Brief Introduction to Medical Device Administrative Control System (MDACS)

Medical Device Division
Department of Health

Rev. 2023-11-30

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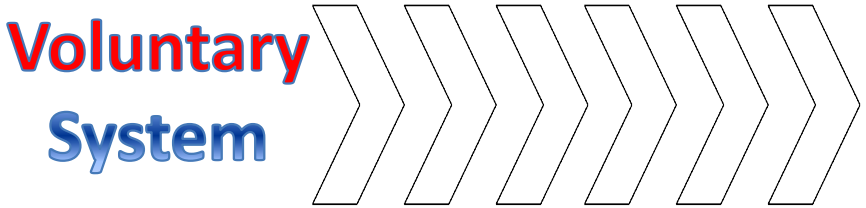
MDACS



- Purpose of MDACS
  - **Raise** public's awareness of the use of **safe** medical devices
  - Enable the traders to **familiarize** themselves with the future **mandatory requirements**
  - Provide an opportunity to collect more information and feedback from the industry as a reference to **fine-tune** the long-term **regulatory framework**

Definition of Medical Device

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Medical Device means any instrument, apparatus, implement, machine, appliance, implant, **in vitro reagent or calibrator**, **software**, material or other similar or related article, **intended by the manufacturer** to be used, alone or in combination, **for human beings for** one or more of the specific purpose(s) of –

a) diagnosis, prevention, monitoring, treatment or alleviation of disease; or
b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury; or
c) investigation, replacement, modification, or support of the anatomy or of a physiological process; or
d) supporting or sustaining life; or
e) control of conception; or
f) disinfection of medical devices; or
g) **providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body**;

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its intended function by such means. (Ref.: GN-00, sec. 2.36)

IVD Medical Devices

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- **In Vitro Diagnostic (IVD) medical device means a device**, whether used alone or in combination, **intended by the manufacturer for the in-vitro examination of specimens derived from the human body** solely or principally to **provide information for diagnostic, monitoring or compatibility purposes**.
- **This includes reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles**
  (Ref.: GN-00, sec. 2.27)

MDACS

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Medical Device Administrative Control System (MDACS)

Pre-market Control		Post-market Control
Listing System (1) Medical Devices ➢ IVD Medical Devices (Classes B – D) (2) Traders ➢ Local Responsible Person (LRP) ➢ Local Manufacturer ➢ Importer ➢ Distributor	Conformity Assessment Body (CAB) Recognition Scheme	Medical Device Safety Alert System & Adverse Event Reporting System

MDACS

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New procurement requirement of the Department of Health (DH)

→ Starting from 21 June 2023

Medical devices (MDs) being purchased by DH should preferably be listed under the Medical Device Administrative Control System (MDACS).

- DH will include the new procurement requirement in the quotation/tender exercises that the MD under purchase is **preferably** be listed under the MDACS. For details of the procurement requirements for a particular MD procurement, please refer to the tender/quotation documents.

→ ensure that the MDs being purchased by DH will meet the **safety, quality and performance** requirements comparable to international standard

- Please refer to individual invitation documents issued by DH for details of other procurement requirements.
- Please refer to the following website for details: https://www.mdd.gov.hk/en/whats-new/procurement-requirement/index.html

Listing of Traders

Local Responsible Person (LRP)

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LRP

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- What is a Local Responsible Person (LRP)?
  - Authorized representative of the medical device manufacturer
  - The person responsible for placing the device on HK market
  - The person responsible for making the application for listing medical devices under the MDACS and bears multiple responsibilities in relation to the listed devices

LRP

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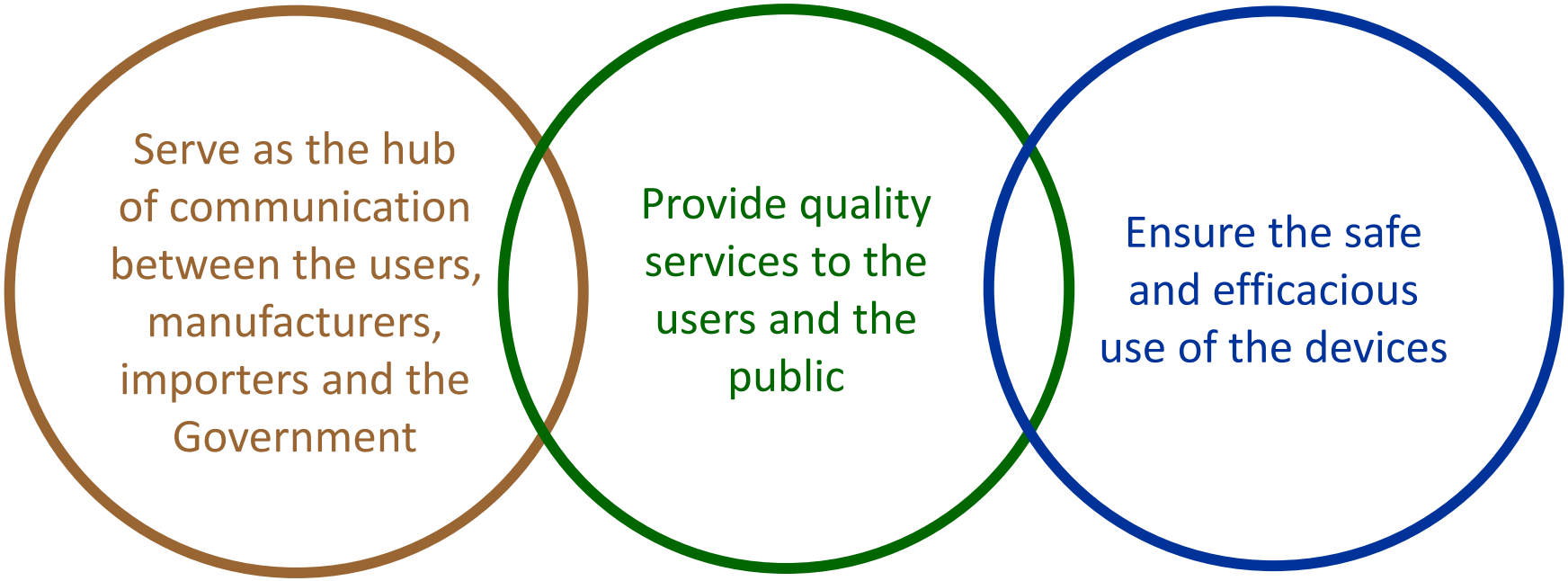
- The need for LRP



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Requirements for LRP

Either a legal person incorporated in Hong Kong, **or** A natural or legal person with business registration in Hong Kong ~~A Hong Kong permanent resident~~ ★	Either the manufacturer of the device **or** supported by the manufacturer of the device to perform the obligations of an LRP for the device	Submit the listing application to the Medical Device Division **(The application for listing of LRP is integrated with the application for listing of Medical Devices)**	Establish documented procedures according to the requirements stipulated by the Medical Device Division

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- Documented procedures:

(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

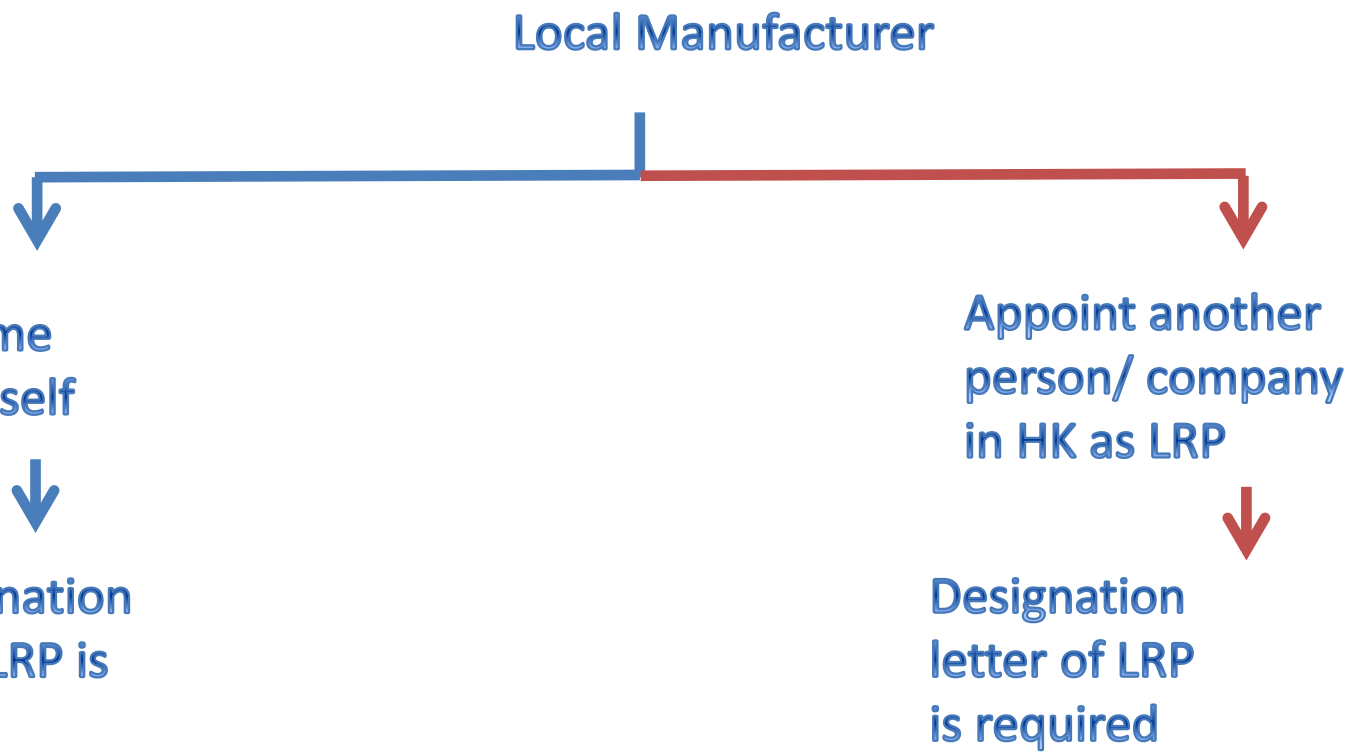
(v) Complaints handling

(vi) Maintenance and service arrangements (if applicable)

★ ~~Customer survey procedure~~

LRP

- Relationship between LRP and Local Manufacturer



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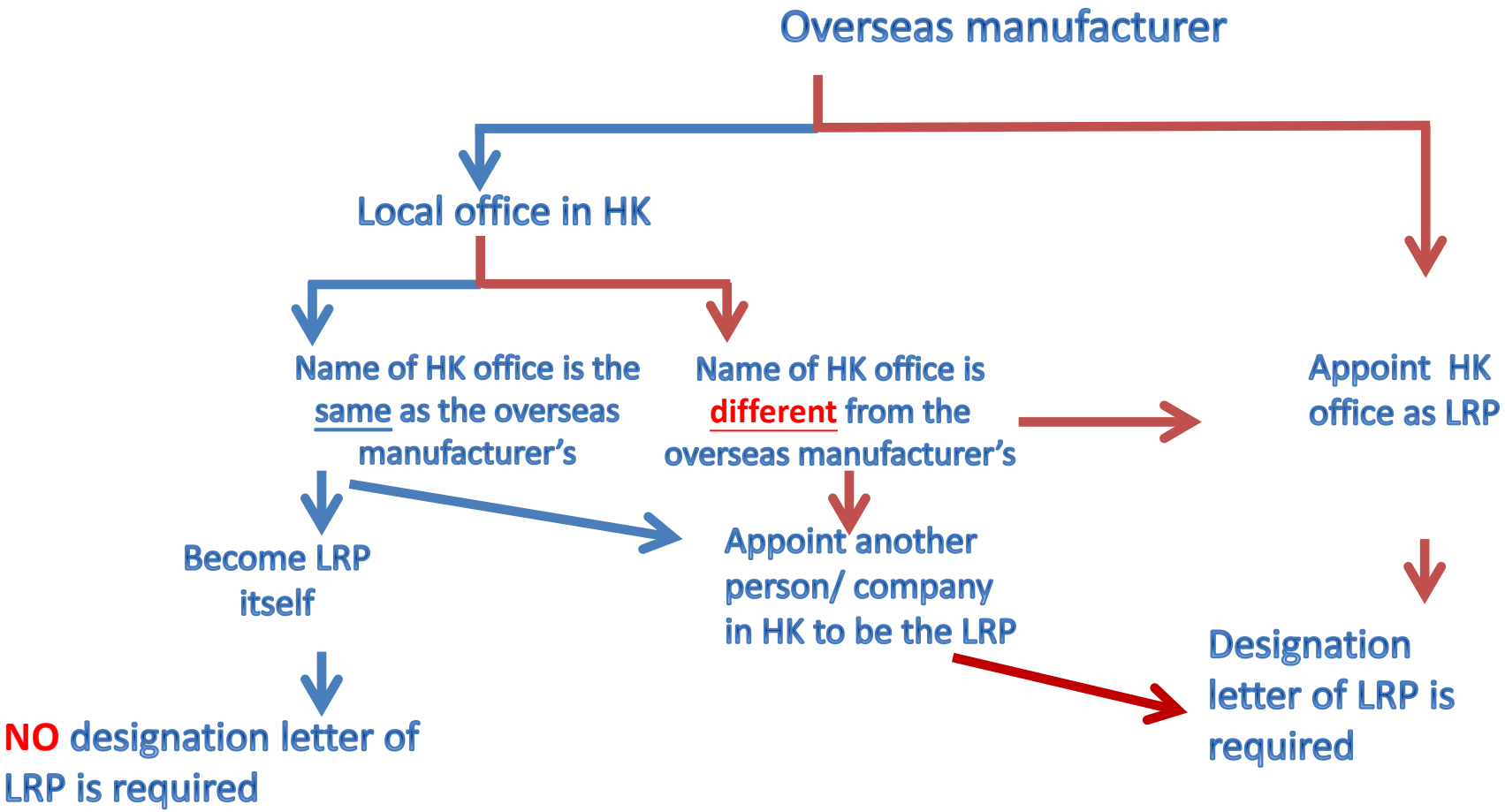
- Relationship between LRP and overseas manufacturer



LRP

- Sample letter for designating a LRP

(Source: GN-01, Appendix 2)

Sample Letter for Designating a Local Responsible Person

<Name of manufacturer>
<Address of manufacturer>

Date:

<Name of LRP>
<Address of LRP>

Dear Sirs,

Re: Designation of Local Responsible Person for <Brief description of devices>

In accordance with the requirements of the Medical Device Administrative Control System (MDACS) of the Hong Kong Special Administrative Region, we hereby designate you, <Name of LRP>, as the Local Responsible Person in respect of the following devices:

<Descriptions of devices including their makes, models, types, and other relevant identifiers>

This designation will require you to comply with, with immediate effect, all the requirements (including but not limited to all the pre-market and post-market requirements) that the MDACS imposes on you as the Local Responsible Person in respect of the above-mentioned devices. We undertake to provide you timely with all the items (documents, information, device and labelling samples etc.) and support that must necessarily originate from us, and which you will need in order to apply for the listing of the afore-mentioned devices and to fulfil your obligations under the MDACS. These items and support include but are not limited to:

(i) details of design related to the safety and performance of the device;
(ii) a copy of documents as required in the application form for the listing of devices;
(iii) any subsequent changes and modifications;
(iv) details of any recalls, alerts, and related preventive and corrective actions; and
(v) investigations and reports related to adverse incidents and post market surveillance.

Yours faithfully,

(signature)

(name and title of official signing this letter)

(official chop (if any) of the manufacturer)

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- Application for listing medical devices
  - Submit the completed application form and required information according to the listing requirements of IVD medical devices under the MDACS
  - Establish efficient communication channels with the Government in relation to their application
  - ★ Submit an renewal application to the MDD at least **3 months (but no more than 1 year)** before the expiry of Listing (5 years)

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Hub of Communication

Efficient Communication Channels

Responsible for communicating with the users, importers, public and the Government and to manage the pre-market and post-market matters of the corresponding devices.

Making Records Available for Inspection

Produce the required originals or certified copies for inspection within two weeks after receiving the notice from the MDD.

Transaction Records

Maintain an updated list of importers and the transaction records of devices imported.

Reporting Changes

Inform the MDD when there is any **major** change to the information submitted in relation to the listing application as soon as possible and in no case later than 10 calendar days.

LRP
Reporting changes for Listed MDs

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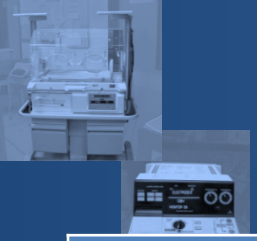
- **The document "Guidance Notes on Changes for Listed Medical Devices" (GN-10) has been issued.**
  (https://www.mdd.gov.hk/en/useful-information/forms/index.html)

- GN-10 aims to assist the LRPs in categorising, managing and reporting changes of listed medical devices.

- Starting from 1 January 2024, the LRPs shall comply with the new requirements, and submit the Change Applications with the revised Change Application Form.

LRP
Reporting changes for Listed MDs



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	Major Changes	Minor Changes
Meaning	Affect the safety, quality or performance (SQP) of a medical device.	Do not fall in the definition of Major Change
How to determine	Use the flowchart in section 4 or refer to the Example of Changes in Appendix 1. Or otherwise, the LRP may contact MDD for further assistance.	
How to implement	Need approval before implementation. Application for changes is required to get the approval from MDD.	No need approval before implementation. But notification of changes to MDD is required.
How to report or notify	By submitting a Change Application Form	By submitting a Change Application Form
When to report or notify	At least 12 weeks before any planned implementation	notify MDD within 24 weeks from the time the LRP is aware of the change.

LRP
Reporting changes for Listed MDs

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	Concurrent supply (section 6.1)
Possible?	Yes
How	Fill in the "proposed schedule" in the Change Application Form
Requirement	1. Original version is still in compliance with the Essential Principles of Safety and Performance of Medical Devices as stipulated in MDACS. 2. Ensure that appropriate mechanisms to differentiate and identify the changed version and original version. 3. Ensure traceability of both versions.
Transition to changed version	Normally completed in 24 weeks, or any time upon MDD's instruction

LRP
Reporting changes for Listed MDs

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- 3.3 If the medical device undergoes any changes without notifying MDD or obtaining prior approval from MDD (as appropriate):
  - The listing of the medical device will become invalid immediately
  - no longer be regarded as listed under MDACS
  - The LRP shall cease to supply the medical device in a way that purports that the device is still listed under MDACS,
  - e.g. displaying the HKMD number on the outer package or making such claims in the promotional materials

New Change Application Form

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Original Change Form for Listed Medical Devices

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Medical Device Division

Change Form for Listed Medical Devices

To: Medical Device Division (Fax No: 3157 1286) **MDD Reference: AN**_____

(Attn: Secretary to MDLAB)

Listing No: HKMD No. _____

LRP Name: _____

☐ **Application for Change(s) to the existing Listing**
We, _____ [Name of the LRP], confirm that there is/are change(s) to the listed medical device details since the latest approval. Attached please find the completed change form together with valid supporting document(s) for your consideration.

☐ **Application for Withdrawal of the Listing (Delisting)**
We, _____ [Name of the LRP], confirm to remove the captioned listing from the List of Medical Devices under the Medical Device Administrative Control System. We will continue with all the post market surveillance and vigilance activities stipulated in the *Code of Practice COP-01: Code of Practice for Local Responsible Persons* and *Guidance Notes GN-03: Adverse Incident Reporting by Local Responsible Persons* for products supplied to users. Moreover, we confirm that the assigned HKMD No. will no longer be used in any advertisement, promotional materials and/or other labeling of the device(s) from the date of delisting.

Please complete the following checklist and return it to Medical Device Division with valid supporting document(s):

Item	Description	Check the *box, if there is any change/update*	Details *(Use separate sheet if necessary)*
1	**Particulars of Local Responsible Person (LRP)**		
	(a) Business Registration Certificate of LRP *(Please provide a copy of valid Business Registration Certificate of LRP.)*	☐	
	(b) LRP's name (in English / Chinese*)	☐	
	(c) LRP's address in Hong Kong (in English / Chinese*)	☐	
	(d) Contact details (e.g. Contact Person and Post, E-mail, Telephone, Fax, contact telephone for public enquiries, mobile telephone for urgent use (24 hours), etc.)	☐	

Original Change Form for Listed Medical Devices

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2	**Particulars of Manufacturer**		
	(a) Manufacturer's address (in English / Chinese*)	☐	
	(b) Quality Management System Certificate (i.e. ISO13485 certificate)	☐	
3	**Particulars of the Device**		
	(a) Model name(s) / product code(s) of device(s) *(Please indicate Addition/Deletion/Amendment* of device(s) in the existing Certificate of Listing, if any)**	☐	
	(b) Intended use / Indications for use	☐	
	(c) Contraindications	☐	
	(d) Device labeling (including instructions for use, device package labels and Special Listing Information) *(Please provide details on changes(s) to content of the instructions for use)*	☐	
	(e) Manufacturing site(s)	☐	

Original Change Form for Listed Medical Devices

	(f) Device design and performance specifications	☐	
	(g) Sterilization method	☐	
	(h) Shelf life	☐	
	(i) Risk analysis and/or clinical/performance evaluation*	☐	
	(j) AMDNS code and term (as device description) *(Please provide AMDNS code and term if they have not been covered in the existing Certificate of Listing.)*	☐	
4	**Marketing Approvals and Essential Principles**		
	(a) TGA ARTG Certificate	☐	
	(b) EC Certificate(s) and EC Declaration of Conformity (EC DoC)	☐	
	(c) Health Canada Licence	☐	
	(d) Japan (Ministry of Health, Labour and Welfare) Certificate	☐	
	(e) U.S. FDA 510(k) Letter / Pre-Market Approval (PMA) Letter / Certificate to Foreign Government (CFG)*	☐	
	(f) MDACS Conformity Assessment Certificate issued by the Conformity Assessment Bodies recognized by MDD	☐	
	(g) Essential Principles Conformity Checklist (Form MD-CCL in most recent version) or Essential Requirements Checklist in accordance with relevant EU directives or regulations supplemented with Essential Principles Declaration of Conformity (EP DoC)	☐	
5	**Others (please specify) (e.g. LRP designation letter):** _____	☐	

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Medical Device Division

Change Application Form for Listed Medical Devices

To: **Medical Device Division**
(Attn: Secretary to MDLAB)

MDD Reference: AN_____
(for official use only)

Listing No: **HKMD No.** _____

LRP Name: _____

☐ Application for Change(s) to the existing Listing [Please complete Part A-D]

☐ Application for Withdrawal of the Listing (Delisting) [Please complete Part E]

Points to note:

1. For the change in contact details of LRP (e.g. Contact Person and Post, E-mail, Telephone, Fax, Contact Telephone for public enquiries, Mobile Telephone for urgent use (24 hours), etc.), please send email to mdd_app@dh.gov.hk to process separately. Submission of this form is not required for such changes.
2. Update of validity date of a certificate is not regarded as a change.

Please complete the following checklist and return it to Medical Device Division with valid supporting document(s) in Part D:

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Item	Description	Major Change	Minor Change	Description of change
(A)	**Changes related to Medical Devices**			
1	Change in manufacturing processes, facility or Quality Management System (including Quality Control, QC) [Please refer to Guidance Notes on Changes for Listed Medical Device, clause 4.3(b) – Flowchart A]			
1.1	Change of manufacturer's address	☐		_____
1.2	Addition/Removal/Change of manufacturing site	☐		_____
1.3	Other changes in manufacturing processes, facility or Quality Management System (including Quality Control)	☐	☐	Please specify: _____
2	Changes in Design for Medical Devices [Please refer to Guidance Notes on Changes for Listed Medical Device, clause 4.3(c) – Flowchart B]			
2.1	Change to the control mechanisms or operating principles	☐		_____
2.2	Addition/Removal/Change of models or product codes	☐	☐	_____
2.3	Change to the design, or addition/removal/modification of a component	☐	☐	_____
2.4	Change in Magnetic Resonance (MR) safety or compatibility	☐		_____
2.5	Other changes in design	☐	☐	Please specify: _____

New Change Application Form

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Item	Description	Major Change	Minor Change	Description of change
3	Changes to Sterilisation Facility and its Process or Quality Management System [Please refer to Guidance Notes on Changes for Listed Medical Device, clause 4.3(d) – Flowchart C]			
3.1	Change in sterilisation method and related processes	☐	☐	_____
3.2	Change in sterilisation facilities	☐	☐	_____
3.3	Other changes to Sterilisation Facility and its Process or Quality Management System	☐	☐	Please specify: _____
4	Changes to Software for Medical Devices [Please refer to Guidance Notes on Changes for Listed Medical Device, clause 4.3(e) – Flowchart D]			
4.1	Addition of new features or software applications	☐	☐	_____
4.2	Enhancement of current features		☐	_____
4.3	Other changes to software	☐	☐	Please specify: _____
5	Changes in Materials [Please refer to Guidance Notes on Changes for Listed Medical Device, clause 4.3(f) – Flowchart E and clause 4.3(g) – Flowchart F]			
5.1	Changes in materials	☐	☐	Please specify: _____

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6	Changes to Labelling and Special Listing Information [Please refer to Guidance Notes on Changes for Listed Medical Device, clause 4.3(h) – Flowchart G]			
6.1	Change in indications / intended use	☐	☐	_____
6.2	Change in any warnings, precautions, contraindication and potential adverse events	☐	☐	_____
6.3	Change in shelf-life or storage conditions	☐		_____
6.4	Change in the Special Listing Information (refer to GN-01)	☐	☐	_____
6.5	Addition/Removal of symbols	☐	☐	_____
6.6	Change in artwork/formatting of label, such as change of date format, addition of 2D barcodes		☐	_____
6.7	Other changes in labelling	☐	☐	Please specify: _____
7.	Other changes that are not specified in above sections	☐	☐	Please specify: _____
(B)	**Changes related to Local Responsible Person (LRP)**			
8	Change of Particulars of LRP [Please also complete part 6.4, if applicable]			
8.1	Change of name of LRP (Not transfer of LRP)	☐		_____
8.2	Change of LRP's Address in Hong Kong	☐		_____

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(C)	**Changes to Marketing approvals and/or essential principles** Please specify: _____	☐
9	Proposed schedule for concurrent supply upon approval of Change Application (if applicable):	☐
	Transition to the changed version be completed in (e.g. 5 weeks) _____ weeks [Please refer to clause 6.1 of Guidance Notes on Changes for Listed Medical Device, transition to the changed version shall be completed in 24 weeks]	
(D)	Submission of supporting documents regarding the changes in Parts A-C (if applicable)	

☐ ISO 13485 certificate	☐ Business Registration Certificate	☐ LRP Designation letter
☐ Instructions for Use (IFU)	☐ Device Label	☐ Special Listing Information
☐ Risk analysis/ management	☐ Clinical evaluation	☐ Others, e.g. test/study report
☐ Marketing approval(s)	☐ Essential Principles Conformity Checklist MD-CCL	☐ Essential Requirements Checklist / General Safety and Performance Requirements Checklist in accordance with relevant EU directives or regulations and Essential Principles Declaration of Conformity

New Change Application Form

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(E)	**Apply for delisting**	
	We, _____ [Name of the LRP], wish to remove the captioned listing from the List of Medical Devices under the Medical Device Administrative Control System. We will continue with all the post market surveillance and vigilance activities stipulated in the Code of Practice COP-01: Code of Practice for Local Responsible Persons and Guidance Notes GN-03: Adverse Event Reporting by Local Responsible Persons for products supplied to users. Moreover, we confirm that the assigned HKMD No. will no longer be used in any advertisement, promotional materials and/or other labelling of the device(s) from the date of delisting. Reason for delisting: _____	☐

Signature Name _____ Position _____ Date _____	(Company chop)

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Quality of Services

Maintenance and Services Arrangements

Offer or arrange other parties to provide **preventive and corrective maintenance (if applicable)**

Complaint Handling

Have a **documented procedure to handle complaints** and provide contact methods, such as hotline or telephone number, to the public for collecting comments and complaints from the users and the public.

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Product alerts, modifications and recalls

Inform the MDD any alerts, modification notices and recalls issued by the manufacturer or overseas authorities, as soon as possible and not later than 10 calendar days after their issuance.

Document procedures for the temperature requirements of IVDMDs during storage and transportation

Responsibilities in respect of advertisements

See GN-01, sec. 4.4.11

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- **Medical Device Adverse Event Reporting**
  - **Guidance Notes for Adverse Event Reporting by Local Responsible Persons (GN-03)**
  - **Any adverse event that meets** all of **the following criteria should be reported** by the LRP to the MDD:
    - The LRP becomes aware of information regarding an adverse event that has occurred with his listed device(s)
    - LRP's device is associated with the adverse event
    - **The adverse event led to** one of the following outcomes**:**
      - **Death** of a patient, user or other person**;**
      - **Serious injury** of a patient, user or other person**;**
      - **No death or serious injury occurred but the event might lead to death or serious injury** of a patient, user or other person **if the event recurs**

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◆Use error

- ☐means act or omission of an act that has a different result to that intended by the manufacturer or expected by the operator
- ☐Reportable use errors:
  1. **Use error that results in death or serious injury / serious public health concern**
     - » **Serious public health concern** means any incident type, which results in imminent risk of death, serious injury, or serious illness that may require prompt remedial action to prevent significant risk of substantial harm to the public
  2. **When the LRP or manufacturer notes a change in trend or a change in pattern of an issue that can potentially lead to death or serious injury or public health concern**
  3. **When the LRP or manufacturer initiates corrective action to prevent death or serious injury or serious public health concern**

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- **Timeframes for Submitting Adverse Event Reports to MDD**
  - **Adverse event that has posed or likely to pose a public health risk must be reported within 48 hours**
  - **Adverse events that result in death or serious injury must be reported as soon as possible, but not later than 10 calendar days** after the LRP becomes aware of the incident
  - **All other reportable adverse events must be reported** as soon as possible, but **not later than 30 calendar days** after the LRP becomes aware of the event

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- **Means of Reporting Adverse Events**
  - Medical Device Adverse Event Report Form – for Local Responsible Persons (Form-Eng AIR-LRP), which is available at:

    https://www.mdd.gov.hk/en/mdacs/report-adverse-events/index.html

https://www.mdd.gov.hk/en/mdacs/report-adverse-events/index.html

Department of Health | M...

檔案(F) 編輯(E) 檢視(V) 我的最愛(A) 工具(T) 說明(H)

Department of Health
The Government of the Hong Kong Special Administrative Region

MEDICAL DEVICE DIVISION

Report Medical Device Adverse Events

The objective of this Medical Device Adverse Event Reporting System is to improve the protection of health and safety of patients, users and others through information dissemination that may reduce the likelihood of, or prevent, repetition of adverse events, or alleviate consequences of such repetition.

This System is designed for the Local Responsible Persons to submit the reportable adverse events related to their listed products, and which are suspected to have caused death or serious injury, or which may lead to death or serious injury if it recurs. *The act of reporting an event is not to be construed as an admission of manufacturer, user, or patient liability for the event and its consequences. Submission of an adverse event report does not, in itself, represent a conclusion by the manufacturer that the content of this report is complete or confirmed, that the devices listed failed in any manner. It is also not a conclusion that the device caused or contributed to the adverse event.*

The Local Responsible Person is responsible to conduct investigations into the events of their listed devices and submit the report to the Medical Device Division as required under the Medical Device Administrative Control System. The event could be reported by filling in the reporting form and send back to us.

Reporting form

- Medical Device Adverse Event Report Form – for Medical Device Users
- Medical Device Adverse Event Report Form – for Local Responsible Persons

Please submit the report through the following channels:

1. By Mail: Medical Device Division, Room 604, 6/F, 14 Taikoo Wan Road, Taikoo Shing, Hong Kong.
2. By Fax: (852) 3157 1286;

10:00
03/10/2022

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Page 1

MEDICAL DEVICE DIVISION
Medical Device Adverse Event Report Form – for Local Responsible Persons

LRP Report No.

MDD Report No. (Official Use Only)

I. ADMINISTRATIVE INFORMATION

1. Report Type (select one):

☐ Initial ☐ Follow-up ☐ Final ☐ Trend

2. Classification:

☐ Serious Public Health Concern ☐ Death

☐ Serious Injury ☐ Other Reportable Event

3. Date of this report (dd-mmm-yyyy)	
4. Date of adverse event (dd-mmm-yyyy)	
5. LRP awareness date (dd-mmm-yyyy)	
6. Expected date of next report (dd-mmm-yyyy)	

Particulars of the LRP Submitting this Report:

7. Name	
8. Company	
9. Address	

10. Phone		11. Fax.	
12. E-mail			

13. Name(s) of regulatory authorities that this event has also been reported to by the LRP:

II. CLINICAL EVENT INFORMATION

1. Description:

2. No. of affected people		3. No. of devices	

III. HEALTHCARE FACILITY INFORMATION

1. Name of the Facility	
2. Name of Contact Person	
3. Facility Report No.	
4. Address	

5. Phone		6. Fax.	
7. E-mail			

IV. DEVICE INFORMATION

Device Information:

1. MDD Listing No.	
2. Make	
3. Brand Name	
4. Model	
5. Catalogue No.	
6. Serial No.	
7. Lot/Batch No.	

Manufacturer Information:

8. Manufacturer Name	
9. Contact Person	
10. Address	

11. Phone		12. Fax	
13. E-mail			

14. Operator of device at the time of the adverse event:

☐ Healthcare Professional ☐ Patient ☐ Other ☐ None

15. Usage of Device:

☐ Initial Use ☐ Reuse of Single-Use Device

☐ Reuse of Reusable Device ☐ Re-serviced / Refurbished

☐ Other, please specify:

16. Device Disposition / Current Location:

Form-Eng AIR-LRP (2021 Edition)

LRP

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Page 2

V. RESULT OF MANUFACTURER'S INVESTIGATION

1. Manufacturer's Device Analysis Results:

2. Remedial Action / Corrective Action / Preventive Action:

VI. INFORMATION OF PATIENT

1. Age at time of the adverse event (months, years)

2. Gender (M/F) | 3. Weight (kg)

4. List of devices involved with the patient (see Section IV):

5. Corrective action taken relevant to the care of the patient:

6. Patient outcome:

VII. OTHER REPORTING INFORMATION

Any other cases with this device with the same root cause?

☐ Yes, please specify:_____ ☐ No

VIII. COMMENTS

IX. SUBMISSION OF REPORT

By Mail: Medical Device Division
Department of Health
Room 604, 6/F,
14 Taikoo Wan Road, Taikoo Shing, Hong Kong.

By E-mail: mdd_air@dh.gov.hk By Fax.: (852) 3157 1286

X. DISCLAIMER

Submission of this report does not constitute an admission of manufacturer, LRP, user, or patient liability for the adverse event and its consequences. It does not, in itself, represent a conclusion by the LRP that the content of this report is complete or confirmed, that the device(s) listed failed in any manner. It is also not a conclusion that the device(s) caused or contributed to the adverse event.

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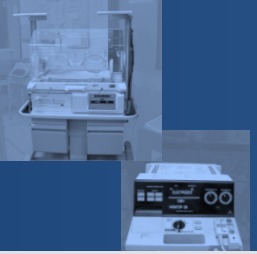

LRP

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https://eform.one.gov.hk/form/dh0038/en/

1) Introduction
2) Report Form
3) Supplementary Information
4) Form Data Verification
5) Acknowledgement

General FAQs

You can either use Form filling with iAM Smart e-ME or type in your personal information

Form Filling with iAM Smart e-ME

More Info

I. ADMINISTRATIVE INFORMATION

Report Type *
Initial Follow-up Final Trend

Classification of Event *
Serious Public Health Concern
Death
Serious Injury
Other Reportable Event

Date of this report *
YYYY-MM-DD

Date of adverse event
YYYY-MM-DD

LRP awareness date *
YYYY-MM-DD

Expected date of next report *
YYYY-MM-DD

Particulars of the LRP Submitting this Report - Name *

Particulars of the LRP Submitting this Report - Company *

Listing of Traders (continued)

Local Manufacturer/ Importer/ Distributor

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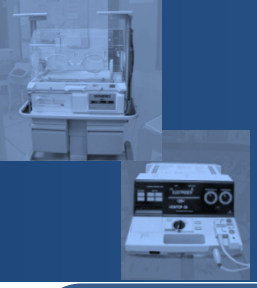

Local Manufacturer/Importer/Distributor

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Local Manufacturer

- a natural person or legal person with responsibility for the design, manufacture, packaging and labelling of a medical device before it is placed on the market under **its own name**, regardless of whether these operations are carried out by that person **himself or on its behalf by a third party**; or
- A natural or legal person who assembles, packages, processes, fully refurbishes or labels one or more ready-made products or assigns to them their intended purpose as a medical device with a view to their being placed on the market under **its own name**, apart from a person who assembles or adapts medical devices already on the market to their intended purpose for an individual patient

Importer

- a legal person **who brings or causes to be brought into Hong Kong** any medical devices falling within the scope of the MDACS for **supply in Hong Kong**

Distributor

- a legal person (other than a manufacturer, an importer or a retailer) in the supply chain who carries on business of **distributing medical devices** falling within the scope of the MDACS by **sale for use in Hong Kong** either on his own behalf or to another distributor.

Local Manufacturer/Importer/Distributor

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- Establish documented procedures

	Local Manufacturer	Importer	Distributor
1. Keeping of transaction records	Per ISO 13485 (or equivalent) requirements	✓	✓
2. Handling, storage and delivery of medical device	Per ISO 13485 (or equivalent) requirements	✓	✓
3. Managing product alerts, modifications and recalls	✓	✓	✓
4. Managing reportable adverse events in Hong Kong	✓	✓	✓
5. Handling of complaints	✓	✓	✓
6. Tracking of specific medical devices	Per ISO 13485 (or equivalent) requirements	✓	✓
7. Arranging maintenance and services	Per ISO 13485 (or equivalent) requirements	✓	✓
8. Ensuring the standard of medical devices imported	N.A.	✓	N.A.

Local Manufacturer/Importer/Distributor

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Obligations

	Local Manufacturer	Importer	Distributor
Making records available for inspection	✓ (Records and documents regarding to QMS or products)	✓ (e.g. transaction records)	✓ (e.g. transaction records)
Reporting adverse events (Guidance Note GN-03)	✓	✓	✓
Notifying the changes	✓ (Including any major changes in relation to the QMS)	✓	✓
Conforming to the advertising requirements	✓	✓	✓
Others	**Suggested** to submit renewal application **at least 6 months** before the expiry of Listing	Required to submit renewal application **at least 3 months** before the expiry of Listing	Required to submit renewal application **at least 6 months** before the expiry of Listing

Brief Summary

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	*LRP	Local Manufacturer	Importer	Distributor
Validity of Listing	Equivalent to the listing of medical devices	5 years	3 years	3 years
Guidance Notes	GN-01, GN-06	GN-08	GN-07	GN-09
Application Form	MD-IVD	LM	MD-IP+D	MD-IP+D
Business Registration Certificate	✓	✓	✓	✓
Documented Procedures	✓	✓	✓	✓
Other Information	❑ Designation Letter ❑ QMS certificate (if applicable)	❑ ISO 13485 certificate or equivalent ❑ List of medical device manufactured	❑ List of medical devices imported ❑ QMS certificate (if applicable)	❑ List of medical devices distributed ❑ QMS certificate (if applicable)

***The application for listing of LRP is integrated with the application for listing of Medical Devices**

Listing of IVD Medical Devices

Classification of IVD Medical Devices

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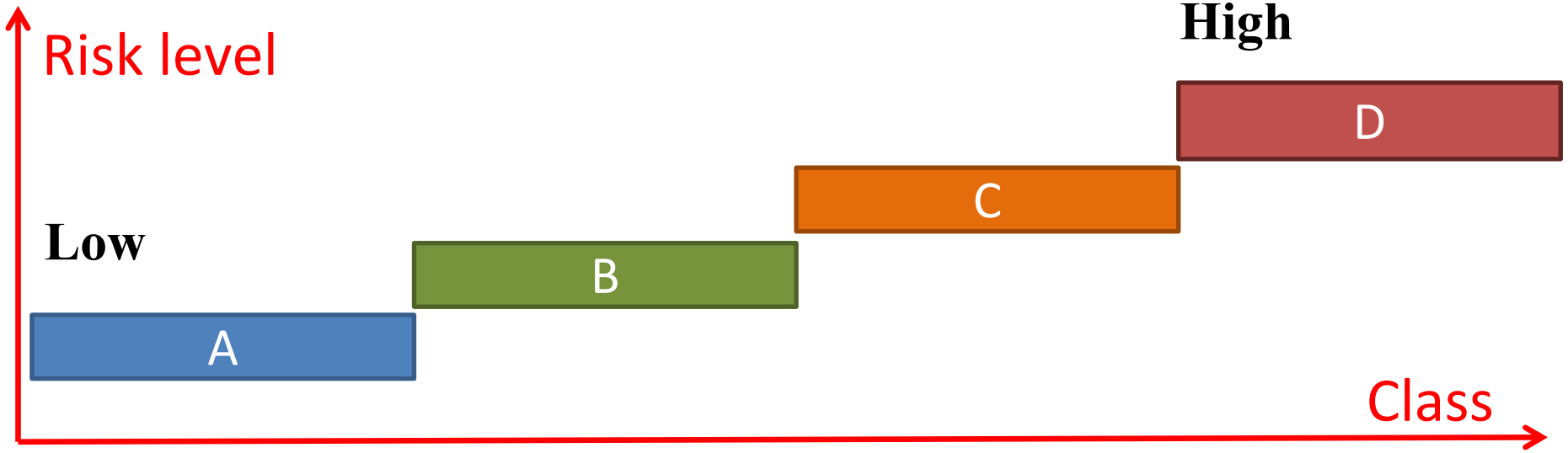
Classification of IVD Medical Device

- Classified into **4 classes** according to the **risk**
  - Class A – Lowest risk
  - **Class D – Highest risk**
- The level of control would be **proportionate to** the degree of risk classified for the medical devices



Classification of IVD Medical Device

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Class	Individual Risk	Public Health Risk
D	High	High
C	High	Moderate
B	Moderate	Low
A	Low	Low

Classification of IVD Medical Devices

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- All classification rules in Technical Reference TR-006 must be taken into consideration
- If more than one rules applies, the rule putting the device into the highest class prevails

Classification of IVD Medical Devices

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Rule 1 => Class D

- To detect the presence of, or exposure to, a transmissible agent in blood, blood components, blood derivatives, cells, tissues or organs in order to assess their **suitability** for transfusion or transplantation, or
- To detect the presence of, or exposure to, a transmissible agent that causes a life-threatening, often incurable, disease with a high risk of propagation
  - E.g. **Tests to detect infection by HCV**, HTLV

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Rule 2

- **To be used for blood grouping or tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissues or organs that are intended for transfusion or transplantation are Class C (e.g. HLA), except for ABO system** [A(ABO1), B(ABO2), AB(ABO3)], **Rhesus System** [RH1(D), RH2(C), RH3(E), RH4(c), RH5(e)], **Kell System** [Kell(K)], **Kidd System** [JK1(Jka), JK2(Jkb)] **and Duffy System** [FY1(Fya), FY2(Fyb)] **determination which are Class D**.

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Rule 3

- **IVD MDs are Class C if they are intended for use in:**
  - **detecting the presence of, or exposure to, a sexually transmitted agent**
    - Examples: Sexually transmitted diseases, such as *Chlamydia trachomatis, Neisseria gonorrhoeae.*
  - **detecting the presence in cerebrospinal fluid or blood of an infectious agent with a risk of limited propagation**
    - Examples: *Neisseria meningitidis* or *Cryptococcus neoformans.*

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Rule 3 (continued)

- **pre-natal screening of women** in order **to determine their immune status towards transmissible agents**
  - Examples: Immune status tests for Rubella or Toxoplasmosis
- **genetic testing**
  - Examples: Huntington's Disease, Cystic Fibrosis

Rule 3 (continued)

- **management of patients suffering from a life-threatening infectious disease**
  - **Examples: HCV viral load**, HIV Viral Load and HIV and HCV geno- and subtyping
- **screening for congenital disorders in fetus**
  - Examples: Spina Bifida or Down Syndrome
- **Please refer to TR-006 for the rest parts of the rule**

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Rule 4

- IVD MDs intended for:
  - **self-testing are Class C**
    - **except those devices from which the result is not determining a medically critical status, or is preliminary and requires follow-up with the appropriate laboratory test in which case they are Class B**
      - **E.g. fertility testing**
  - **blood gases and blood glucose determinations for near-patient testing would be Class C**
    - Near patient (testing): testing performed outside a laboratory environment by a healthcare professional not necessarily a laboratory professional, generally near to, or at the side of, the patient. (TR-006, sec. 4)

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Rule 5

- **The following IVD MDs are Class A:**
  - **Reagents or other articles which possess specific characteristics intended by the manufacturer to make them suitable for IVD procedures related to a specific examination**
    - **E.g. wash solutions**
  - **Instruments intended by the manufacturer specifically to be used for IVD procedures**
  - **Specimen receptacles**
    - **E.g. plain urine cup**

Rule 6

- **IVD MDs not covered in Rules 1 through 5 are Class B**
  - **Examples: Blood gases**, *H. pylori and* ***physiological markers such as hormones,*** **vitamins, enzymes**, metabolic markers, specific IgE assays and celiac disease markers.

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Rule 7

- IVD MDs that are controls without a quantitative or qualitative assigned value are Class B.

Classification of IVD Medical Devices

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Recommendations (TR-006, sec. 6)

- Calibrators intended to be used with an IVD reagent should be placed in the same class as the IVD reagent
- Stand alone control materials with quantitative or qualitative assigned values intended for one specific analyte or multiple analytes should be placed in the same class as the IVD reagent(s)

Classification of IVD Medical Devices

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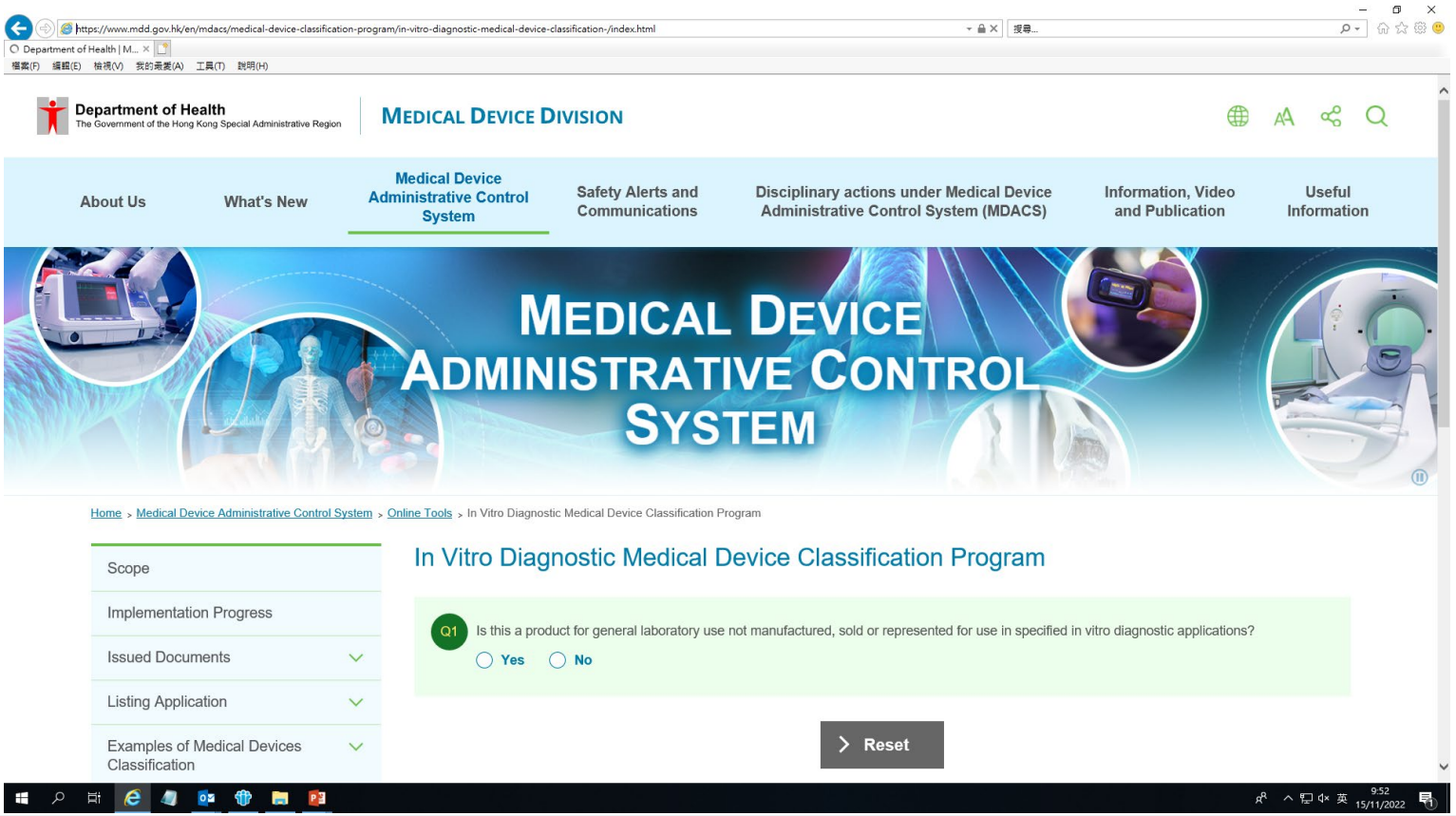
- Online classification program for IVD medical devices

https://www.mdd.gov.hk/en/mdacs/medical-device-classification-program/in-vitro-diagnostic-medical-device-classification-/index.html



Classification of IVD Medical Devices

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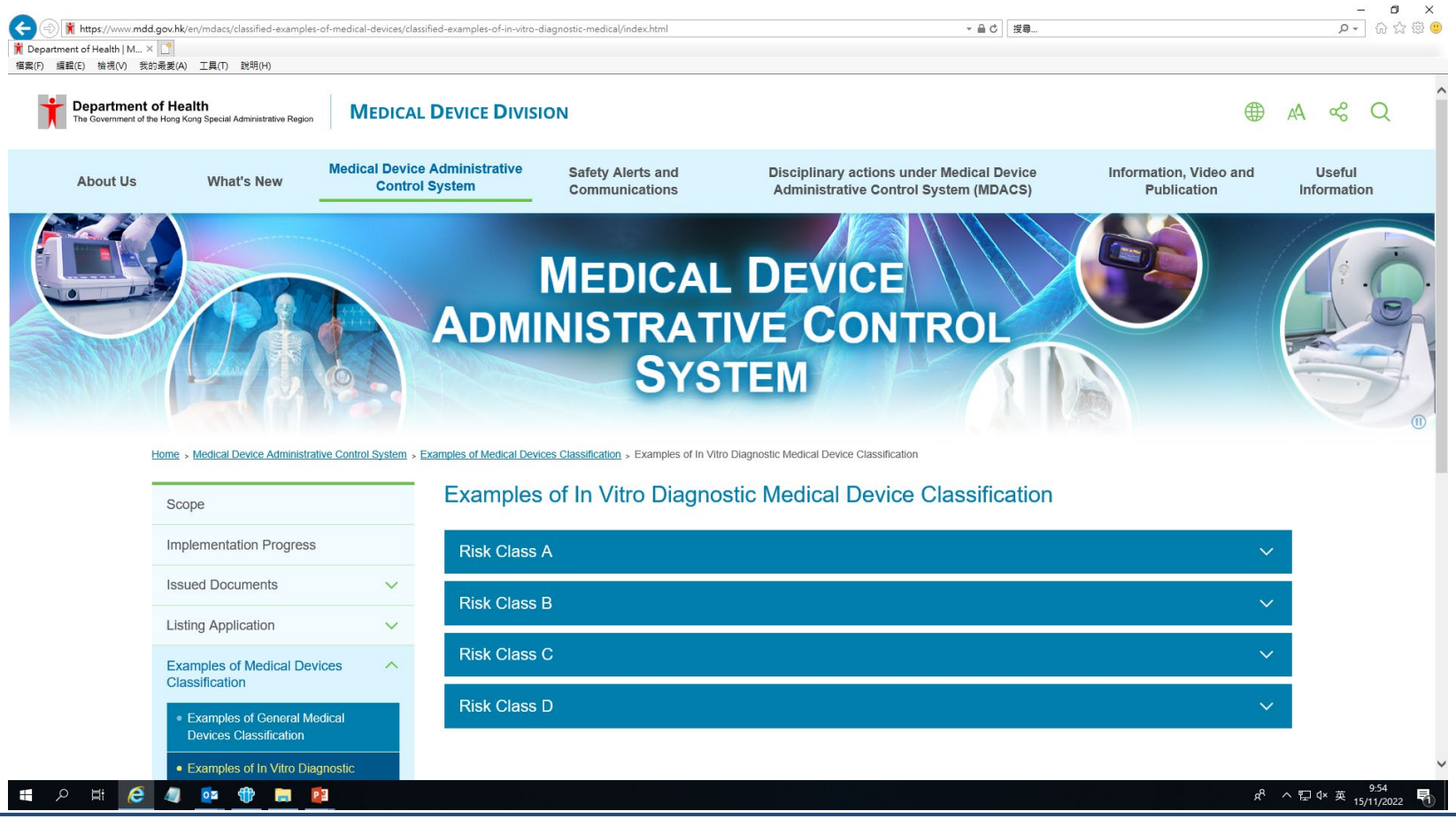
- **Classified Examples of IVD Medical Devices:**
  https://www.mdd.gov.hk/en/mdacs/classified-examples-of-medical-devices/classified-examples-of-in-vitro-diagnostic-medical/index.html



Listing of IVD Medical Devices (continued)

- Preparation of Application Documents

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Preparation of Application Documents

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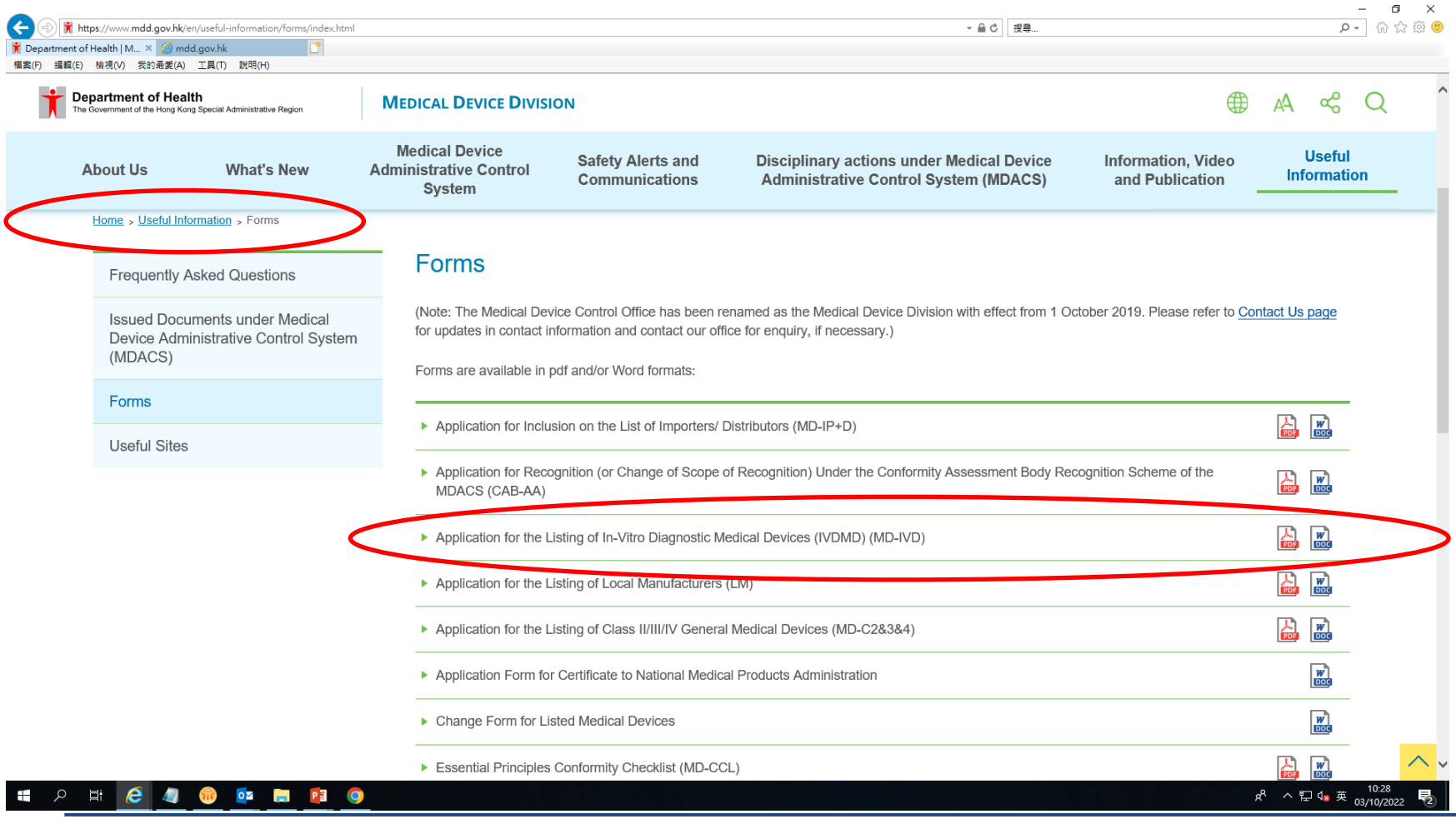
https://www.mdd.gov.hk/en/useful-information/forms/index.html



