Medical Device Division
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 and uploaded to the MDD website 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, brand name and model of the device (C001), and (iv) the intended use of the device (C005). 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.
5. Only submissions with duly completed application forms and required documents will be processed. Materials provided with any submission will not be returned.

<table>
<tr><th>Note</th><th colspan="4">Part A: Particulars of Manufacturer</th><th>Encl.</th></tr>
<tr><td rowspan="6">A001</td><td rowspan="2">Manufacturer's name*</td><td>in English</td><td colspan="2"></td><td rowspan="6"></td></tr>
<tr><td>in Chinese</td><td colspan="2"></td></tr>
<tr><td rowspan="2">Address of Head Office*:</td><td>in English</td><td colspan="2"></td></tr>
<tr><td>in Chinese</td><td colspan="2"></td></tr>
<tr><td colspan="3">Post Code:</td><td colspan="2">Country:</td></tr>
<tr><td colspan="3">Contact person:</td><td colspan="2">Telephone:</td></tr>
<tr><td colspan="3">Fax:</td><td colspan="2">Email:</td></tr>
<tr><td colspan="5">Website*:</td></tr>
<tr><td rowspan="4">A002</td><td colspan="5">☐ Registered place of business in Hong Kong (If applicable): _____</td><td rowspan="4">(A1) ☐</td></tr>
<tr><td colspan="5">☐ Copy of business registration certificate (with business registration number _____) is enclosed</td></tr>
<tr><td colspan="3">Contact person:</td><td colspan="2">Telephone:</td></tr>
<tr><td colspan="3">Fax:</td><td colspan="2">Email:</td></tr>
<tr><td>A003</td><td colspan="5"><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:
☐ ISO13485
☐ System certified by _____ (certification body), and a copy of the certificate is enclosed</td><td>(A2) ☐</td></tr>
<tr><td>A004</td><td colspan="5">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 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>

<table>
<tr><th>Note</th><th colspan="4">Part B: Particulars of Local Responsible Person (LRP)</th><th>Encl.</th></tr>
<tr><td rowspan="8">B001</td><td rowspan="2">LRP's name*</td><td>In English</td><td colspan="2"></td><td rowspan="8">(B1)
☐</td></tr>
<tr><td>In Chinese</td><td colspan="2"></td></tr>
<tr><td rowspan="2">Address in Hong Kong (Please give the registered place of business, if any)*</td><td>In English</td><td colspan="2"></td></tr>
<tr><td>In Chinese</td><td colspan="2"></td></tr>
<tr><td colspan="3">Contact person:</td><td colspan="2">Telephone:</td></tr>
<tr><td colspan="3">Position:</td><td colspan="2">Email:</td></tr>
<tr><td colspan="3">Contact telephone for public enquiries:*</td><td colspan="2">Fax:</td></tr>
<tr><td colspan="5">Mobile telephone for urgent use (24 hours):</td></tr>
<tr><td colspan="5"><u>Business Registration</u>
○ Copy of business registration certificate (with business registration number: _____) is enclosed
○ Not applicable</td></tr>
<tr><td>B002</td><td colspan="4">Date designated as LRP by the manufacturer: _____
☐ Manufacturer's designation letter is enclosed</td><td>(B2)
☐</td></tr>
<tr><td>B003</td><td colspan="4"><u>Established Quality Management System</u>
☐ ISO9001 ☐ ISO13485 ☐ None
☐ System certified by _____ (certification body), and a copy of the certificate is enclosed</td><td>(B3)
☐</td></tr>
<tr><td>B004</td><td colspan="4"><u>Documented Procedures Established and Maintained</u>

○ The applicant <u>does not</u> have any medical device listed under the Medical Device Administrative Control System
☐ The procedures indicated in items (i) to (vi) below are enclosed
(i) Keeping of transaction records
(ii) Management of product recalls and field safety notices
(iii) Handling of reportable adverse incidents in Hong Kong
(iv) Temperature requirements of IVDMDs during storage and transportation
(v) Complaints handling
(vi) Maintenance and service arrangements (if applicable)

○ The applicant already has one or more medical device listed under the Medical Device Administrative Control System (LRP number: _____)
○ There is no change to the procedures indicated in items (i) to (vi). (Please go to B005); OR
○ The procedures indicated in items (i) to (vi) have been updated and enclosed.</td><td>(B4)
☐</td></tr>
</table>

B005	☐ The LRP is also an importer and/or distributor of the device named in Part C Listing No. of Importer (if applicable): _____ Listing No. of Distributor (if applicable): _____	
B006	☐ The device named in Part C is currently a listed device (under another LRP), with Listing No.: _____ (if applicable)	

Note	Part C: Particulars of the In Vitro Diagnostic Medical Device (IVDMD)			Encl.
C001	Make*	*in English*		
		in Chinese		
	Brand Name*	*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 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	Description of the device: *(Please enter the appropriate AMDNS term. If none of the terms in AMDNS appears appropriate, enter a short description of the device.)*			
	AMDNS Code:			
	Other Codes *(Please enter if known):*			

<table>
<tr><td>C004</td><td colspan="3">Other common descriptions of the device:</td><td></td></tr>
<tr><td rowspan="2">C005</td><td rowspan="2">Intended use of the device*</td><td>in English</td><td></td><td rowspan="2"></td></tr>
<tr><td>in Chinese</td><td></td></tr>
<tr><td>C006</td><td colspan="3">Accessories and parts covered by the Marketing Approvals and Essential Principles under Note D001 of Part D. (Please provide its identifier(s) (e.g. part number) and description). (Use separate sheet if required):
☐ Additional information similar to MDS-02 attached</td><td>(C1)
☐</td></tr>
<tr><td>C007</td><td colspan="3">The device
Yes No
○ ○ is manufactured from or incorporating human cells/tissues/derivatives
○ ○ is manufactured from or incorporating animal cells/tissues/derivatives
☐ If the IVDMD contains substance(s) from human or animal origin, please state the location of such descriptions inside the submitted documentation, e.g. the Instruction for Use, or the additional information provided separately.</td><td>(C2)
☐</td></tr>
<tr><td rowspan="2">C008</td><td colspan="3">Class of the IVDMD:
○ Class B ○ Class C ○ Class D</td><td rowspan="2"></td></tr>
<tr><td colspan="3">Reasons for the classification:</td></tr>
<tr><td>C009</td><td colspan="3">Manufacturing site(s) (Use separate sheet if required):</td><td>(C1)
☐</td></tr>
</table>

C010	History of previous recalls, reportable adverse incidents, banning in other countries or post-market surveillance studies ◉ No ◉ Yes (Please check the appropriate boxes and provide details): ☐ Recalls completed or in progress ☐ Reportable adverse incidents bearing implications to the device ☐ The device banned previously in other countries ☐ Proactive post-market surveillance studies	(C2) ☐
C011	Usage ☐ The IVDMD is for single use ☐ The IVDMD is supplied as sterile product ☐ Disposal of used device or any part thereof (including any used accessories or consumables) requires special precautions. ☐ The device is intended to be used/operated by healthcare professionals only ☐ The device is intended to be used/operated by laypersons ☐ It is intended for self-use	
C012	Repair & Servicing ☐ The IVDMD requires regular servicing/testing/checking/calibration ☐ 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 , please specify: _____	
C013	Labelling Requirements Instructions for use are available (Note: Devices intended for self-use by consumers must be accompanied by instructions for use written in both English and Chinese): ☐ in English ☐ in Chinese ☐ A set of copies of device labelling is enclosed ☐ Electronic labelling is available: _____ ☐ Sample of Special Listing Information is enclosed Please indicate where in the labelling 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	Licencing Requirements The device is subject to provisions under the following ordinances and a copy of the required licence(s) is/are enclosed: Yes No ○ ○ Radiation Ordinance (Cap. 303) ○ ○ Pharmacy and Poisons Ordinance (Cap. 138) ○ ○ Antibiotics Ordinance (Cap. 137) ○ ○ Dangerous Drugs Ordinance (Cap. 134)	(C4) ☐
C015	Verification during IVDMD batch release (for Class D IVDMD only) ○ Batch Verification by the Notified Body as the IVDMD is included in Annex II List A of European Council Directive 98/79/EC ○ Others, please provide details _____	(C5) ☐
C016	Conformity Assessment ☐ MDACS Conformity Assessment Certificate issued by Conformity Assessment Bodies recognized by MDD. MDACS Conformity Assessment Body number: _____	(C6) ☐
C017	Performance and Risk Analysis Specifications, international or national standards with which the device complies: _____ ☐ Risk analysis conducted: report or summary is enclosed. ☐ Type test performed: report or test certificate is enclosed	(C7) ☐
C018	Performance Evaluation ☐ Performance evaluation report of the IVDMD 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 ☐ Report demonstrating full equivalence to a well established product is enclosed	(C8) ☐

Note	Part D: Marketing Approvals and Essential Principles	Encl.
D001	Marketing Approvals in Foreign Countries ☐ Approval obtained for the IVDMD 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 relevant EU directives or regulations and a copy of the EC Declaration of Conformity is enclosed ☐ Japan (Ministry of Health, Labour and Welfare) ☐ United States of America (U.S. Food and Drug Administration) Essential Principles ○ Earliest approval obtained on or before 31 December 2004 ○ Earliest approval obtained on or after 1 January 2005 ○ Essential Principles Conformity Checklist for In Vitro Diagnostic Medical Devices (MDIVD-CCL) is attached; OR ○ Essential Requirements Checklist / General Safety and Performance Requirements in accordance with relevant EU directives or regulations and Essential Principles Declaration of Conformity are enclosed	(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 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):

_____

Date: _____

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.

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)

Medical Device Division, Department of Health

Room 604, 6/F, 14 Taikoo Wan Road,

Taikoo Shing, Hong Kong

Telephone number: 3107 8453

Email address: mdd@dh.gov.hk.

Please quote your application number when you make the enquiries.