Introduction of Medical Device Administrative Control System (MDACS)

Medical Device Division
Department of Health

Rev. 2024-04-17

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Brief Introduction to Medical Device Administrative Control System (MDACS)

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Brief Introduction to MDACS

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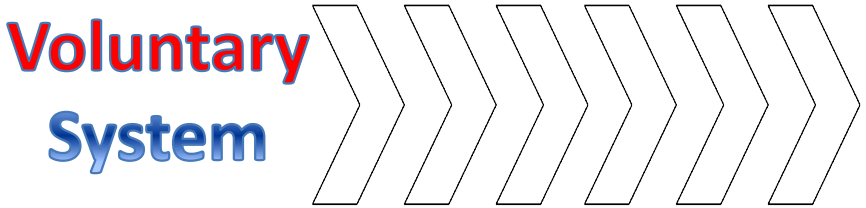
- Currently, there is **no specific legislation** to regulate the manufacture, import, distribution, supply and use of MDs in Hong Kong.
- However, depending on the nature, characteristics and claims of the MDs concerned, some products may be regulated by other pieces of legislation such as:
  - Pharmacy and Poisons Ordinance (Cap 138)
  - Radiation Ordinance (Cap 303)
  - Telecommunications Ordinance (Cap 106)
  - Consumer Goods Safety Ordinance (Cap. 456)
  - Undesirable Medical Advertisements Ordinance (Cap. 231)
  - Trade Descriptions Ordinance (Cap. 362)

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**

MDACS

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- Scope
  - Products fall within the definition of Medical Device
  - Some Medical Devices are excluded from the current scope of MDACS,
    For example: Medical Device incorporates human tissue

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)

Definition of Medical Device

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- **Examples of medical devices:**
  - **Condom**
  - **Medical device sterilizer**
  - **Blood pressure monitor**
  - **Thermometer**

MDACS

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Medical Device Administrative Control System (MDACS)

Pre-market Control		Post-market Control
Listing System (1) Medical Devices ➢ General Medical Devices (Class II – IV) (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**

New procurement requirements of the DH and HA

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- **New procurement requirements of the Department of Health (DH) and Hospital Authority (HA)**

→ 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

MDs being purchased by HA should also preferably be listed under the MDACS

(Please refer to individual invitation documents issued by HA for details of other procurement requirements)

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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Requirements of LRP

Either a legal person incorporated in Hong Kong,
Or
A natural or legal person with business registration in Hong Kong

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 using the same application form)

Establish documented procedures according to the requirements stipulated by the Medical Device Division

LRP

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- **LRP shall refrain from misrepresenting the efficacy or performance of their products for medical purposes.**

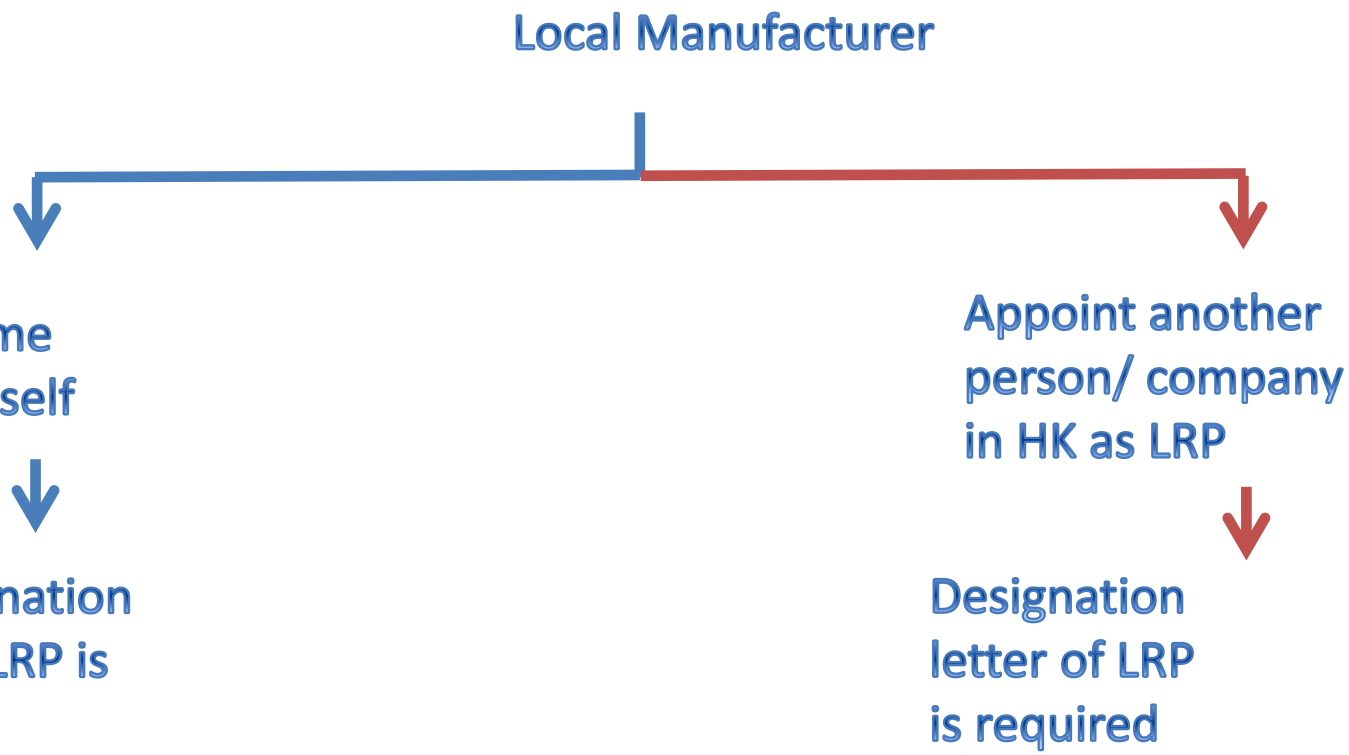
- Depending on the nature, characteristics and claims of the MDs concerned, some products may be regulated by other pieces of legislation.
  - e.g. the Undesirable Medical Advertisements Ordinance (Cap. 231)