Preparation of Application Documents

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- Medical Device Division accepts marketing approval from the Nation Medical Products Administration (NMPA)
  (Until 31st December 2023)

Preparation of Application Documents

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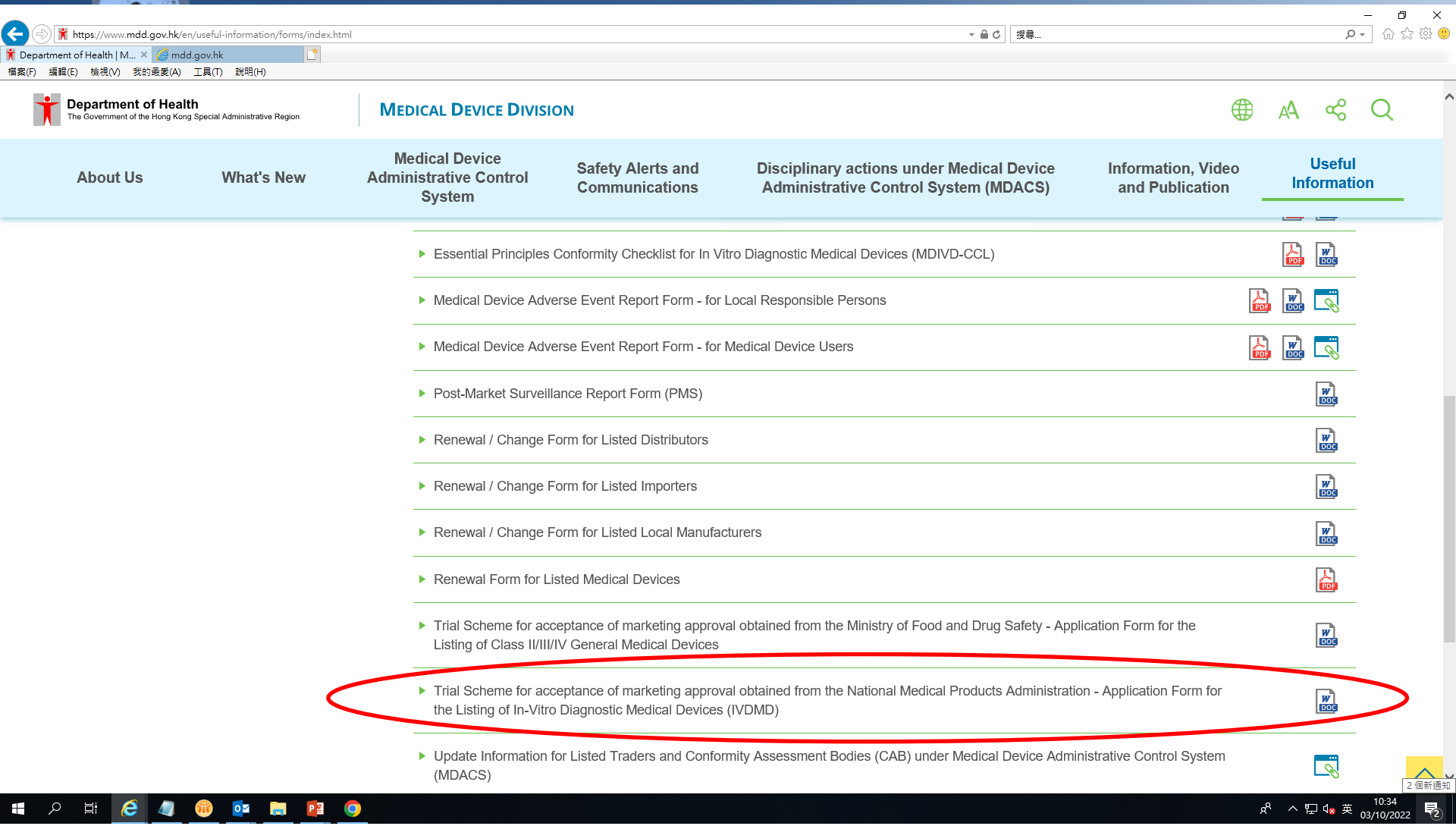

https://www.mdd.gov.hk/en/useful-information/forms/index.html

Department of Health | M... | mdd.gov.hk

檔案(F) 編輯(E) 檢視(V) 我的最愛(A) 工具(T) 說明(H)

Department of Health
The Government of the Hong Kong Special Administrative Region

MEDICAL DEVICE DIVISION

About Us | What's New | Medical Device Administrative Control System | Safety Alerts and Communications | Disciplinary actions under Medical Device Administrative Control System (MDACS) | Information, Video and Publication | Useful Information

- Essential Principles Conformity Checklist for In Vitro Diagnostic Medical Devices (MDIVD-CCL)
- Medical Device Adverse Event Report Form - for Local Responsible Persons
- Medical Device Adverse Event Report Form - for Medical Device Users
- Post-Market Surveillance Report Form (PMS)
- Renewal / Change Form for Listed Distributors
- Renewal / Change Form for Listed Importers
- Renewal / Change Form for Listed Local Manufacturers
- Renewal Form for Listed Medical Devices
- Trial Scheme for acceptance of marketing approval obtained from the Ministry of Food and Drug Safety - Application Form for the Listing of Class II/III/IV General Medical Devices
- Trial Scheme for acceptance of marketing approval obtained from the National Medical Products Administration - Application Form for the Listing of In-Vitro Diagnostic Medical Devices (IVDMD)
- Update Information for Listed Traders and Conformity Assessment Bodies (CAB) under Medical Device Administrative Control System (MDACS)

2 個新通知

10:34
03/10/2022

Preparation of Application Documents

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- Refer to Guidance Notes **GN-06**
  - **Appendix 1:** sample completed application form
- Application Form includes:
  - Part A: Particulars of Manufacturer
  - Part B: Particulars of Local Responsible Person
  - Part C: Particulars of the Device
  - Part D: Marketing Approvals and Essential Principles

Part A: Particulars of Manufacturer

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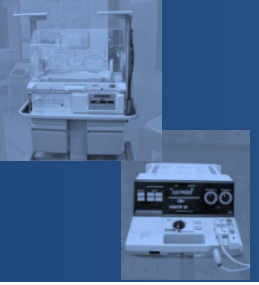
Note	Part A: Particulars of Manufacturer			Encl.
A001	Manufacturer's name*	*in English*	ABC Medical limited	
		in Chinese	N/A	
	Address of Head Office*:	*in English*	1342N, Derby Road, Arlington VA, USA	
		in Chinese	N/A	
	Post Code: VA 12345-6780		Country: USA	
	Contact person: John Smith		Telephone: 800.332.2354	
	Fax: 703.276.0314		E-mail: jsmith@abcmed.com	
	Website*: http;//www.abcmedical.com			



Part A: Particulars of Manufacturer

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A002	☐ Registered place of business in Hong Kong:_____	(A1) ☐
	☐ Copy of business registration certificate (with business registration number _____) is enclosed	
	Contact person: / Telephone:	
	Fax: / Email:	
A003	Established Quality Management System ☒ Full quality management system covering device design, production, and post-production processes ☐ Partial quality management system covering processes: _____ Standards with which the system complies: ☒ ISO 13485 ☒ System certified by *CAB Systems Ltd* (certification body), and a copy of the certificate is enclosed	(A2) ☒
A004	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	

Part B: Particulars of Local Responsible Person

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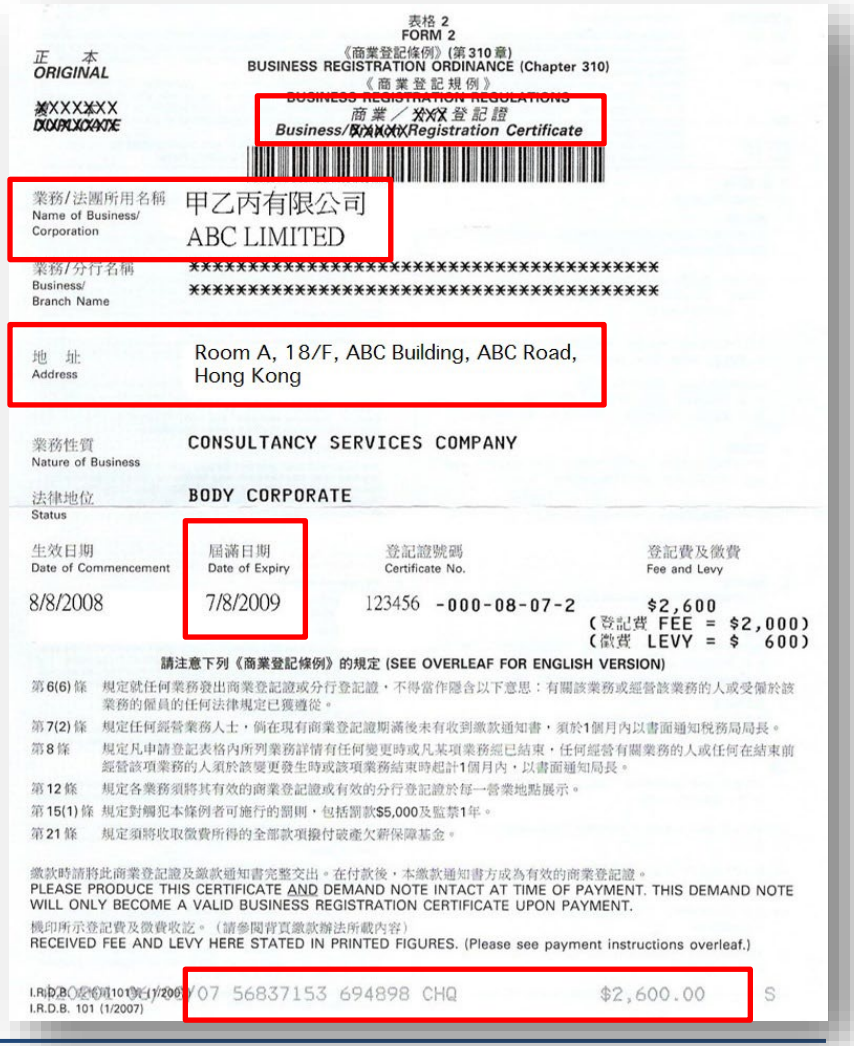
Department of Health

B001	LRP's name*	*In English*	*REAGENT SUPPLIES LTD.*	(B1) ☒
		In Chinese	*試劑供應有限公司*	
	Address in Hong Kong *(Please give the registered place of business, if any)**	*In English*	*32/F., HOPEWELL CENTRE, 183 QUEEN'S ROAD EAST, WANCHAI, HONG KONG*	
		In Chinese	*香港灣仔皇后大道東183號合和中心32樓*	
	Contact person: *CHAN TAI-MAN*		Telephone: *2800 0000*	
	Position: *General Manager*		Email: tchan@reagent.com.hk	
	Contact telephone for public enquiries:* *2000 0000*		Fax: *2900 0000*	
	Mobile telephone for urgent use (24 hours): *9000 0000*			
	☒ Copy of business registration certificate (with business registration number: *BR123467*) is enclosed			
B002	Date designated as LRP by the manufacturer: *30 June 2010* ☒ Manufacturer's designation letter is enclosed			(B2) ☒
B003	Established Quality Management System ☒ ISO 9001 ☐ ISO 13485 ☐ None ☒ System certified by *ABC Agency* (certification body), and a copy of the certificate is enclosed			(B3) ☒

Part B: Particulars of Local Responsible Person

- Valid Business Registration Certificate of LRP

  (Enclosure B1)



表格 2
FORM 2
正 本
ORIGINAL
《商業登記條例》(第 310 章)
BUSINESS REGISTRATION ORDINANCE (Chapter 310)
《商業登記規例》
BUSINESS REGISTRATION REGULATIONS
商業／分行登記證
Business/Branch Registration Certificate

業務/法團所用名稱
Name of Business/ Corporation
甲乙丙有限公司
ABC LIMITED

業務/分行名稱
Business/ Branch Name

地 址
Address
Room A, 18/F, ABC Building, ABC Road, Hong Kong

業務性質
Nature of Business
CONSULTANCY SERVICES COMPANY

法律地位
Status
BODY CORPORATE

生效日期 Date of Commencement	屆滿日期 Date of Expiry	登記證號碼 Certificate No.	登記費及徵費 Fee and Levy
8/8/2008	7/8/2009	123456 -000-08-07-2	$2,600 (登記費 FEE = $2,000) (徵費 LEVY = $ 600)

請注意下列《商業登記條例》的規定 (SEE OVERLEAF FOR ENGLISH VERSION)

第6(6)條 規定就任何業務發出商業登記證或分行登記證，不得當作隱含以下意思：有關該業務或經營該業務的人或受僱於該業務的僱員的任何法律規定已獲遵從。
第7(2)條 規定任何經營業務人士，倘在現有商業登記證期滿後未有收到繳款通知書，須於1個月內以書面通知稅務局局長。
第8條 規定凡申請登記表格內所列業務詳情有任何變更時或凡某項業務經已結束，任何經營有關業務的人或任何在結束前經營該項業務的人須於該變更發生時或該項業務結束時起計1個月內，以書面通知局長。
第12條 規定各業務須將其有效的商業登記證或有效的分行登記證於每一營業地點展示。
第15(1)條 規定對觸犯本條例者可施行的罰則，包括罰款$5,000及監禁1年。
第21條 規定須將收取徵費所得的全部款項撥付破產欠薪保障基金。

繳款時請將此商業登記證及繳款通知書完整交出。在付款後，本繳款通知書方成為有效的商業登記證。
PLEASE PRODUCE THIS CERTIFICATE AND DEMAND NOTE INTACT AT TIME OF PAYMENT. THIS DEMAND NOTE WILL ONLY BECOME A VALID BUSINESS REGISTRATION CERTIFICATE UPON PAYMENT.
機印所示登記費及徵費收訖。（請參閱背頁繳款辦法所載內容）
RECEIVED FEE AND LEVY HERE STATED IN PRINTED FIGURES. (Please see payment instructions overleaf.)

