Medical Device Division
Department of Health

Medical Device Administrative Control System
Takeover Form for Listed Medical Devices

For official use only

Date Received: _____ *Application No.:* _____ *Officer:* _____
Date Approved/Rejected: _____ *HKMD No(s).:* _____
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 also be included in The List of Local Responsible Persons and The List of Medical Device if this application is approved. 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 in The List of Local Responsible Persons for the reference of the public.
2. Please check the corresponding boxes in the "Encl." column if any document is enclosed under respective indexes of the submission folder.
3. Submitted documents not in Chinese or English shall be accompanied by Chinese or English translations.
4. Please check the boxes as appropriate.

Note	**Part A: Particulars of Applicant**			**Encl.**
1001	Name*	*in English*		(A1) ☐
		in Chinese		
	Address in Hong Kong (Please give the registered place of business, if any)*	*in English*		
		in Chinese		
	Contact person:		Telephone:	
	Position:		Email:	
	Contact telephone for public enquiries*:		Fax:	
	Mobile telephone for urgent use (24 hours): ☐ Copy of business registration certificate (with business registration number: _____) is enclosed			

1002	Is the applicant on the List of Local Responsible Person (LRP)? ○ Yes and LRP Number is: _____ ○ No (please submit the following documented procedures) ☐ (i) Keeping of distribution records ☐ (ii) Management of product recalls and field safety notices ☐ (iii) Handling of reportable adverse incidents in Hong Kong ☐ (iv) Tracking of specific medical devices (if applicable) ☐ (v) Complaints handling ☐ (vi) Maintenance and service arrangements (if applicable)	(A2) ☐
1003	Does the applicant have a certified Quality Management System (QMS)? ○ No ○ Yes, the QMS is certified to: ○ ISO 9001 or equivalent (a copy of the certificate is enclosed) ○ ISO 13485 or equivalent (a copy of the certificate is enclosed)	(A3) ☐
1004	Date designated as LRP by the manufacturer: _____ ☐ Manufacturer's designation letter is enclosed	(A4) ☐
1005	☐ The applicant is also an importer of the medical devices covered in Listing Number(s) named in Part B Listing No. of Importer: _____	

Note	**Part B: Particulars of the listed Medical Devices to be taken over**		**Encl.**
2001	Listing Number(s) of medical device(s) to be taken over:		
2002	Name of existing LRP of the listed device(s)	*in English*	
		in Chinese	
2003	Special Listing Information: A sample of Special Listing Information is enclosed ☐		(B1) ☐

Note	**Part C: Undertakings for the taking over**	**Encl.**
3001	☐ Agreement has been reached among the applicant, the existing LRP and the manufacturer for the taking over and the Transfer Form is enclosed.	(C1) ☐

DECLARATION

1. To the maximum extent permitted by law and in consideration of the Department of Health of the Government of the Hong Kong Special Administrative Region ("the Government") processing our application under the MDACS, we, _____ *[name and address of the Applicant]*, 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 of our device or devices;
   c. any use of any of the information supplied by us or our employees or agents in relation to our device or devices whether or not such information has materially contributed to the inclusion of the device or devices 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 device or devices on 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 the devices (including any spares or replacement parts) listed or considered for listing under the MDACS, whether or not they are included in the List of Medical Devices, are of merchantable quality or are fit for the purposes for which they are commonly bought and that the spares or replacement parts are readily available.
3. We confirm that the information contained in our application is true and correct and that our device or devices (including any spares or replacement parts) are of merchantable quality and are fit for the purposes for which they are commonly bought.
4. We fully understand and agree that any future changes or additions to the requirements of the Medical Device Administrative Control System (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. It is one of the current requirements of the MDACS that the LRP will, within two weeks after receiving the request from the Department of Health, produce the originals or certified copies of the documents that, according to the claims in this submission, are within the possession of the LRP or the manufacturer.
5. We confirm 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.

Signature: _____

Name: _____

Position: _____

Contact telephone number: _____

The Applicant (Local Responsible Person): _____

(Company chop)

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 Division, Department of Health (facsimile number 3157 1286; telephone number 3107 8484, e-mail address: mdd@dh.gov.hk). Please quote your application number when you make the enquiries.

Transfer Form for Taking Over Listed Medical Devices
under the Medical Device Administrative Control System

We, the following parties (Party 1, Party 2 and Party 3),

Party 1

Name of applicant:

Address:

Party 2

Name of existing Local Responsible Person (LRP):

Address:

Party 3

Name of manufacturer:

Address:

hereby agree that:

1. The Local Responsible Person (LRP) of the following listed medical devices under the MDACS is to be changed from Party 2 to Party 1 with effect from the taking over date approved by the Director of Health, Hong Kong. The proposed taking over date is (dd/mm/yyyy) _____.

Make	Model	Medical Device Listing No. (HKMD No.)

2. The applicant (Party 1) undertakes to (i) assume all the responsibilities and obligations of the existing LRP (Party 2) including pre-market and post-market requirements and activities related to the medical devices depicted in Section 1 above; and (ii) comply with all the requirements of being a Local Responsible Person of the related products under the Medical Device Administrative Control System.

3. The existing LRP (Party 2) undertakes to provide the applicant (Party 1) with all necessary support and information including distribution and maintenance records etc. required for taking up the LRP obligations of the devices depicted in Section 1. The existing LRP also undertakes that it will continue with all the LRP obligations of the related products until the taking over date approved by the Director of Health, Hong Kong.
4. The manufacturer (Party 3) undertakes to provide the applicant with all the necessary information and support so as to enable the applicant (Party 1) to fulfil its LRP obligations under the Medical Device Administrative Control System.

For and on behalf of the applicant (Party 1)

Signature: Date:

Name:

Position:

Company Name:

(Company chop)

For and on behalf of the existing LRP (Party 2)

Signature: Date:

Name:

Position:

Company Name:

(Company chop)

For and on behalf of the manufacturer (Party 3)

Signature: Date:

Name:

Position:

Company Name: