Medical Device Division
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*:	*in English*		
		in Chinese		
	Address*:	*in English*		
		in Chinese		
	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*:	*in English*		
		in Chinese		

No. of employees (for medical devices only) at this manufacturing site:			
Site No. 2			
Address*:	*in English*		
	in Chinese		
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:	
☐ Copy of business registration certificate (with business registration number _____) is enclosed			(A1) ☐
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	Certified Quality Management System (QMS) (a) Standards with which the QMS complies: ○ ISO13485 ○ Others _____ (please specify) System certified by _____ (certification body), and a copy of the certificate is enclosed (b) For each of the standards with which the QMS complies, does the scope of certification of the QMS include design and development controls? ○ Yes ○ No Remarks: (c) Does the manufacturer outsource any process (e.g., design and development, manufacturing, warehousing, sterilization, etc.) of the QMS? ○ Yes ○ No If yes, please indicate the outsourced processes below:	(A2) ☐
1003	Documented Procedures Established ☐ Complaints handling ☐ Reportable adverse events in Hong Kong (A copy of the documented procedure shall be submitted together with this application form.) ☐ Recalls (A copy of the documented procedure shall be submitted together with this application form.)	(A3) ☐
1004	Products of the manufacturer Please indicate the full range of medical device products of which the applicant is the manufacturer. (Please refer to Technical References TR-003 or TR-006 for the classification rules for general medical devices or in vitro diagnostic medical devices (IVDMD).) ☐ Class I (Please indicate the Class I products below.) ☐ Class II (Please indicate the Class II products below.) ☐ Class III (Please indicate the Class III products below.) ☐ Class IV (Please indicate the Class IV products below.)	

☐ IVDMD Class A (Please indicate the Class A products below.)
☐ IVDMD Class B (Please indicate the Class B products below.)
☐ IVDMD Class C (Please indicate the Class C products below.)
☐ IVDMD Class D (Please indicate the Class D products below.)

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 Department for the management and implementation of the MDACS.

The provision of personal data is voluntary. If you do not provide sufficient information in the application as specified, we may not be able to process your application and assess your eligibility for a listing certificate.

2. Classes of Transferees

The personal data you provided 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 paragraph 1 above, if required. Apart from this, the data may only be disclosed to parties where you have given consent to such disclosure or where such disclosure is allowed under the Personal Data (Privacy) Ordinance.

3. Access to Personal Data

You have a right to request access to and correction of your personal data as provided in accordance with the Personal Data (Privacy) Ordinance (Cap. 486).

Your right of access includes the right to obtain a copy of your personal data provided by you during the occasion as mentioned in paragraph 1 above. A fee may be imposed for complying with a data access request.

4. Enquiries

Enquiries in relation to the personal data, including requests for making access or corrections to the data, should be addressed to:

Executive Officer
Medical Device Division, Department of Health
Room 604, 6/F, 14 Taikoo Wan Road,
Taikoo Shing, Hong Kong
Telephone number: 3107 8453
E-mail address: mdd@dh.gov.hk.

Please quote your application number when you make the enquiries.