I.R.D.B. 101 (1/2007) 07 56837153 694898 CHQ $2,600.00 S

Part B: Particulars of Local Responsible Person

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Designation Letter

(Enclosure B2)

(GN-01 Appendix 2)

- ✓ Manufacturer's name and address
- ★ ✓ LRP's name~~, Tel./fax no.~~ and address
- ✓ Descriptions of the device(s)
- ✓ Manufacturer's signature and official stop (if applicable)
- ✓ Date

<Name of manufacturer>
<Address of manufacturer>

Date:

<Name of LRP>
<Address of LRP>

Dear Sirs,

Re: Designation of Local Responsible Person for <Brief description of devices>

In accordance with the requirements of the Medical Device Administrative Control System (MDACS) of the Hong Kong Special Administrative Region, we hereby designate you, <Name of LRP>, as the Local Responsible Person in respect of the following devices:

<Descriptions of devices including their makes, models, types, and other relevant identifiers>

This designation will require you to comply with, with immediate effect, all the requirements (including but not limited to all the pre-market and post-market requirements) that the MDACS imposes on you as the Local Responsible Person in respect of the above-mentioned devices. We undertake to provide you timely with all the items (documents, information, device and labelling samples etc.) and support that must necessarily originate from us, and which you will need in order to apply for the listing of the afore-mentioned devices and to fulfil your obligations under the MDACS. These items and support include but are not limited to:

(i) details of design related to the safety and performance of the device;
(ii) a copy of documents as required in the application form for the listing of devices;
(iii) any subsequent changes and modifications;
(iv) details of any recalls, alerts, and related preventive and corrective actions; and
(v) investigations and reports related to adverse incidents and post market surveillance.

Yours faithfully,

(signature)

(name and title of official signing this letter)

(official chop (if any) of the manufacturer)

Part B: Particulars of Local Responsible Person

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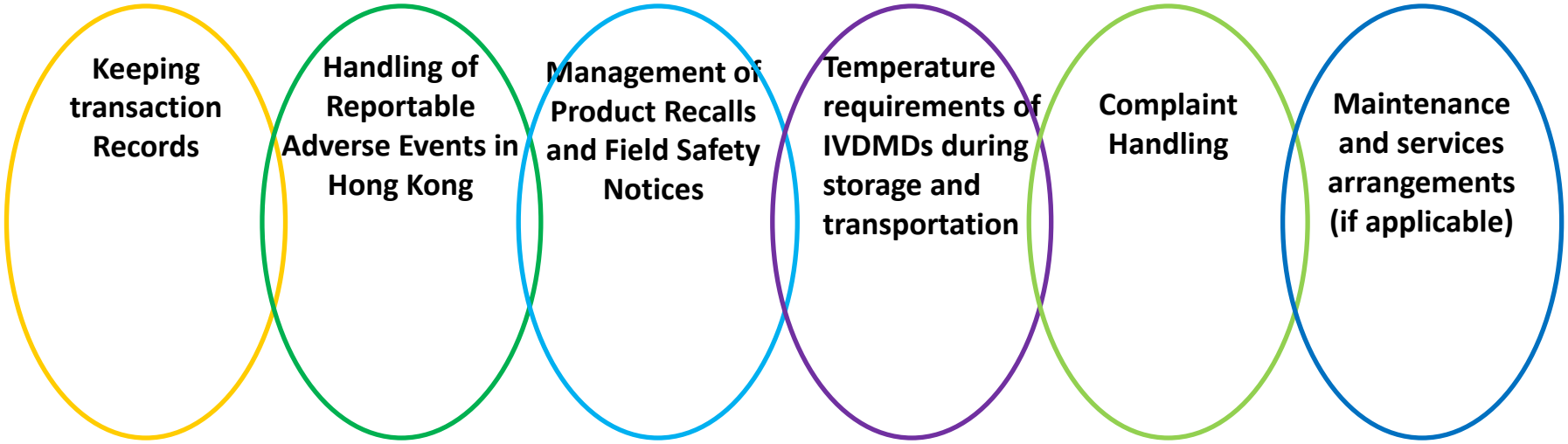
B004	<u>Documented Procedures Established and Maintained</u> ☒ The applicant <u>does not</u> have any medical device listed under the Medical Device Administrative Control System ☒ The procedures indicated in items (i) to (vi) below are enclosed (i) Keeping of supply records (ii) Management of product recalls and field safety notices (iii) Handling of reportable adverse events 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.	(B4) ☒

Part B: Particulars of Local Responsible Person

- Documented Procedure of LRP (Enclosure B4)
  - The documented procedures of LRP below (B004 items (i) to (vi)) must be submitted with the application form when first applying for listing:



Part B: Particulars of Local Responsible Person

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B005	☒ The LRP is also an importer and/or distributor of the device named in Part C Listing No. of Importer: IMP0123456 (if applicable) Listing No. of Distributor: DIS0345678 (if applicable)	
B006	☐ The device named in Part C is currently a listed device (under another LRP), with Listing No.	

Part C: Particulars of the Device

Note	Part C: Particulars of the In Vitro Diagnostic Medical Device (IVDMD)			Encl.
C001	Make*	*in English*	*ABC Medical*	
		in Chinese	*N.A.*	
	Brand Name*	*in English*	*VGOOD*	
		in Chinese	*N.A.*	
	Model*	*in English*	*HCV Antigen Kit version 2.3*	
		in Chinese	*N.A.*	
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) Probe cleaning solution, matrix cell wash solution and line diluent solution In addition, please provide the additional required information of the IVDMD in the following space, if any. Use separate sheets if required. _____ _____			(C1) ☒

The Make is the same as the manufacturer's name but without the wording Co., Ltd., etc.

The Model should be identical to that of the marketing approval documents

Part C: Particulars of the Device

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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.)* *Reagents, Serology, Virus, Hepatitis C, Core Antigen*		
	AMDNS Code: *19062*		
	Other Codes *(Please enter if known)*: E.g., Global Medical Device Nomenclature (GMDN) Code		
C004	Other common descriptions of the device: *Hepatitis C antigen determination reagents* Please provide this information as far as possible		
C005	Intended use of the device*	*in English*	*To detect the presence of Hepatitis C virus antigen in patient serum samples. (Infectious immunology, hepatitis viruses, kit for Hepatitis C virus antigen).*
		in Chinese	*檢測病人血液樣本中，是否存在丙型肝炎的抗原。*
C006	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)*:		(C1) ☒

The intended use of the devices should be in accordance with that of the instructions for use

Part C: Particulars of the Device

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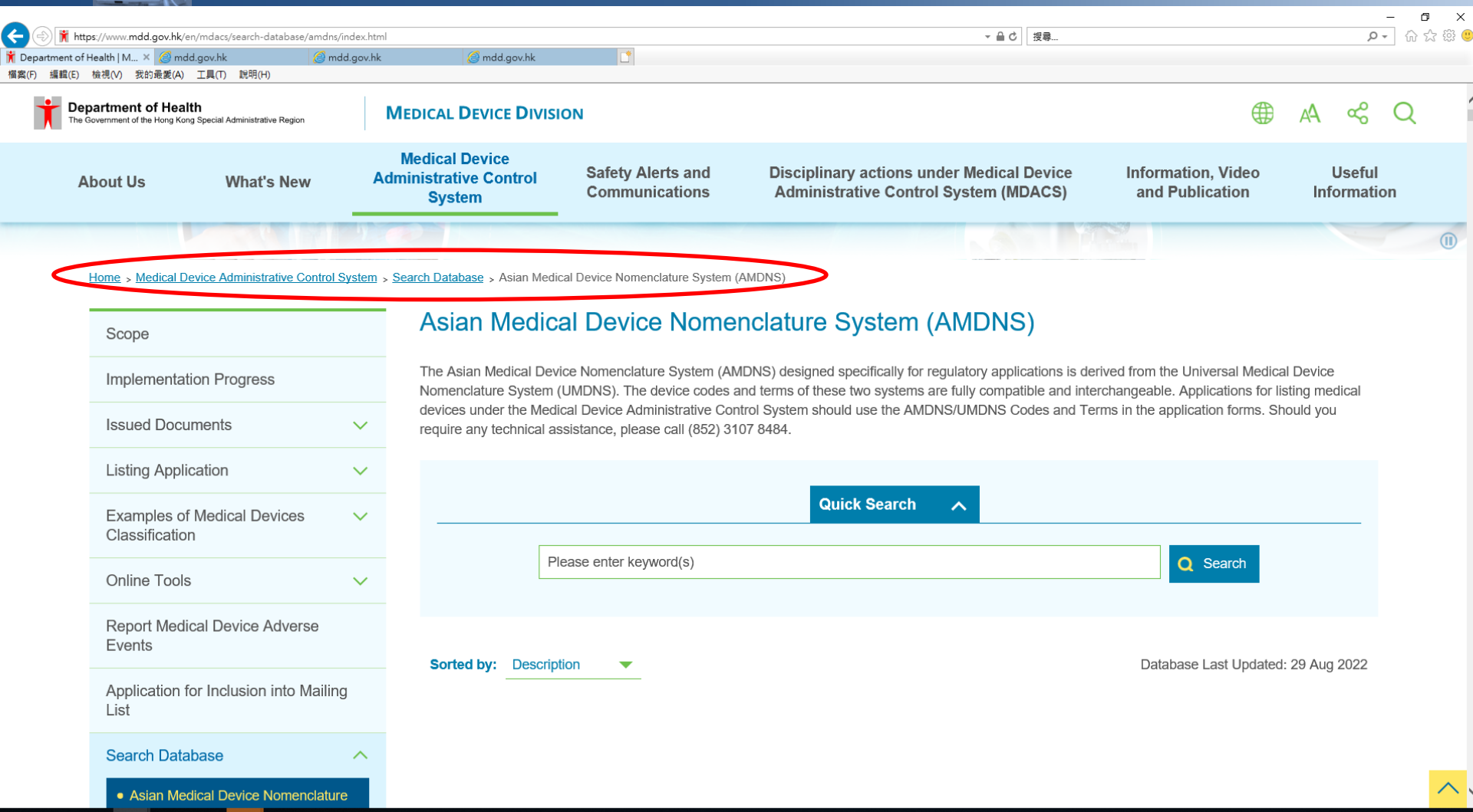

Part C: Particulars of the Device

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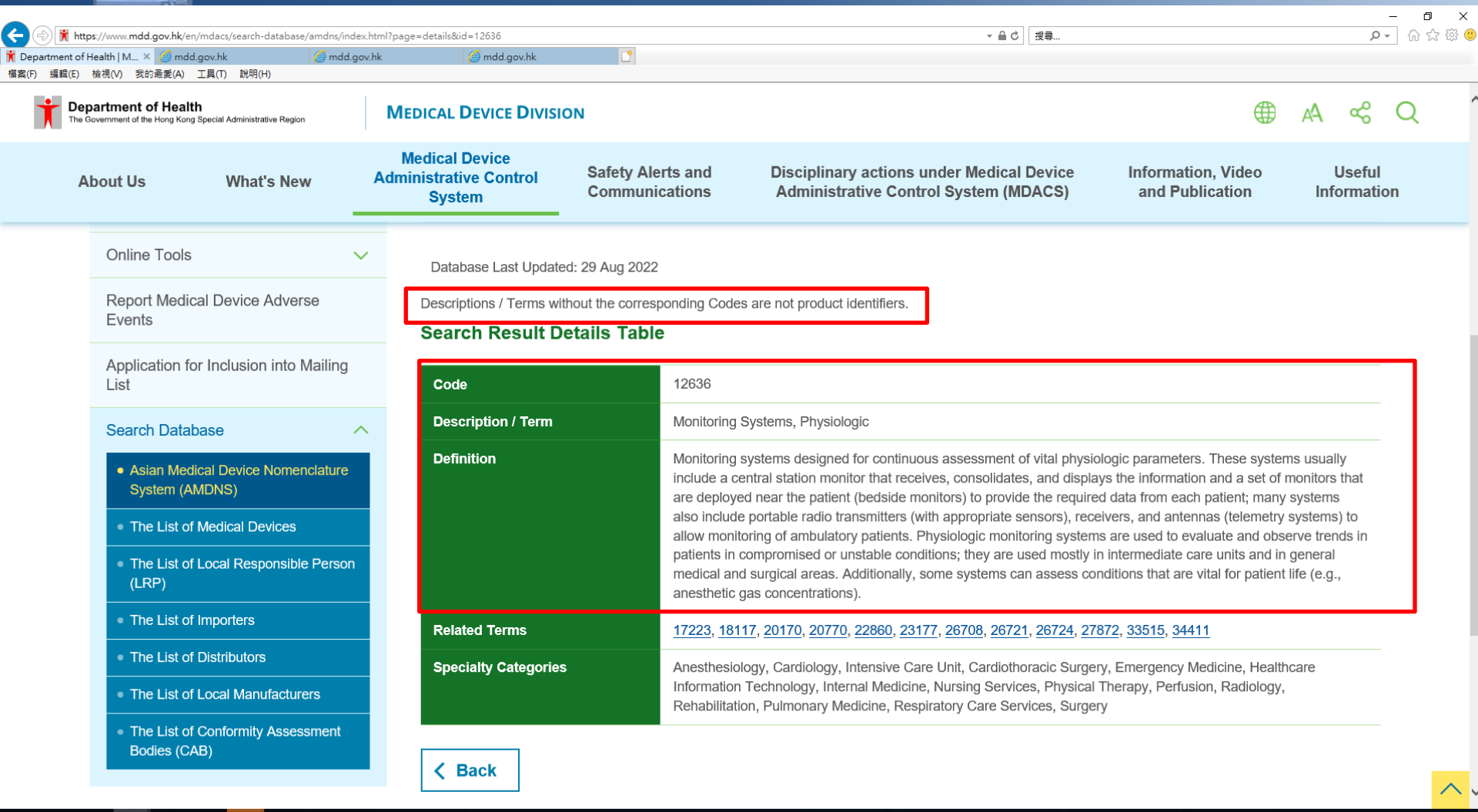

https://www.mdd.gov.hk/en/mdacs/search-database/amdns/index.html?page=details&id=12636

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MEDICAL DEVICE DIVISION

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Search Database

- Asian Medical Device Nomenclature System (AMDNS)
- The List of Medical Devices
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- The List of Distributors
- The List of Local Manufacturers
- The List of Conformity Assessment Bodies (CAB)

Database Last Updated: 29 Aug 2022

Descriptions / Terms without the corresponding Codes are not product identifiers.

