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醫療儀器的規管

Regulation of Medical Devices

Code of Practice
for
Listed Local Manufacturers

Code of Practice: COP-03

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 document is to stipulate the requirements that the listed local manufacturers have to comply with.

1.2 The primary requirement for the listing of a local manufacturer is that the manufacturer shall establish, document, implement and maintain a quality management system.

1.3 The requirements for a quality management system together with the other conformity assessment elements are intended to ensure that medical devices manufactured, or (as the case may be) designed and manufactured, under the quality management system will be safe and perform as intended by the manufacturer.

1.4 Manufacturers are listed on the List of Local Manufacturers by their names, Listing Numbers and Listed Scope of Manufacture. The Listed Scope of Manufacture of a listed manufacturer shall not exceed the scope of its quality management system. If the manufacturer manufactures or places on market (whether under its name or not) a product that falls outside its Listed Scope of Manufacture, it shall not claim itself as a listed manufacturer of that product or imply such a claim.

1.5 A listed manufacturer needs to demonstrate its ability to provide medical devices within its Listed Scope of Manufacture that consistently meet customer requirements and the Medical Device Administrative Control System (MDACS) requirements applicable to those medical devices. Manufacturers must demonstrate compliance with this requirement through an established and effectively implemented quality management system that meets the MDACS requirements.

1.6 The scope and complexity of the quality management system that the manufacturer needs to establish is influenced by varying needs, objectives, products provided, processes employed, the size and structure of the organization, and the specific MDACS requirements.

2. Requirements for Listing of Local Manufacturers

For a manufacturer to be included on the List of Local Manufacturers, and for as long as it remains on the list, it shall meet the following requirements:

2.1 The manufacturer shall be a local manufacturer, and shall maintain its business registration for its business as a manufacturer of medical devices or for a business of which its business as a manufacturer of medical devices is a part.

2.2 The local manufacturer shall establish, document, implement and maintain a quality management system which complies with the requirements of ISO 13485 or equivalent which also covers all the MDACS requirements.

2.3 The local manufacturer shall demonstrate compliance with ISO 13485 or equivalent by means of certification by a recognized conformity assessment

body. Alternatively, it may obtain the certification of its quality management system by a certification body that has been accredited by a member of the International Accreditation Forum as a body competent in certifying quality management systems.

2.4 Manufacturers of Classes III and IV devices shall have a full quality management system that includes design and development. Manufacturers of Classes I and II devices shall have a quality management system that need not include design and development activities.

2.5 If the manufacturer places any classes of medical devices on the market (in or outside Hong Kong), it shall provide the full list of the devices to the MDCO. The list shall include the makes, models and, preferably, the classes and common names or descriptions of the devices. The local manufacturer shall submit an updated list (preferably in soft copy) to the MDCO at every 12 month intervals even if there is no change.

2.6 The listing of a local manufacturer or assignment of a Listing Number to the manufacturer does not in any way denote approval or listing of the manufacturer's products. The product labelling shall not include or refer to the local manufacturer's Listing Number or any communications that claim or suggest that the manufacturer has been listed, registered or approved by the Medical Device Control Office (MDCO)/ Department of Health/ HKSAR Government.

2.7 Requirements in Respect of Advertisements, Promotional Materials etc.

2.7.1 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 manufacturer is a listed local manufacturer, or that the manufacturer is in compliance with the MDACS requirements on listed local manufacturers, it shall at the same time

(1) clearly state the manufacturer's Listed Scope of Manufacture;
(2) include a statement to the effect that the listing of a manufacturer carries no implication that its medical device products are listed, whether or not they are within the Listed Scope of Manufacture; and
(3) clearly state whether any of the medical devices presented in the same article are listed under the MDACS or not.

2.7.2 Where the representation that the manufacturer is a listed local manufacturer, or that the manufacturer is in compliance with the MDACS requirements on listed local manufacturers, is in writing, then the statements required by 2.7.1(1) to (3) above shall be in the same format (in terms of font size, colour, etc.) as the aforesaid representation.

2.8 The incident reporting requirements of the Guidance Notes GN-03 (entitled "Guidance Notes for Adverse Incident Reporting by Local Responsible Person") shall be extended to the reporting of incidents involving any of the products (including Class I products) that fall within the manufacturer's Listed Scope of

Manufacture. This extension requires the manufacturer to report such incidents according to the requirements of the Guidance Notes GN-03 as if it were the Local Responsible Person for those products.

2.9 The manufacturer shall inform the MDCO of any major changes in its quality management system, including any change in respect of the certification of the system e.g. change of the scope of certification, or suspension or withdrawal of certification, not later than 4 weeks after either the change takes effect or the manufacturer has noticed the change, whichever is the earlier.

2.10 Upon request of the MDCO, the manufacturer shall:

2.10.1 as soon as possible provide the requested records or documents related to the manufacturer's quality management system or products to the MDCO for inspection;

2.10.2 allow the MDCO to perform audits on the manufacturer and any major contract manufacturers/sterilizers that it employs. The manufacturer must make provision for such audits and provide all the necessary assistance to the MDCO to facilitate the conduct of the audits.

3. Undertaking by the Listed Local Manufacturer

3.1 A listed local manufacturer 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 local manufacturer to the Government.

3.2 It is open to the listed local manufacturer to take out insurance to cover any of the insurable liabilities that it might incur under the Undertaking.

4. Delisting

4.1 A listed local manufacturer may be removed from the List of Local Manufacturers at the discretion of the Local Manufacturer Listing Approval Board if:

4.1.1 the manufacturer does not comply with the MDACS requirements including but not limited to those in section 2; or

4.1.2 the manufacturer has been wound up or has ceased to exist; or

4.1.3 the delisting is requested by the manufacturer; or

4.1.4 where the manufacturer is also a Local Responsible Person for its products , it does not comply with any of the MDACS requirements that are imposed on it as a Local Responsible Person; or

4.1.5 the manufacturer 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 (whether or not the products fall within its Listed Scope of Manufacture); or

4.1.6 the Local Manufacturer Listing Approval Board considers the delisting is necessary for public health or safety considerations; or

4.1.7 the manufacturer has made a false, unjustified or misleading claim when advertising its medical device products (whether or not the products fall within its Listed Scope of Manufacture).

5. Appeal

5.1 The manufacturer may appeal against a decision of the Local Manufacturer Listing Approval Board to reject an application for listing a local manufacturer or to remove a listed manufacturer from the List of Local Manufacturers within 4 weeks of being notified of the decision.

5.2 To appeal, the manufacturer must write to the Secretary to Medical Device Administration Appeal Committee, c/o Medical Device Control Office, stating its grounds of appeal.

5.3 The lodging of an appeal against a decision of the Local Manufacturer Listing Approval Board to reject an application or to delist a manufacturer does not suspend the decision unless the Medical Device Administration Appeal Committee decides otherwise.

5.4 An appeal lodged after the time limit specified in section 5.1 will not be considered.

6. Enquiries

Enquiries concerning this document and the listing of local manufacturers 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
E-mail address: mdco@dh.gov.hk