



**Medical Device Control Office  
Department of Health**

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

<i>For official use only</i>		
Date Received: _____	Application No.: _____	Officer: _____
Date Approved/Rejected: _____	Importer No. _____	
Remarks: _____		
_____		
_____		

	<b>Particulars of Applicant</b>			<b>Encl.</b>
1001	<i>Name</i>	<i>in English</i>		
		<i>in Chinese</i>		
1002	<i>Business Name (if any) (see Note 1)</i>	<i>in English</i>		
		<i>in Chinese</i>		
1003	<i>Address in Hong Kong</i>	<i>in English</i>		
		<i>in Chinese</i>		
1004	<i>Status and Identity (Please provide documentary proof; see Note 2)</i>	<input type="checkbox"/> Body corporate <input type="checkbox"/> Partnership <input type="checkbox"/> Individual ( <i>Please give below your HKID Card no. or, if you do not hold a HKID Card, your passport no.</i> ) <input type="checkbox"/> HKID Card No. _____ <input type="checkbox"/> Passport No. _____		<b>(A1)</b> <input type="checkbox"/>
1005	<i>Contact Information</i>	<i>Contact Person (Name a contact person unless applicant is an individual)</i>	<i>Name</i>	
			<i>Position</i>	
		<i>Telephone</i>		
		<i>Fax</i>		
		<i>E-mail</i>		
		<i>Website</i>		

<b>Applicant's Intent to Import Medical Devices</b>		
2001	<p><i>Please tick against the description that applies to your case:</i></p> <p><input type="checkbox"/> The import intended or envisaged will be in the name of or for the purpose of a business that the applicant carries on. The business has been registered with the business registration number _____ _____.</p> <p><i>(Please enclose a copy of the business registration certificate. If your business name as appears on the certificate (see Note 1) 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 listed on the List of Importers by your business name as appears on the business registration certificate.)</i></p> <p><input type="checkbox"/> The applicant is a body corporate not carrying on a business and has intent to import medical devices.</p> <p><input type="checkbox"/> The applicant is an individual with intent to import medical devices otherwise than for the purpose of a business he/she carries on. It is not the intention of the applicant that the devices are for use exclusively in the treatment or care of himself/herself, his/her immediate family members, relatives or dependents (see Clause 6.6 of the Guidance Notes GN-07 on Exclusion)</p>	(A2) <input type="checkbox"/>
2002	<p>Medical devices intended to be imported fall within the following categories:</p> <p><input type="checkbox"/> devices for general medical use</p> <p><input type="checkbox"/> devices for use in the medical specialties of _____ _____</p>	
2003	<p>Medical devices intended to be imported are of the following countries of origin: _____ _____</p>	

<b>Quality Management and Vigilance Practices</b>		
3001	<p>The applicant's established procedures in respect of medical devices that it imports include documented procedures on:</p> <p><input type="checkbox"/> complaint handling</p> <p><input type="checkbox"/> adverse incident handling</p> <p><input type="checkbox"/> handling advisory notices (recall notices, hazard alerts etc.) issued by manufacturers and Local Responsible Persons</p> <p><input type="checkbox"/> maintenance of distribution records</p>	(A3) <input type="checkbox"/>
3002	<p>The applicant has in place</p> <p><input type="checkbox"/> a quality management system having been certified by a third party certification body, namely, _____, _____, and which has incorporated all/part of the established procedures above mentioned (Please enclose a copy of the certificate with the completed application form).</p> <p><input type="checkbox"/> a quality management system incorporating all/part of the established procedures above mentioned. The system has not been independently certified.</p> <p><input type="checkbox"/> no quality management system yet.</p>	(A4) <input type="checkbox"/>
<b>Notes</b>		
<ol style="list-style-type: none"> <li>The business name given in item 1002 must be the same as the Name of Business that appears on your business registration certificate.</li> <li>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). If the applicant is an individual, the documentary proof must include (if the applicant holds a HKID card) a copy of the applicant's HKID card or (if the applicant does not hold a HKID card) a copy of the main information page(s) of the applicant's passport.</li> </ol>		

## 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 all appendices) and GN-07 (with all appendices) issued by the Department of Health in relation to the Medical Device Administration Control System (MDACS) and the listing of importers of medical devices thereunder.

In consideration of the promise of the Government in the Guidance Notes GN-07 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 Importers 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 Importers 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.

Form MD-IP (2007 Edition)

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 you provide the Department of Health (“the Department”) in connection with the Medical Device Administrative Control System (MDACS) or with this application in particular will be used by the Department for the management and implementation of the MDACS.

2. Class of Transferees

The personal data are mainly for use by the Department, but may also be disclosed to other Government bureaux/departments or other parties for the purpose stated in para. 1 above or for the purpose of a related matter. 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 in relation to the personal data, including requests for making access or corrections to the data, should be addressed to the Medical Device Control Office, Department of Health (facsimile number 3157 1286; telephone number 2961 8788, e-mail address: mdco@dh.gov.hk). Please quote your application number when you make the enquiries.