- → you are advised to consult your legal advisor on lawful import and supply of your products in Hong Kong.

  (You may also refer to the website https://www.elegislation.gov.hk/ for Hong Kong Legislation.)

LRP

- Relationship between LRP and Local Manufacturer



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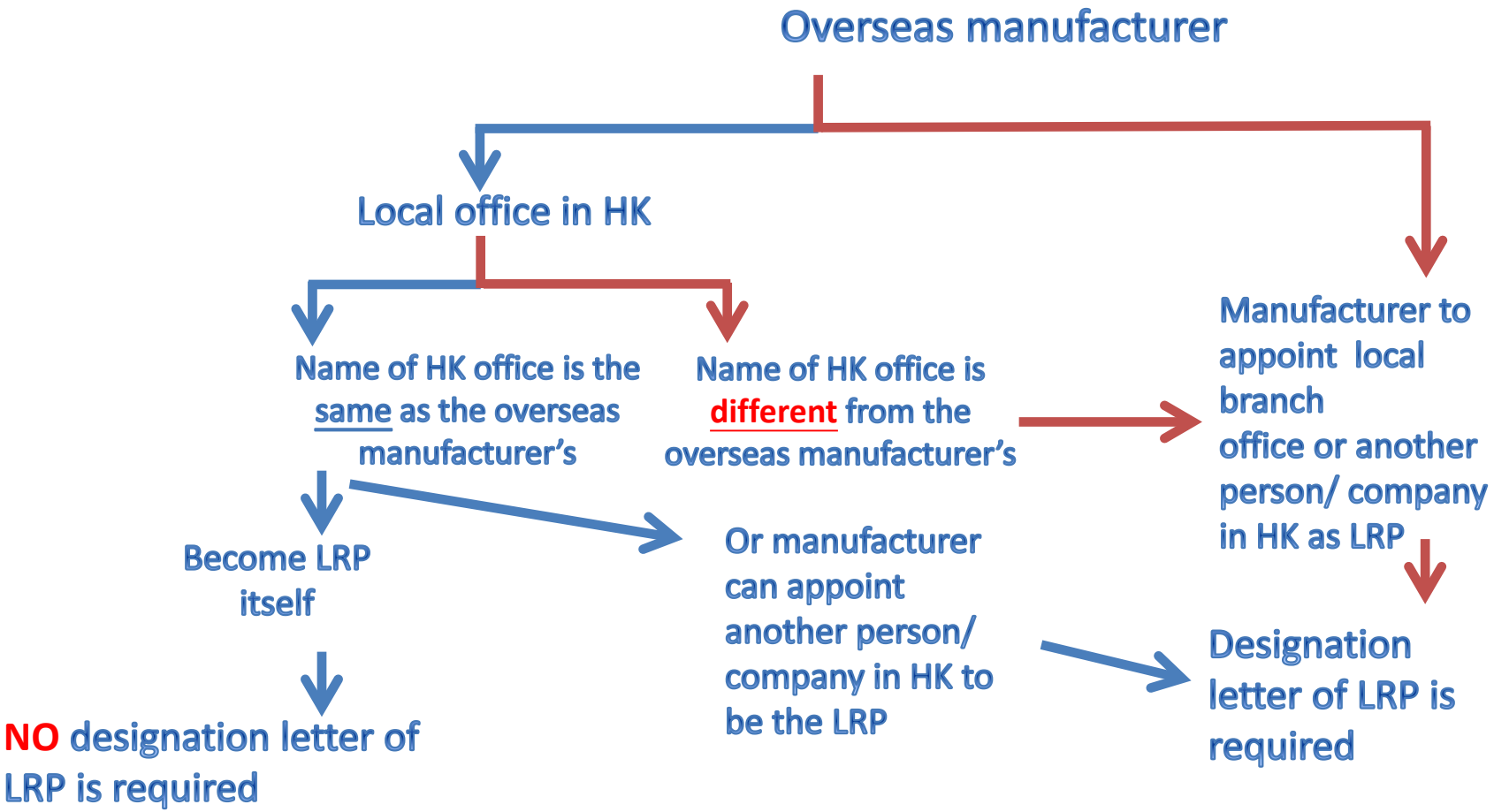
- Relationship between LRP and overseas manufacturer



LRP

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- 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 manufacturer, 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 events and post market surveillance.

