Medical Device Control Office
Department of Health
Medical Device Administrative Control System
Application for the Listing of
In-Vitro Diagnostic Medical Devices (IVDMD)

For official use only

Date Received: _____ *Application No.:* _____ *Officer:* _____
Date Approved/Rejected: _____ *Listing No.:* _____
Tracking Required: ____Y / N____ *PMS Report Required:* ____Y / N____
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 Medical Devices if this application is approved. They include (i) the manufacturer's name, address of its head office and its website (A001), (ii) the LRP's name, address in Hong Kong, and contact telephone number for public enquiries (B001), (iii) the make and model of the device (C001), and (iv) the intended use of the device (C006). The details will normally appear on The List of Medical Devices 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 Medical Devices 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. 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.

Note	Part A: Particulars of Manufacturer				Encl.
A001	Manufacturer's name*	*in English*			
		in Chinese			
	Address of Head Office*:	*in English*			
		in Chinese			
	Post Code:			Country:	
	Contact person:			Telephone:	
	Fax:			E-mail:	
	Website*:				

<table>
<tr><td rowspan="4">A002</td><td colspan="2">☐ Registered place of business in Hong Kong: _____</td><td rowspan="4">(A1)
☐</td></tr>
<tr><td colspan="2">☐ Copy of business registration certificate (with business registration number _____) is enclosed</td></tr>
<tr><td>Contact person:</td><td>Telephone:</td></tr>
<tr><td>Fax:</td><td>E-mail:</td></tr>
<tr><td>A003</td><td colspan="2"><u>Established Quality Management System</u>
☐ Full quality management system covering device design, production, and post-production processes
☐ Partial quality management system covering processes: _____
Standards with which the system complies:
☐ ISO9001:2000 ☐ ISO13485:2003 ☐ GMP
☐ Others _____ (please specify)
☐ System certified by _____ (certification body), and a copy of the certificate is enclosed</td><td>(A2)
☐</td></tr>
<tr><td>A004</td><td colspan="2">Has the manufacturer designated any Local Responsible Person (LRP)? (N.B. If the manufacturer has no registered place of business in Hong Kong, it must designate a legal person incorporated in Hong Kong or a natural or legal person with a registered place of business in Hong Kong as the LRP.)
☐ Yes ☐ No, manufacturer itself acts as the LRP</td><td></td></tr>
</table>

	Part B: Particulars of Local Responsible Person (LRP)			
B001	LRP's name*	*in English*		(B1) ☐
		in Chinese		
	Address in Hong Kong *(Please give the registered place of business, if any)**	*in English*		
		in Chinese		
	Contact person:		Telephone:	
	Position:		E-mail:	
	Contact telephone for public enquiries * :		Fax :	
	Mobile telephone for urgent use (24 hours) :			
	☐ Copy of business registration certificate (with business registration number: _____) is enclosed			
B002	Date designated as LRP by the manufacturer: _____ ☐ Manufacturer's designation letter is enclosed			(B2) ☐
B003	Established Quality Management System ☐ ISO9001:2000 ☐ ISO13485:2003 ☐ none ☐ Others _____ ☐ System certified by _____(certification body), and a copy of the certificate is enclosed			(B3) ☐
B004	Documented Procedures Established There are devices submitted by the LRP and listed under the Medical Device Administrative Control System ☐ Yes (LRP account number _____) ☐ No (please complete the followings) ☐ Distribution records ☐ Complaint handling ☐ Maintenance and service arrangements ☐ Recalls (procedures are enclosed) ☐ Alerts and modifications ☐ Reportable adverse incidents in Hong Kong ☐ Low temperature requirements of IVDMDs during storage & transportation			(B4) ☐
B005	☐ The LRP is also an importer of the device named in Part C			
B006	☐ The device named in Part C is currently a listed device (under another LRP), with Listing No. _____.			

	Part C: Particulars of the In-Vitro Diagnostic Medical Device (IVDMD)			
C001	Make*	*in English*		
		in Chinese		
	Model*	*in English*		
		in Chinese		
C002	An IVDMD may include reagents, calibrators, control materials, specimen receptacles, software and related instruments or apparatus or other articles. Please specify all the component(s) of this IVDMD for all the followings that apply. ☐ Reagent(s) ☐ Control material(s) ☐ Calibrator(s) ☐ Others (Please specify.) _____ In addition, please provide the additional required information of the IVDMD in the following space, if any. Use separate sheets if required. _____ _____			(C1) ☐
C003	Universal Product Number (if any):			
	Other identifiers (if any) of the device:			
C004	Description of the device: *(Please enter the appropriate AMDNS/UMDNS term. If none of the terms in AMDNS/UMDNS appear appropriate, enter a short description of the device.)*			
	AMDNS Code *(Same as UMDNS Code):*			
	Other Codes *(e.g. GMDN) (Please enter if known):*			
C005	Other common descriptions of the device:			
C006	Intended use of the device*	*in English*		
		in Chinese		

