GN-08:2021(E)

Medical Device Administrative Control System (MDACS)

Guidance Notes for Listing of Local Manufacturers of Medical Devices

Guidance Notes: GN-08

中華人民共和國
香港特別行政區政府衞生署

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

Revision History

Edition Number	Date of Revision	Summary of Revisions	Reference Number
0	23 March 2007	• First issue of GN-08	GN-08:2007(E)
1.0	19 April 2021	• Update document style and layout; • Rename of Medical Device Control Office to Medical Device Division; • Clause 2 (Scope) has been updated; • Clause 3 (Definitions and Abbreviations) has been updated. Reference is made to Guidance Notes GN-00 (Guidance Notes for Definitions and Abbreviations for Medical Device Administrative Control System) for definitions; and • Clause 10 (References) has been updated	GN-08:2021(E)

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1. Introduction

1.1 The purpose of this document is to define the requirements for the listing of local manufacturers of medical devices.

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 of Medical Devices 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 these requirements 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 are influenced by varying needs, objectives, products provided, processes employed, the size and structure of the organization, and the specific MDACS requirements.

1.7 Application for inclusion on the List of Local Manufacturers of Medical Devices is on a

voluntary basis and is free of charge.

2. Scope

2.1 This document is applicable to the listing of local manufacturers of medical devices who have a business registration in Hong Kong.

2.2 This document specifies the requirements for the listing of local manufacturers of medical devices only. Please refer to GN-02 and GN-06 for the requirements for the listing of Class II/III/IV general medical devices and Class B/C/D in vitro diagnostic medical devices respectively.

3. Definitions and Abbreviations

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

3.1.1 The Listed Scope of Manufacture (see clause 1.4 above) of the local manufacturer shall satisfy the following requirements:

3.1.1.1 The medical devices or categories of medical device that are covered by the Listed Scope of Manufacture shall fall within the scope of the MDACS.

3.1.1.2 The manufacturer, even if it is the manufacturer of more than one medical device product, may choose to be listed with a Listed Scope of Manufacture that is more restrictive than the range of products of which it is the manufacturer. Any medical device product of which falls within its Listed Scope of Manufacture shall also be covered by the scope of certification of its quality management system referred to in clause 4.1.3.

3.1.2 'the scope of the MDACS' is interpreted in the same way as in the Guidance Notes GN-01.

4. Requirements for Listing of Local Manufacturers of Medical Devices

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

4.1.1 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.

4.1.2 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.

4.1.3 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. In either case, when applying to be listed, a copy of the quality management system certificate shall be submitted by the manufacturer along with the completed application form LM.

4.1.4 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 MDD. 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 in soft copy to the MDD at 12-month intervals even if there is no change.

4.1.5 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 Division (MDD)/ Department of Health/ HKSAR Government.

4.1.6 Requirements in Respect of Advertisements, Promotional Materials etc.

4.1.6.1 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

(a) clearly state the manufacturer's Listed Scope of Manufacture;

(b) 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

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

4.1.6.2 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 4.1.6.1 (a) to (c) above shall be in the same format (in terms of font size, colour, etc.) as the aforesaid representation.

4.1.7 The adverse event reporting requirements of the Guidance Notes GN-03 (Guidance Notes for Adverse Event Reporting by Local Responsible Persons) shall be extended to the reporting of adverse events involving any of the products (including Class I general medical device or Class A IVDMD products) that fall within the manufacturer's Listed Scope of Manufacture. This extension requires the manufacturer to report such events according to the requirements of the Guidance Notes GN-03 as if it were the Local Responsible Person for those products.

4.1.8 The manufacturer shall inform the MDD 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.

4.1.9 Upon request of the MDD, the manufacturer shall:

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

4.1.9.2 allow the MDD 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 MDD to facilitate the conduct of the audits.

5. The Processing, Approval and Rejection of Applications

5.1 Each application for listing a local manufacturer will be subject to processing by the MDD before it is considered by the Local Manufacturer Listing Approval Board. The Board will decide whether to approve or reject the application or remit the application for further processing.

5.2 The processing of an application will include, but not be limited to, the following:

5.2.1 the checking of the completed application form for adequacy and accuracy of the information and supporting documents provided by the applicant;

5.2.2 Where necessary the MDD will request the applicant to provide supplementary information or additional documents in support of its application; and

5.2.3 For documents referenced, or photocopies of documents submitted, by the

applicant, the MDD may, at its discretion, request for inspection of the originals or certified true copies of the documents, and within two weeks of receiving such a request the applicant shall produce the originals or certified true copies for inspection.

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

5.4 The processing and approval of an application will normally be completed within a period of 12 weeks, provided at the time of the commencement of this period a properly completed application form (which must include inter alia a duly completed and signed Undertaking) in respect of this application, together with all the necessary supporting documents, has reached the MDD.

5.5 Unless otherwise decided by the Local Manufacturer Listing Approval Board, the inclusion of a manufacturer on the List of Local Manufacturers of Medical Devices following the approval of the manufacturer's application will last for a period of five years.

6. Undertaking by the Applicant

6.1 The applicant 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 applicant to the Government. Please see also clause 5.3 above.

6.2 It is open to the applicant to take out insurance to cover any of the insurable liabilities that it might incur under the Undertaking.

7. Delisting

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

7.1.1 the manufacturer does not comply with the MDACS requirements including but not limited to those in clause 4;

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

7.1.3 the delisting is requested by the manufacturer;

7.1.4 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;

7.1.5 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);

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

7.1.7 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).

8. Appeal

8.1 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 of Medical Devices within 4 weeks of being notified of the decision.

8.2 To appeal, the manufacturer must write to the Secretary to Medical Device

Administration Appeal Committee, c/o Medical Device Division, stating its grounds of appeal.

8.3 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.

8.4 An appeal lodged after the time limit specified in clause 8.1 will not be considered.

9. Enquiries

9.1 Enquiries concerning this document and the listing of local manufacturers of medical devices should be directed to:

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

9.2 Latest versions of the Guidance Notes for the MDACS and the application forms for listing are available at the website: https://www.mdd.gov.hk

10. References

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

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

10.3 Department of Health. Guidance Notes for Listing Class II/III/IV General Medical Devices. Guidance Notes GN-02.

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

10.5 Department of Health. Guidance Notes for Listing Class B, C and D In Vitro Diagnostic Medical Devices. Guidance Notes GN-06.