Search Result Details Table

Code	12636
Description / Term	Monitoring Systems, Physiologic
Definition	Monitoring systems designed for continuous assessment of vital physiologic parameters. These systems usually include a central station monitor that receives, consolidates, and displays the information and a set of monitors that are deployed near the patient (bedside monitors) to provide the required data from each patient; many systems also include portable radio transmitters (with appropriate sensors), receivers, and antennas (telemetry systems) to allow monitoring of ambulatory patients. Physiologic monitoring systems are used to evaluate and observe trends in patients in compromised or unstable conditions; they are used mostly in intermediate care units and in general medical and surgical areas. Additionally, some systems can assess conditions that are vital for patient life (e.g., anesthetic gas concentrations).
Related Terms	17223, 18117, 20170, 20770, 22860, 23177, 26708, 26721, 26724, 27872, 33515, 34411
Specialty Categories	Anesthesiology, Cardiology, Intensive Care Unit, Cardiothoracic Surgery, Emergency Medicine, Healthcare Information Technology, Internal Medicine, Nursing Services, Physical Therapy, Perfusion, Radiology, Rehabilitation, Pulmonary Medicine, Respiratory Care Services, Surgery

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Part C: Particulars of the Device

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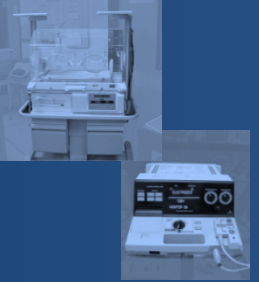
C007	The device Yes No ☒ ☐ is manufactured from or incorporating human cells/tissues/derivatives ☐ ☒ is manufactured from or incorporating animal cells/tissues/derivatives If the IVDMD contains substance(s) from human or animal origin, please state the location of such descriptions inside the submitted documentation, e.g. the Instruction for Use, or the additional information provided separately. *Information can be found inside the operator's manual (Page 2, section 1)*	(C2) ☒
C008	Class of the IVDMD: ☐ Class B ☐ Class C ☒ Class D	
	Reasons for the classification: *It is a test system of reagents to detect the presence of HCV antigen in serum (Rule 1, Paragraph 2)*	
C009	Manufacturing site(s) *(Use separate sheet if required)*: *(1) 1324N, Derby Road, Arlington, VA 12345-6789, USA* *(2) DEF Medical Inc., 1000 Butler Road, Plymouth Place, PA 12486-1248, USA*	(C1) ☒

If the company name of the manufacturing site is different from the manufacturer's name, it should be specified.



Part C: Particulars of the Device

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Department of Health

C010	History of previous recalls, reportable adverse events, 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 events 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:_____ _____	

Part C: Particulars of the Device

★	**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: *http://www.abcmedical.com/hcv_antigen_kit* ☒ Sample of Special Listing Information is enclosed	
C013	Please indicate where in the labelling the following information is given: *(1)* Indications for use of the IVDMD: *Pages 4 – 8 of the operator's manual* *(2)* Contraindications against use of the IVDMD: *Pages 9 – 11 of the operator's manual* *(3)* Cleaning, disinfection and/or sterilization procedures: *Pages 45 of the operator's manual* *(4)* User precautions: *Pages 24 – 28 of the operator's manual* *(5)* Disposal precautions: *N. A.*	(C3) ☒

Part C: Particulars of the Device

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Special Listing Information (GN-01, sec. 4.4.13)

The Special Listing Information comprises:

(i) The device's Listing Number, and in case the device's instructions for use are available only in English or only in Chinese, a supplementary statement to inform the user of this fact.

(ii) The LRP information including the name, address, ~~email address~~ and contact telephone / fax numbers in both English and Chinese wherever Applicable.

LRP should provide Special Listing Information:

(1) on the outer packaging of the medical device, or on a document delivered together with the medical device; and/or

(2) on a document in which the Special Listing Information is printed, such as a receipt

Part C: Particulars of the Device

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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) Yes ☐ No ☒ Pharmacy and Poisons Ordinance (Cap. 138) Yes ☐ No ☒ Antibiotics Ordinance (Cap. 137) Yes ☐ No ☒ 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) ☒

Part C: Particulars of the Device

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C016	Conformity Assessment ☐ MDACS Conformity Assessment Certificate issued by Conformity Assessment Bodies recognized by MDD. MDACS Conformity Assessment Body number: _____	(C6) ☐

Part C: Particulars of the Device

- C016: Conformity Assessment Certificate
  - **Conformity Assessment Body (CAB)** means a body recognized by the MDD to engage in the performance of procedures for determining whether the device fulfills the relevant MDACS requirements
  - Recognized CAB for IVD medical devices: BSI

Part C: Particulars of the Device

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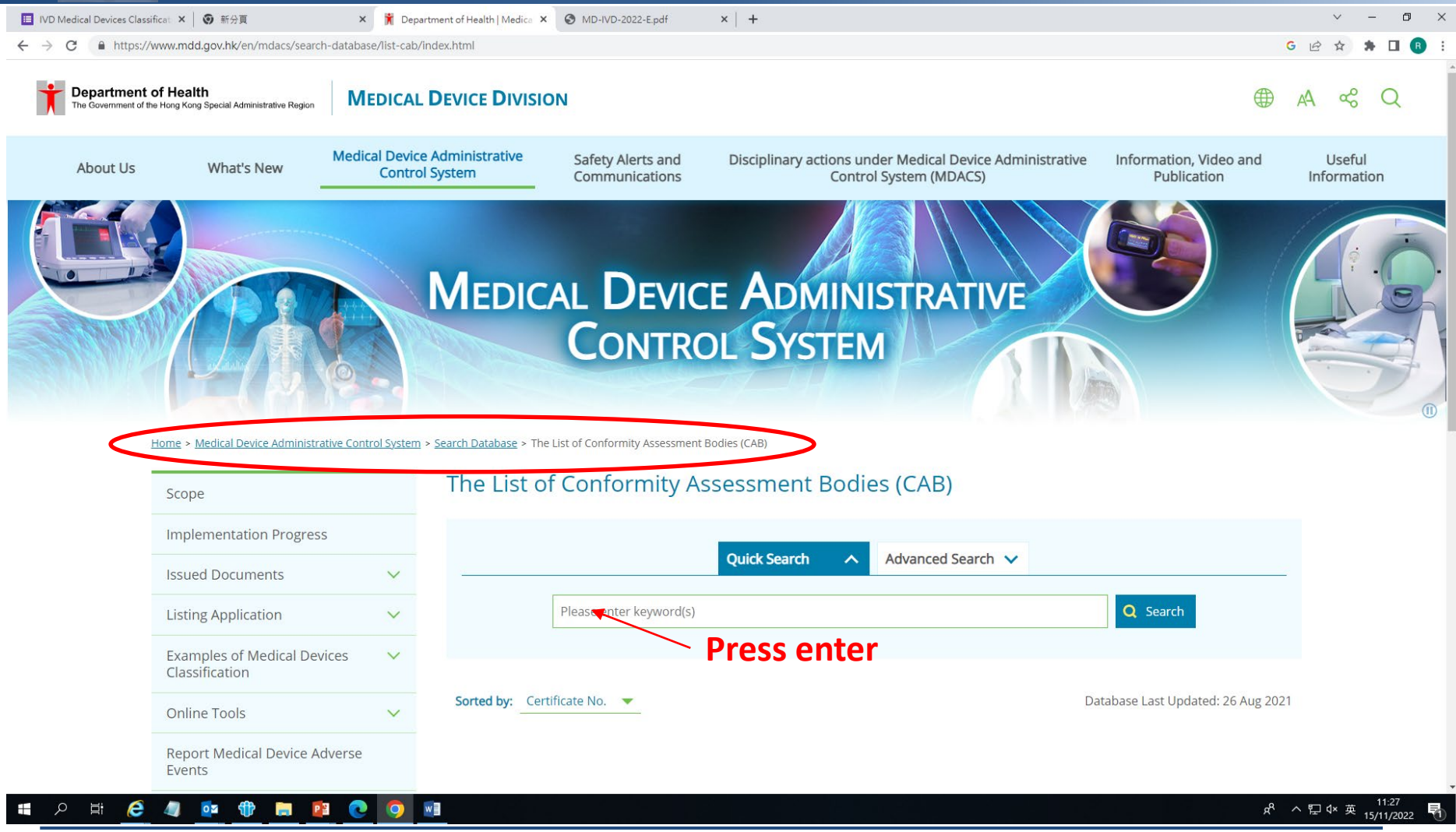

Part C: Particulars of the Device

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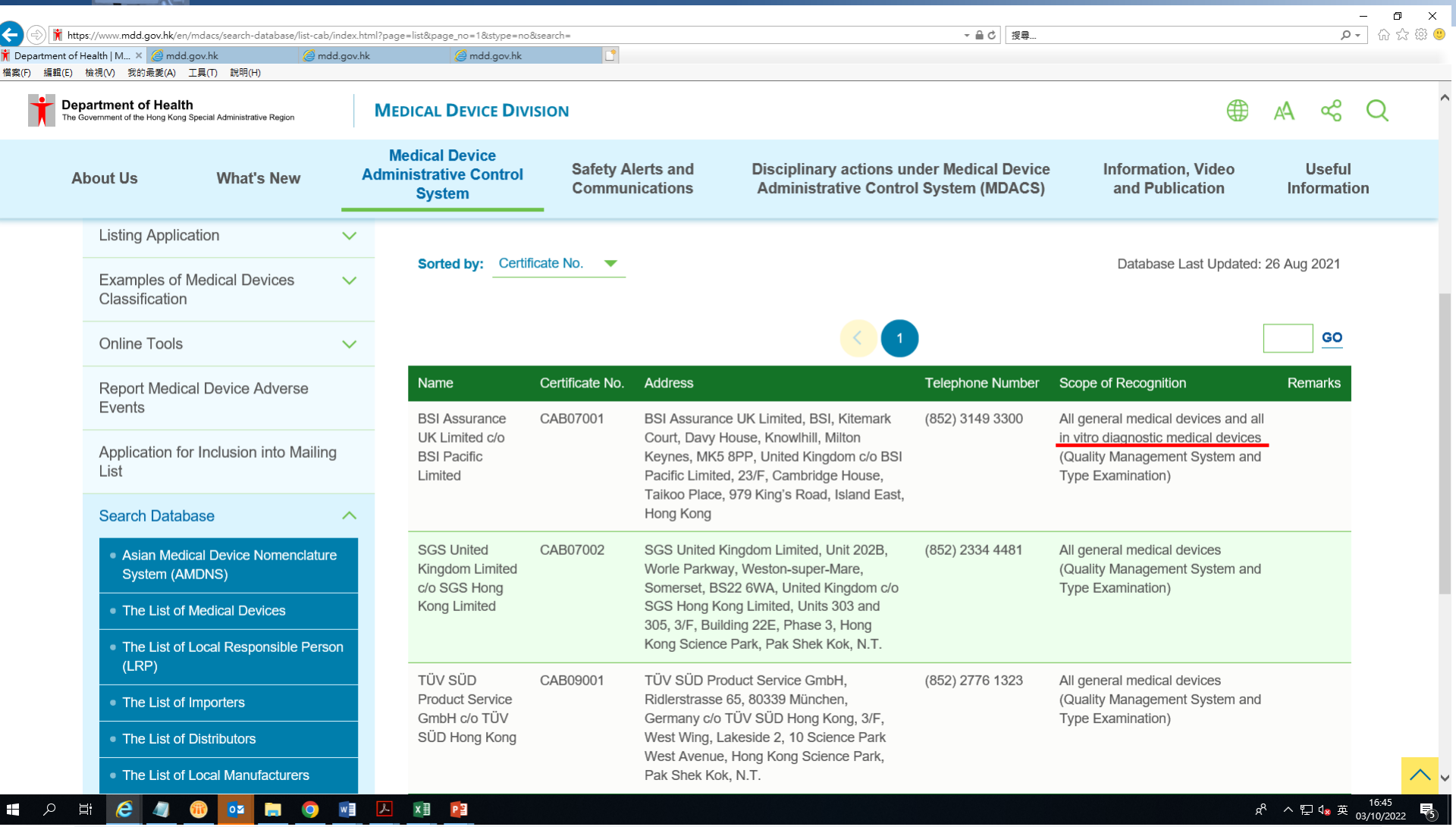

https://www.mdd.gov.hk/en/mdacs/search-database/list-cab/index.html?page=list&page_no=1&stype=no&search=

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檔案(F) 編輯(E) 檢視(V) 我的最愛(A) 工具(T) 說明(H)

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MEDICAL DEVICE DIVISION

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- Examples of Medical Devices Classification
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- Report Medical Device Adverse Events
- Application for Inclusion into Mailing List
- Search Database
  - Asian Medical Device Nomenclature System (AMDNS)
  - The List of Medical Devices
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  - The List of Importers
  - The List of Distributors
  - The List of Local Manufacturers

Sorted by: Certificate No.

