.com
BCD Co. Ltd.	D	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 email: 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 email: bates.wong@cde.com
Advance Ltd.	M	Mr. Ken Yeung, Sales Manager Flat 1123, Healthy Building, Kowloon Bay, Hong Kong. Tel: +852 8888 5555 Fax: +852 8888 7777 email: kenyeung@advance.com
LMN Co. Ltd.	L	Mr. Nick Lee, Regulatory Affairs Officer Room B, 18/F, Wise Centre, Tsim Sha Tsui, Hong Kong. Tel: +852 6666 7777 Fax: +852 6666 7788 email: nlee@lmn.com
EFG Co.	A	Ms. Candy Chan, Maintenance department Flat C, 22/F, Fo Tan Industrial Building, NT, Hong Kong. Tel: +852 2222 5555 Fax: +852 2222 7777 email: candychan@efg.com

Annex III

Contact information of staff involved in the import of the medical devices (XYZ Co. Ltd.)

Staff	Post Title	Main Duties	Contact Information
Scarlett Wong	Director	Overall in-charge of the Company	Tel: +852 6000 0001 Fax: +852 6000 0009 email: scarlett.wong@xyz.com
Mandy Chan	Accounts and Administration Manager	Sales and record management related to medical devices	Tel: +852 6000 0002 Fax: +852 6000 0009 email: mandy.chan@xyz.com
Marco Wong	Logistics Department Manager	Logistics activities related to the storage, delivery and transportation of medical devices	Tel: +852 6000 0003 Fax: +852 6000 0009 email: marco.wong@xyz.com