

Code of Practice: COP-04

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醫療儀器的規管



Regulation of
Medical Devices

Code of Practice
for
Listed Importers of Medical Devices

Code of Practice: COP-04



中華人民共和國

香港特別行政區政府衛生署

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 document is to stipulate the requirements with which the listed importer of medical devices have to comply.
- 1.2 Importers are listed on the List of Importer of Medical Devices by their names, telephone numbers, addresses and Listing Numbers.
- 1.3 A listed importer needs to demonstrate its ability to provide medical devices under the Medical Device Administrative Control System (MDACS) requirements.

2. Requirements for Listing of Importer of Medical Devices

For an importer to be included on the List of Importer of Medical Devices, and for as long as it remains on the list, it shall meet the following requirements:

- 2.1 Establishment of Procedures

The listed importer shall maintain the distribution records for the products it imports. The distribution records shall be retained for a period of time at least equivalent to the service life of the said products as specified by the manufacturer, but not less than seven years from the date of distribution by the listed importer. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of distribution records. For the products that it imports with a view to distribution or use in Hong Kong, the listed importer shall establish in conjunction with the respective Local Responsible Persons (LRPs), or manufacturers if there is no LRP, the procedures (especially the procedures in respect of the interface between the listed importer and the LRP or manufacturer if there is no LRP) to follow in the following circumstances:

 - 2.1.1 when the listed importer receives complaints about any of the products;
 - 2.1.2 when advisory notices (recall notices, hazard alerts, etc.) affecting any of the products are issued by manufacturers or LRPs;
 - 2.1.3 when a reportable or potentially reportable adverse incident as defined in Guidance Notes GN-00 (Definitions and Abbreviations for Medical Device Administrative Control System) involving any of the products has come to the attention of the listed importer. The listed importer is required to seek the consent of the reporting party to refer the reportable adverse incident to the Local Responsible Person (or the manufacturer and the MDCO if there is no LRP). If the reporting party does not consent, the listed importer should ask the reporting party to report the adverse incident directly to the Local Responsible Person (or the manufacturer and the MDCO if there is no LRP). Please refer to the Guidance Notes for Adverse Incident Reporting by Local Responsible Persons (GN-03) for details about reportable adverse incidents.

- 2.2 Making Distribution Records etc. Available for Inspection
Upon the request from the MDCO, the listed importer shall make available to the MDCO for inspection the distribution records and other documents maintained by the listed importer.
- 2.3 Requirements in Respect of Advertisement, Promotional Materials etc.
- 2.3.1 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:
- (1) include a statement to the effect that the listing of an importer carries no implication that its medical device products are listed, and
 - (2) clearly state whether any of the medical devices presented in the same article are listed under the MDACS or not.
- 2.3.2 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 2.3.1(1) and (2) above shall be in the same format (in terms of font size, colour, etc) as the aforesaid representation.
- 2.4 Listed importer shall notify the MDCO of any changes to the information submitted. The MDCO has the discretion to request the listed importer to produce documentary evidence of the change so notified. The listed importer shall answer MDCO's enquiries as soon as possible, but no later than three working days.

3. Undertaking by the Listed Importer of Medical Devices

- 3.1 A listed importer shall, on the terms set out in the Undertaking 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: any act or default of the applicant, any defective design of the medical device products of the applicant, any defect in such products, and any information supplied by the listed importer to the Government.

4. Delisting

- 4.1 A listed importer may be removed from the List of Importer of Medical Devices at the discretion of the Importer of Medical Devices Listing Approval Board if:
- 4.1.1 (in case the listed importer is a body corporate or a partnership) the listed importer has been wound up, dissolved or otherwise has ceased to exist, or (in case the listed Importer is an individual) the listed importer has died;
 - 4.1.2 the delisting is requested by the listed importer;
 - 4.1.3 the listed importer fails to comply with the MDACS requirements

- including but not limited to those stipulated in section 2;
- 4.1.4 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 device products or to a public health or public safety concern; or
 - 4.1.5 the MDCO considers the delisting necessary for the public health or safety considerations.

5. Appeal

- 5.1 The importer may appeal against a decision of the Importer of Medical Devices Listing Approval Board to reject an application for listing an importer or to remove a listed importer from the List of Importer of Medical Devices within 4 weeks of being notified of the decision.
- 5.2 To appeal, the importer must write to the Secretary to Medical Device Administration Appeal Committee, c/o Medical Device Control Office, stating its grounds of appeal.
- 5.3 An appeal lodged after the time limit will not be considered.

6. Enquiries

Enquiries concerning this document and the listing of importer should be directed to:

Medical Device Control Office, Department of Health,
~~18/F, Wu Chung House~~ Rm 3101, 31/F, Hopewell Centre,
~~213 Queen's Road East~~ 183 Queen's Road East,
Wanchai, Hong Kong
Facsimile number: 3157 1286
Telephone number: ~~2961 8788~~ 3107 8484
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