C007	Accessories and parts covered by the Marketing Approvals and Essential Principles under Item D001 of Part D. *(Please provide its identifier(s) (e.g. part number), description and, if any, Universal Product Number. Use separate sheet if required)*:	(C1) ☐
C008	Class of the IVDMD: ☐ Class A ☐ Class B ☐ Class C ☐ Class D	
	Reasons for the classification:	
C009	Manufacturing sites *(Use separate sheet if required)*:	(C1) ☐
C010	<u>History</u> ☐ No previous recalls, reportable adverse incidents, banning in other countries or post-market surveillance studies ☐ Yes (Please check the appropriate boxes and provide details): ☐ Recalls completed or in progress ☐ Any reportable adverse incidents bearing implications to the device ☐ The device banned previously in other countries ☐ Proactive post-market surveillance studies	(C2) ☐
C011	<u>Usage</u> ☐ The IVDMD is for single use ☐ The IVDMD is supplied as sterile product ☐ The IVDMD is for self-testing purpose ☐ Disposal of used device or any part thereof (including any used accessories or consumables) requires special precautions.	
C012	<u>Repair & Servicing</u> ☐ The IVDMD is non-repairable ☐ The IVDMD requires regular servicing/testing/checking/calibration ☐ Repairs and servicing not provided ☐ Repairs and servicing provided by the LRP or appointed party in Hong Kong ☐ All repairs and servicing performed in Hong Kong ☐ Part of the repairs and servicing performed in Hong Kong ☐ Technical support provided by the manufacturer	
C013	<u>Labelling Requirements</u> Instructions for use are available: ☐ in English ☐ in Chinese (Please note that IVDMD for self-testing purpose, the instruction for use in Chinese shall be available.) ☐ Labelling samples are enclosed. Please indicate where in the samples the following information is given: (1) Indications for use of the IVDMD: _____ (2) Contraindications against use of the IVDMD: _____ (3) Cleaning, disinfection and/or sterilization procedures: _____ (4) User precautions: _____ (5) Disposal precautions: _____	(C3) ☐

C014	Verification during IVDMD batch release (for Class D IVDMD only) ☐ Batch Verification by the MDACS Conformity Assessment Body ☐ Batch Verification by the Notified Body as the IVDMD is included in Annex II List A of European Council Directive 97/79/EC ☐ Others, please provide details. _____	(C4) ☐
C015	Conformity Assessment ☐ MDACS Conformity Assessment Certificate issued by Conformity Assessment Bodies recognized by MDCO Conformity Assessment Body number: _____	(C5) ☐
C016	Performance and Safety International or national standards with which the device complies: _____ ☐ Test report or certificate is enclosed ☐ Risk analysis conducted: report or summary is enclosed	(C6) ☐
C017	Performance Evaluation ☐ Performance evaluation report of the IVDMD is enclosed ☐ Bibliography of references from the Index Medicus concerning the device is enclosed ☐ Demonstration of equivalence to another IVDMD (equivalent IVDMD) or a published method of diagnosis where safety and efficacy of which are well established: ☐ Performance evaluation report of the equivalent IVDMD or a published method of diagnosis and a report of demonstration of equivalence are enclosed ☐ Bibliography of references from the Index Medicus concerning the equivalent IVDMD or a published method of diagnosis and a report for demonstration of equivalence are enclosed ☐ Report demonstrating full equivalence to a well established product is enclosed	(C7) ☐

	Part D: Marketing Approvals and Essential Principles	
D001	Marketing Approvals in Foreign Countries ☐ Approval obtained for the medical device to be placed on the market of the following countries: ☐ Australia (The Therapeutic Goods Administration) ☐ Canada (Health Canada) ☐ Member countries of European Union that have implemented the European Council Directives 98/79/EC ☐ Japan (Ministry of Health, Labour and Welfare) ☐ United States of America (U.S. Food and Drug Administration) ☐ Earliest approval obtained on or before 31 December 2004 ☐ Earliest approval obtained on or after 1 January 2005 ☐ Essential Principles Conformity Checklist MD-CCL is attached	(D1) ☐

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 my 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): _____ _____
Date: _____ Company Chop

Personal Data (Privacy) Ordinance

Statement of Purposes

1. Purpose of Collection

The personal data that are provided by you with whom the Department of Health (DH) interacts in connection with 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, Room 3101, 31/F., Hopewell Centre, 183 Queen's Road East, Wanchai, Hong Kong; fascimile number: 3157 1286; telephone number: 2961 8788). Please quote your application number when submitting the request.