Medical Device Division
Department of Health

Medical Device Administrative Control System - Application for Inclusion on the List of Importers/ Distributors

For official use only

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

Date Approved/Rejected: _____

Importer No. _____ *Distributor No.* _____

Remarks: _____

Please read this section carefully before completing the form

1. *Please note that information included in those parts that are marked with asterisks (*) may be included on the List of Importers and/or the List of Distributors and uploaded to the MDD website if this application is approved. They include the name, address, and contact telephone number for public enquiries of the Importer and/or Distributor in Hong Kong (1001, 1002 & 1004). The details will normally appear on the List of Importers and/or the List of Distributors 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 Importers and/or the List of Distributors for the reference of the public.*
2. *Please check the boxes as appropriate and also check the corresponding boxes in the "Encl." column if any document is enclosed under respective indexes of the submission folder.*
3. *Please note that the submitted information may be forwarded to third parties (such as but not limited to foreign regulatory authority, notified body or conformity assessment body) for validation purposes.*
4. *Submitted documents not in Chinese or English shall be accompanied by Chinese or English translations.*

☐ **Application for the Inclusion on the List of Importers**

☐ **Application for the Inclusion on the List of Distributors**

	Particulars of Applicant				**Encl.**
1001	*Company Name** *(see Note 1)*	*in English*			
		in Chinese			
1002	*Address in Hong Kong**	*in English*			
		in Chinese			
1003	*Status and Identity (Please provide documentary proof; see Note 2)*	☐ Body corporate ☐ Partnership			**(A1)** ☐
1004	*Contact Information*	*Contact Person*	*Name*		
			Position		
		*Telephone**			
		Mobile telephone for urgent use (24 hours)			
		E-mail			
		Fax			

	Applicant's Intent to Import and/or Distribute Medical Devices	
2001	The import and/or distribution is in the name of or for the purpose of a business that the applicant carries on. The business has been registered with the following: Business registration number: _____ Name of business: (*Please enclose a copy of the business registration certificate. If the business name appears on the certificate (see Note 1 at bottom of table) is not the same as your name given in item 1001, please provide documentary evidence that you carry on that business, (e.g. an extract of the relevant information from the business register). If your application is successful, you will be included on the List of Importers and/or the List of Distributors by your business name as appears on the business registration certificate.)*	**(A2)** ☐
2002	☐ A full list of the medical devices imported and/or distributed by the applicant is attached. The list shall cover key information of each device including manufacturer, model, device description and listing number of medical device (if applicable).	**(A3)** ☐
2003	The applicant is also ☐ a listed Local Manufacturer with listing no. : _____ ☐ a listed Local Responsible Person with listing no.: _____ ☐ a listed Importer with listing no.: _____ ☐ a listed Distributor with listing no.: _____	
2004	Address of storage/ maintenance/ other facilities (if different from item 1002) and kind of activities conducted in each facility:	

	Quality Management and Vigilance Practices	
3001	The applicant has established and maintained the following documented procedures in respect of the medical devices it imports and/or distributes: **(A copy of all documented procedures shall be submitted together with this application form.)**	

	☐ (For importer only) Ensuring the standard of medical devices imported ☐ Keeping of supply records ☐ Handling, storage and delivery of medical devices ☐ Managing product recalls and field safety notices ☐ Managing reportable adverse events in Hong Kong ☐ Complaints handling ☐ Tracking of specific medical devices ☐ Maintenance and services arrangements	**(A5)** ☐

3002 The applicant is implementing

	☐ a quality management system according to _____ (international standard such as ISO 13485, ISO 9001) certified by a third party certification body, namely, , and which has incorporated all/part of the established procedures mentioned above (Please enclose a copy of the certificate with the completed application form).	**(A6)** ☐
	☐ a quality management system incorporating all or part of the established procedures mentioned above, but the system has not been independently certified.	
	☐ no quality management system yet.	

Notes

	1. The business name given in item 1001 must be the same as the Name of Business that appears on your business registration certificate. 2. An applicant who is a body corporate or a partnership must provide documentary proof of its body corporate or partnership status (a copy of a relevant business registration certificate is acceptable as such proof).	

Undertaking by Applicant

Date: _____

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

We have read the latest editions of the Guidance Notes GN-01 Overview of the Medical Device Administrative System (with all appendices) and GN-07 Guidance Notes for Listing of Importers of Medical Devices (with all appendices) and/or GN-09 Guidance Notes for Listing of Distributors of Medical Devices (with all appendices) issued by the Department of Health in relation to the Medical Device Administration Control System (MDACS) and the listing of Importers and/or Distributors of medical devices thereunder.

In consideration of the promise of the Government in the Guidance Notes GN-07 and/or GN-09 to proceed with the processing of this application under the MDACS, 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 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 our part or on the part of our employees or agents;
   b. any defect in the design, material, workmanship or installation in relation to our medical device product or products;
   c. any use of any of the information supplied by us or our employees or agents in relation to this application or to our medical device product or products, whether or not such information has materially contributed to the inclusion of the applicant on the List of Importers and/or the List of Distributors or the inclusion of any of our product or products on the List of Medical Devices and whether or not such information is misleading, wrong or inaccurate.
2. We also agree and accept that:
   a. the Government, its employees or agents shall not be liable to 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 our application, the inclusion or non-inclusion of any of our information and/or product or products on the Lists being maintained under the MDACS (including but not limited to the List of Importers and/or the List of Distributors 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 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. We undertake that the information contained in our application is true and correct and that 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. 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. We hereby undertake to comply with the latest requirements of the MDACS that are in force.
5. We undertake that 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's 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))

_____
Company Chop

* Delete where appropriate

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. Class 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.