

醫療儀器的規管

Regulation of
Medical Devices

Guidance Notes for Listing of Local Manufacturers

Guidance Notes: GN-08



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 booklet is to define the requirements for the listing of local manufacturers.
- 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.
- 1.7 Application for inclusion on the List of Local Manufacturers 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-05 for the requirements for the listing of Class IV and Class II/III medical devices respectively.

3. Definitions and Abbreviations

For the purposes of this booklet, the definitions and abbreviations given in the

Guidance Notes GN-01 apply unless the context otherwise requires.

- 3.1 'manufacturer' means
 - (a) a natural or legal person with responsibility for the design, manufacture, packaging and labelling of a medical device before it is placed on the market under its own name, regardless of whether these operations are carried out by that person himself or on its behalf by a third party; or
 - (b) any other natural or legal person who assembles, packages, processes, fully refurbishes or labels one or more ready-made products or assigns to them their intended purpose as a medical device with a view to their being placed on the market under its own name, apart from a person who assembles or adapts medical devices already on the market to their intended purpose for an individual patient.
- 3.2 'to list a local manufacturer' means to include a local manufacturer on the List of Local Manufacturers.
- 3.3 'to delist a local manufacturer' means to remove a local manufacturer from the List of Local Manufacturers.
- 3.4 'placing on the market' means the first making available in return for payment or free of charge of a medical device other than a device intended for clinical investigation, with a view to distribution and/or use on the market, regardless of whether it is new or fully refurbished.
- 3.5 'local manufacturer' means a manufacturer whose business as a manufacturer of medical devices has either been registered in Hong Kong pursuant to the Business Registration Ordinance (Cap. 310) or is part of a business which has been so registered.
- 3.6 The Listed Scope of Manufacture (see section 1.4 above) of the local manufacturer shall satisfy the following requirements:
 - 3.6.1 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.
 - 3.6.2 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 section 4.3.
- 3.7 '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

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:

- 4.1 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.
- 4.2 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.
- 4.3 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 (see Appendix 1).
- 4.4 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.
- 4.5 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.
- 4.6 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.
- 4.7 Requirements in Respect of Advertisements, Promotional Materials etc.
 - 4.7.1 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.

4.7.2 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 4.7.1(1) to (3) above shall be in the same format (in terms of font size, colour, etc.) as the aforesaid representation.

4.8 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.

4.9 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.

4.10 Upon request of the MDCO, the manufacturer shall:

4.10.1 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;

4.10.2 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.

5. The Processing, Approval and Rejection of Applications

5.1 Each application for listing a local manufacturer will be subject to processing by the MDCO 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 MDCO 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 MDCO 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 MDCO 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 MDCO.
- 5.5 Unless otherwise decided by the Local Manufacturer Listing Approval Board, the inclusion of a manufacturer on the List of Local Manufacturers 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 section 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 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 section 4; or
- 7.1.2 the manufacturer has been wound up or has ceased to exist; or
- 7.1.3 the delisting is requested by the manufacturer; or
- 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; or
- 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); or
- 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 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 Control Office, 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 section 8.1 will not be considered.

9. Enquiries

Enquiries concerning this booklet 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

Latest versions of the Guidance Notes for the MDACS and the application forms for listing are available at the website: <http://www.mdco.gov.hk>

10. References

- [1]GN-01, Overview of the Medical Device Administrative Control System
- [2]GN-03, Guidance Notes for Adverse Incident Reporting by Local Responsible Persons



**Medical Device Control Office
Department of Health**

**Medical Device Administrative Control System
Application for the Listing of Local Manufacturers**

For official use only

Date Received: _____ Application No.: _____ Officer: _____

Date Approved/Rejected: _____ Listing No.: _____

Remarks: _____

Instructions for Applicant

1. Please read the Statement of Purposes at the last page of this application form.
2. Please note that information included in those parts that are marked with asterisks (*) may be included on The List of Local Manufacturers if this application is approved. The details will normally appear on The List of Local Manufacturers as they appear on this form. Where under an item both the prompts “in English” and “in Chinese” appear, the entry for that item shall be given in both languages wherever applicable such that they could be accordingly recorded on The List of Local Manufacturers for the reference of the public.
3. Please check the corresponding boxes in the “Encl.” column if any document is enclosed under respective indexes of the submission folder.
4. Submitted documents not in Chinese or English shall be accompanied by Chinese or English translations.
5. Please check the boxes as appropriate.
6. Please complete and sign the Undertaking.