Database Last Updated: 26 Aug 2021

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Name	Certificate No.	Address	Telephone Number	Scope of Recognition	Remarks
BSI Assurance UK Limited c/o BSI Pacific Limited	CAB07001	BSI Assurance UK Limited, BSI, Kitemark Court, Davy House, Knowlhill, Milton Keynes, MK5 8PP, United Kingdom c/o BSI Pacific Limited, 23/F, Cambridge House, Taikoo Place, 979 King's Road, Island East, Hong Kong	(852) 3149 3300	All general medical devices and all in vitro diagnostic medical devices (Quality Management System and Type Examination)	
SGS United Kingdom Limited c/o SGS Hong Kong Limited	CAB07002	SGS United Kingdom Limited, Unit 202B, Worle Parkway, Weston-super-Mare, Somerset, BS22 6WA, United Kingdom c/o SGS Hong Kong Limited, Units 303 and 305, 3/F, Building 22E, Phase 3, Hong Kong Science Park, Pak Shek Kok, N.T.	(852) 2334 4481	All general medical devices (Quality Management System and Type Examination)	
TÜV SÜD Product Service GmbH c/o TÜV SÜD Hong Kong	CAB09001	TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 München, Germany c/o TÜV SÜD Hong Kong, 3/F, West Wing, Lakeside 2, 10 Science Park West Avenue, Hong Kong Science Park, Pak Shek Kok, N.T.	(852) 2776 1323	All general medical devices (Quality Management System and Type Examination)	

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Conformity Assessment Routes

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C016:

CAB recognized by **MDD**

Conduct conformity assessment on the medical device and issue CAB certificate

Alternative Route

D001: Demonstrate the medical device **conforms to the Essential Principles of Safety and Performance of IVD Medical Devices** through **valid marketing approvals of the IVD medical devices obtained in specified overseas countries/region***

*Australia, Canada, European Union, Japan and United States of America

Part C: Particulars of the Device

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C017	Performance and Risk Analysis Specifications, international or national standards with which the device complies: *EN ISO14971:2012, EN 13612:2002 & ISO18113:2009* ☒ 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) ☒

Part C: Particulars of the Device

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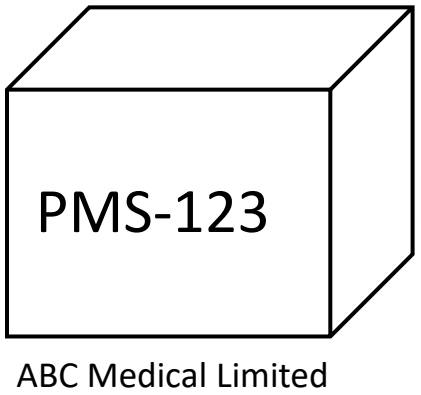

ABC Medical Limited

Family/Series/ System	Accessories	Manufacturing sites' QMS certificates	Appendix (C1)
Human/animal cells, tissues, or derivatives; recalls, adverse events, etc; manufacturing site			Appendix (C2)
IFU	Special Listing Information	Labels	Appendix (C3)
License Requirements (if applicable)			Appendix (C4)
Batch verification (For Class D IVD medical devices only)			Appendix（C5）
MDACS conformity assessment certificate (if applicable)			Appendix (C6)
Complied Standards	Risk Analysis	Type Test	Appendix (C7)
Performance Evaluation			Appendix (C8)

Part D: Marketing Approvals & Essential Principles

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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) ☒

Part D: Marketing Approvals & Essential Principles

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Department of Health

- Marketing Approvals (Appendix D1)- Conformity to the Essential Principles
  - If the device has obtained recognized marketing approvals **on or after 1st January, 2005**, then the applicant has to provide:
    - Essential Principles Conformity Checklist for In Vitro Diagnostic Medical Devices (MDIVD-CCL); or
    - (i) Essential Requirements Checklist prepared for the European IVD Medical Device Directive or General Safety and Performance Requirements (GSPR) Checklist prepared for the European IVD Medical Devices Regulation, and (ii) HK MDACS's Essential Principles Declaration of Conformity (GN-06, Appendix III)

Essential Principles Conformity Checklist for IVD Medical Devices (MDIVD-CCL)

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Medical Device Control Office
Department of Health

Medical Device Administrative Control System
Essential Principles Conformity Checklist
For In Vitro Diagnostic Medical Devices

Make: *ABC Medical*
Brand Name and Model: *VGOOD HCV Antigen Kit version 2.3*

Clause	Essential Principle	Applicable	Method of Conformity	Identity of Specific Documents
General Requirements				
1.	Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training, and the medical and physical conditions of intended users, they will perform as intended by the manufacturer and not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.	*Yes*	1. *The devices are designed and manufactured under a full quality management system in accordance with EN ISO 13485:2016 and presently certified* 2. *The devices are designed and manufactured in conformity with the EU Common Technical Specifications published in OJEC.* 3. *Risk analysis has been performed in accordance with EN ISO 14971:2012. Together with the proactive surveillance studies, it shows that any risks which may be associated with the devices are acceptable when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.*	1. *EN ISO 13485:2016 Certificate No. 012345* 2. *Product Design & Manufacturing files.* 3. *Proactive Surveillance Report PSR-001* 4. *Risk Analysis Report RAR-001*

Essential Principles Conformity Checklist for IVD Medical Devices (MDIVD-CCL)

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18.1	For an IVD medical device a performance evaluation should be conducted in accordance with GHTF guidance. The performance evaluation should review analytical performance data and, where appropriate, clinical performance data in the form of any: • literature; • performance study reports; and • experience gained by routine diagnostic testing. to establish that the IVD medical device achieves its intended performance during normal conditions of use and that the known, and foreseeable risks, and any undesirable effects, are minimised and acceptable when weighed against the benefits of the intended performance.	*Yes*	*Performance evaluation of the devices is to be conducted in accordance with EN 13612:2002.*	*Performance evaluation report PER-001*
18.2	Clinical investigations on human subjects should be carried out in accordance with the spirit of the Helsinki Declaration. This includes every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results.	*Yes*	*Performance evaluation of the devices is to be conducted in accordance with EN 13612:2002*	*Performance evaluation report PER-001*

I confirm that I have neither amended the wording in this form, nor otherwise altered the form in any material manner, apart from filling in the blanks.

I declare that the information provided in this form is accurate and correct and the device conforms to all the applicable requirements stipulated above.

Signature:

Name: *CHAN TAI-MAN*

Position: *GENERAL MANAGER*

The Applicant (Local Responsible Person): *REAGENT SUPPLIES LTD*

Date: *2 Jan 2019*

Company Chop

Essential Principles Declaration of Conformity (GN-06, Appendix 3)

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Department of Health

<Name of Manufacturer/Local Responsible Person>
<Address of Manufacturer/Local Responsible Person>
<Date>

Medical Device Division,
Department of Health.
Room 604, 6/F.
14 Taikoo Wan Road,
Taikoo Shing, Hong Kong

Dear Sirs

Product: <Make> <Brand Name and Model(s)>
<Product Description>
Manufactured by <Manufacturer>
<Address of Manufacturer>

We declare that the captioned product fully complies with all the relevant clauses stipulated under the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices as required under the Medical Device Administrative Control System. We undertake to provide the necessary evidence to demonstrate the compliance within two weeks upon request.

Yours faithfully

<Signature>
<Name and Title>
<Company Name>

Marketing Approvals Samples

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Marketing Approvals

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Countries	Marketing Approvals
China (Trial scheme)	Medical Device Registration Certificate
Australia	Australia Therapeutic Goods Administration (TGA) ARTG Certificate
Canada	Health Canada (HC) Medical Device Licence
Japan	Pre-market Certification (Ninsho) from Registered Certification Body (RCB) Pre-market Approval (Shonin) from Ministry of Health, Labour and Welfare (MHLW)
USA	Premarket Notification [510(k) clearance] Premarket Approval (PMA)
EU	EC/EU Certificates*: • Directive 98/79/EC (IVDD) • Regulation (EU) 2017/746 (IVDR)

* The EC/EU Declaration of Conformity (issued by the manufacturer) shall be submitted in addition to EC/EU Certificates

EU
Marketing Approvals (by EU NB)

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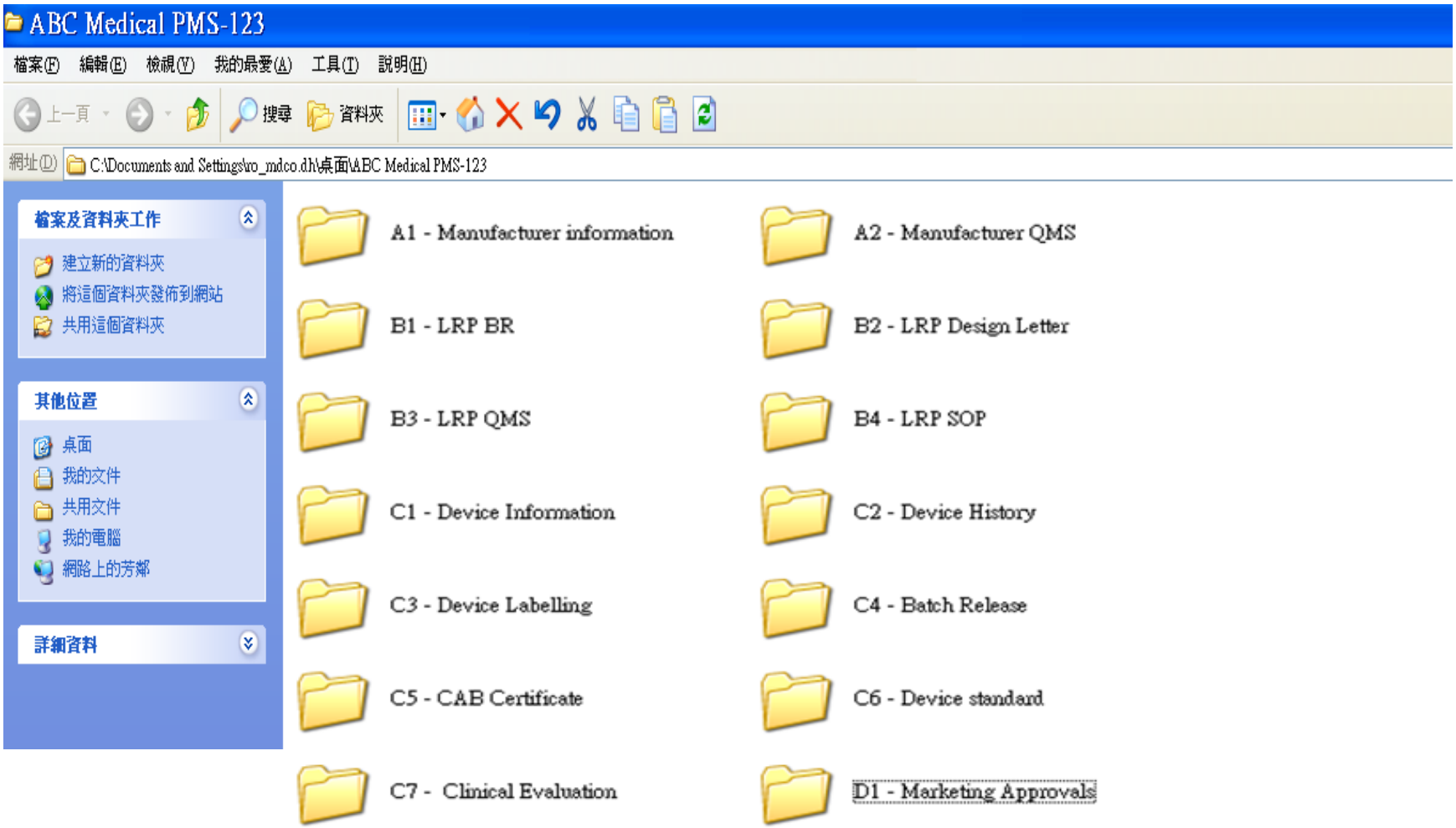
EC Certificates	Directive 98/79/EEC (IVDD)
Full Quality Assurance System Approval Certificate	Annex IV
EC Design Examination Certificate	Annex IV (4) / Annex III (6)
Batch Verification Certificate (List A products only)	Annex IV (6)
EC Type Examination Certificate	Annex V
EC Verification Certificate	Annex VI
Production Quality Assurance System Approval Certificate	Annex VII

Preparation of Application Documents



Further Information

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https://www.mdd.gov.hk/en/useful-information/issued-documents-under-mdacs/index.html

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- Issued Documents under Medical Device Administrative Control System (MDACS)
- Forms
- Useful Sites

Issued Documents under Medical Device Administrative Control System (MDACS)

(Note: The Medical Device Control Office has been renamed as the Medical Device Division with effect from 1 October 2019. Please refer to Contact Us page for updates in contact information and contact our office for enquiry, if necessary.)

Guidance Notes

- [GN-00] Guidance Notes for Definitions and Abbreviations for Medical Device Administrative Control System
- [GN-01] Overview of the Medical Device Administrative Control System
- [GN-02] Guidance Notes for Listing Class II, III & IV Medical Devices
- [GN-03] Guidance Notes for Adverse Event Reporting by Local Responsible Persons
- [GN-04] Conformity Assessment Framework and Conformity Assessment Bodies
- [GN-06] Guidance Notes for Listing In Vitro Diagnostic (IVD) Medical Devices
- [GN-07] Guidance Notes for Listing of Importers of Medical Devices
- [GN-08] Guidance Notes for Listing of Local Manufacturers
- [GN-09] Guidance Notes for Listing of Distributors

Issued Documents
Guidance Note

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Guidance Notes for Definitions and Abbreviations for Medical Device Administrative control System	GN-00
Overview of the Medical Device Administrative Control System	GN-01
Guidance Notes for Listing Class II, III & IV Medical Devices	GN-02
Guidance Notes for Adverse Event Reporting by Local Responsible Persons	GN-03
Conformity Assessment Framework and Conformity Assessment Bodies	GN-04
Guidance Notes for Listing In Vitro Diagnostic (IVD) Medical Devices	GN-06
Guidance Notes for Listing of Importers of Medical Devices	GN-07
Guidance Notes for Listing of Local Manufacturers	GN-08
Guidance Notes for Listing of Distributors	GN-09

Issued Documents
Technical Reference

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Principles of Conformity Assessment for Medical Devices	TR-001
Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices	TR-002
Classification Rules for Medical Devices	TR-003
Essential Principles of Safety and Performance of Medical Devices	TR-004
Additional Medical Device Labelling Requirements	**TR-005**
Principles of In Vitro Diagnostic (IVD) Medical Devices Classification	TR-006

Issued Documents
Code of Practice

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Department of Health

Code of Practice for Local Responsible Person	COP-01
Code of Practice for Conformity Assessment Body	COP-02
Code of Practice for Listed Local Manufacturer	COP-03
Code of Practice for Listed Importers of Medical Devices	COP-04

Contact Us

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Department of Health

Department of Health
Medical Device Division (MDD)

Address:
Room 604, 6/F, 14 Taikoo Wan Road, TaiKoo Shing, Hong Kong

Phone: 3107 8484

Fax: 3157 1286

Email:
mdd@dh.gov.hk

Website:
www.mdd.gov.hk