Note	Particulars of Manufacturer		Encl.	
1001	Manufacturer's name*:	<i>in English</i>		
		<i>in Chinese</i>		
	Address*:	<i>in English</i>		
		<i>in Chinese</i>		
	No. of employees (for medical devices only) at the above address:			
	Website*:		Email:	
	Tel.:		Fax:	
	Manufacturing Sites (if different from the above)			
	Site No. 1			
	Address*:	<i>in English</i>		
<i>in Chinese</i>				

No. of employees (for medical devices only) at this manufacturing site:		
Site No. 2		
Address*:	<i>in English</i>	
	<i>in Chinese</i>	
No. of employees (for medical devices only) at this manufacturing site:		
Management Representative		
Name:	Position:	
Telephone:	E-mail:	
Fax:	Mobile phone:	
Deputy Management Representative		
Name:	Position:	
Telephone:	E-mail:	
Fax:	Mobile phone:	
<input type="checkbox"/> Copy of business registration certificate (with business registration number _____) is enclosed		(A1) <input type="checkbox"/>
Listed Scope of Manufacture* (This must not exceed the scope of certification stated in item 1002 below. If this application is approved, the Listed Scope of Manufacture as appears in the space below may be included, together with the name of the manufacturer, onto the List of Local Manufacturers.)		

1002	<p><u>Certified Quality Management System (QMS)</u></p> <p>(a) Standards with which the QMS complies:</p> <p><input type="checkbox"/> ISO13485:2003 <input type="checkbox"/> Others _____ (please specify)</p> <p><input type="checkbox"/> System certified by _____ (certification body), and a copy of the certificate is enclosed</p> <p>(b) For each of the standards with which the QMS complies, does the scope of certification of the QMS include design and development controls?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Remarks:</p> <p>(c) Does the manufacturer outsource any process (e.g., design and development, manufacturing, warehousing, sterilization, etc.) of the QMS?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, please indicate the outsourced processes below:</p>	(A2) <input type="checkbox"/>
1003	<p><u>Documented Procedures Established</u></p> <p><input type="checkbox"/> Complaints handling</p> <p><input type="checkbox"/> Reportable adverse incidents in Hong Kong (A copy of the documented procedure shall be submitted together with this application form.)</p> <p><input type="checkbox"/> Recalls (A copy of the documented procedure shall be submitted together with this application form.)</p>	(A3) <input type="checkbox"/>
1004	<p><u>Products of the manufacturer</u></p> <p>Please indicate the full range of medical device products of which the applicant is the manufacturer. (Please refer to Appendix 1 of Guidance Notes GN-01 for the classification rules for medical devices.)</p> <hr/> <p><input type="checkbox"/> Class I (Please indicate the Class I products below.)</p> <hr/> <p><input type="checkbox"/> Class II (Please indicate the Class II products below.)</p> <hr/> <p><input type="checkbox"/> Class III (Please indicate the Class III products below.)</p> <hr/> <p><input type="checkbox"/> Class IV (Please indicate the Class IV products below.)</p>	

Undertaking by Applicant

Date: _____

To the Government of the Hong Kong Special Administrative Region (hereinafter “the Government”):

I/We have read the latest editions of the Guidance Notes GN-01 (with Appendices 1 to 5) and GN-08 (with Appendix 1) issued by the Department of Health in relation to the Medical Device Administration Control System (MDACS) and the listing of local manufacturers thereunder.

In consideration of the promise of the Government in section 5.3 of the Guidance Notes GN-08 to proceed with the processing of this application under the MDACS, I/we*, _____

[name and address of the Applicant],

undertake, acknowledge and agree in favour of the Government as follows:

1. To the maximum extent permitted by law I/we agree to exempt, relieve, exonerate, indemnify and hold harmless, and to keep indemnified and harmless, as the case may be, the Government from and/or against any and all losses, claims, demands and proceedings (including but not limited to all costs, charges and expenses) whatsoever and howsoever suffered or incurred by, or made or issued against, the Government, as the case may be, by any third party in respect of any loss of or damage to any property or injury to or death of any person arising out of and/or relating and/or incidental to:
 - a. any act, neglect or default on my/our part or on the part of my/our employees or agents;
 - b. any defect in the design, material, workmanship or installation in relation to my/our medical device product or products;
 - c. any use of any of the information supplied by me/us or my/our employees or agents in relation to this application or to my/our medical device product or products, whether or not such information has materially contributed to the inclusion of the applicant on the List of Local Manufacturers or the inclusion of any of my/our product or products on the List of Medical Devices and whether or not such information is misleading, wrong or inaccurate.
2. I/We also agree and accept that:
 - a. the Government, its employees or agents shall not be liable to me/us for any loss of or damage to property caused by the act, default or neglect of the Government or its employees or agents in the processing of my/our application, the inclusion or non-inclusion of any of my/our information and/or product or products on the Lists being maintained under the MDACS (including but not limited to the List of Local Manufacturers and the List of Medical Devices) or any cause whatsoever arising out of or in connection with the implementation and management of the MDACS;
 - b. neither the Government nor any of its employees or agents makes any representation, statement, warranty or guarantee, express or implied, that any of my/our products (including any spares or replacement parts), whether or not they are included on the List of Medical Devices, are of merchantable quality or are fit for the purposes for which they are commonly bought, used and/or applied and that the spares or replacement parts are readily available.
3. I/We undertake that the information contained in my/our application is true and correct and that my/our medical device product or products (including any spares or replacement parts) are of merchantable quality and are fit for the purposes for which they are commonly bought, used and/or applied.
4. I/We fully understand and agree that any future changes or additions to the requirements of the MDACS can be imposed by the Department of Health without prior notice. I/We hereby undertake to comply with the latest requirements of the MDACS that are in force.

5. I/We undertake that I/we have neither amended any wording in this form, nor otherwise altered the form in any material manner, apart from filling in the appropriate blanks / boxes.

Each of the provisions of this Undertaking is severable and distinct from the others and, if one or more of such provisions or any part thereof is or becomes illegal, invalid or unenforceable, the legality and enforceability of the remainder of this Undertaking shall not be affected or impaired in any way.

The Government shall be entitled to enforce any or all of its rights under this Undertaking.

This Undertaking shall be governed by and construed according to the laws of Hong Kong and the parties irrevocably submit to the non-exclusive jurisdiction of the Courts of Hong Kong.

As witness whereof, this Undertaking has been entered into the day, month and year first above written

SIGNED BY)
)
_____ (name of Applicant or its representative*))
_____ (position))
)
[for and on behalf of)
)
_____ (name of Applicant))
(who hereby warrant(s) that the signatory above has)
the authority to bind the above firm and the partners)
therein for the time being / the above company* to)
this Undertaking)]#)
)
in the presence of)
)
_____ (name))
)
_____ (address))

** Delete where appropriate*

Delete if the applicant is an individual

Personal Data (Privacy) Ordinance

Statement of Purposes

1. Purpose of Collection

The personal data that are provided by you in connection with this application or when you are in contact with the Department of Health (DH) in connection with matters related to the Medical Device Administrative Control System (MDACS) will be used by the DH for the management and implementation of the MDACS.

2. Classes of Transferees

The personal data you provide are mainly for use within the DH but they may also be disclosed to other Government bureaux/departments or relevant parties for the purpose mentioned in para. 1 above, and related matters if required. Apart from this, the data may only be disclosed to parties where you have given consent to such disclosure or where it is allowed under the Personal Data (Privacy) Ordinance.

3. Access to Personal Data

You have a right of access and correction with respect to personal data as provided for in sections 18 and 22 and Principle 6 of Schedule 1 of the Personal Data (Privacy) Ordinance. Your right of access includes the right to obtain a copy of your personal data. A fee may be imposed for complying with a data access request.

4. Enquiries

Enquiries concerning the personal data provided, including the making of access and corrections, should be addressed to the Medical Device Control Office, Department of Health (~~18/F., Wu Chung House, 213 Queen's Road East, Wanchai, Hong Kong~~ Rm 3101, 31/F, Hopewell Centre, 183 Queen's Road East, Wan Chai, Hong Kong; facsimile number: 3157 1286; telephone number: ~~2961-8788~~ 3107 8484). Please quote your application number when submitting the request.