Yours faithfully,
(signature)
(name and title of official signing this letter)
(official chop (if any) of the manufacturer)

LRP

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- Application for listing medical devices
  - Submit the completed application form and required information according to the listing requirements of general medical device under the MDACS
  - Establish efficient communication channels with the Government in relation to their application
  - Submit an renewal application to the MDD at least **12 weeks (but no more than 1 year)** before the expiry of Listing (5 years)

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

LRP

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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**

LRP

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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

LRP

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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

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

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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

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- Listing Application
- Examples of Medical Devices Classification
- Online Tools
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- Application for Inclusion into Mailing List
- Search Database

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

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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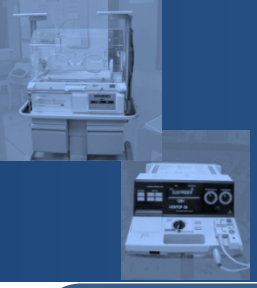

Local Manufacturer/Importer/Distributor

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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 **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 12 weeks** before the expiry of Listing	Required to submit renewal application **at least 12 weeks** before the expiry of Listing	Required to submit renewal application **at least 12 weeks** before the expiry of Listing

Brief Summary

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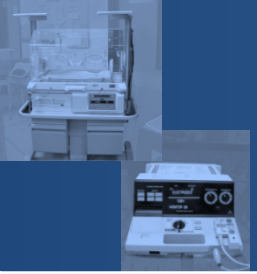
	*LRP	Local Manufacturer	Importer	Distributor
Guidance Notes	GN-01, GN-02, GN-06	GN-08	GN-07	GN-09
Application Form	MD101/MD102	LM	MD-IP+D	MD-IP+D
Business Registration Certificate	✓	✓	✓	✓
Documented Procedures	✓	✓	✓	✓
Other Information	❑ Designation Letter ❑ QMS certificate (if applicable)	❑ ISO 13485 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**



Brief Summary

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Requirements	LRP	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.	✓	N.A.

Listing of Medical Devices

Classification of General Medical Devices

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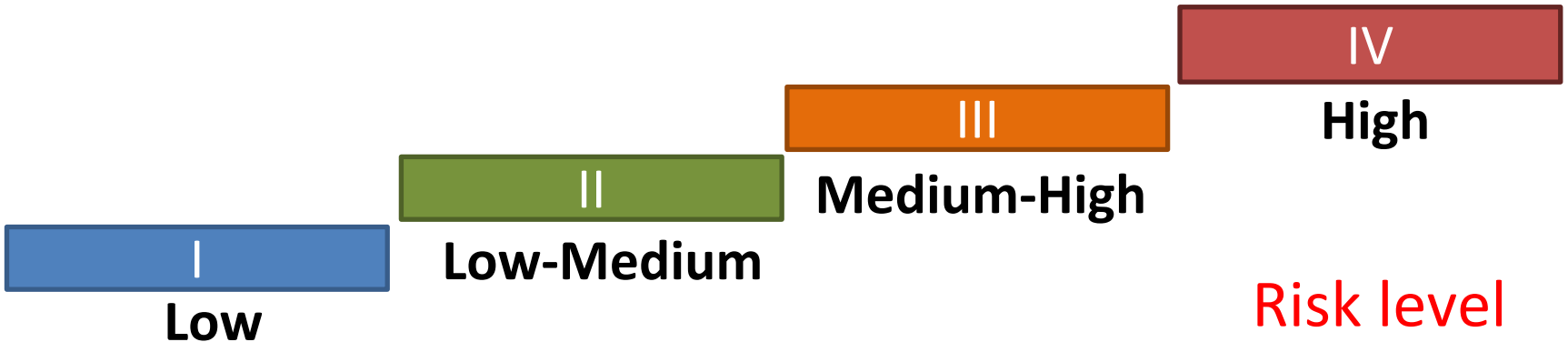
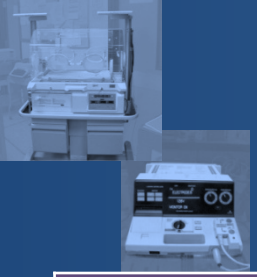
Classification of General Medical Device

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



Classification of General Medical Devices



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Risk Factor *(including but not limited to)*			
Intended Use of the device	***Duration of Contact between Human Body and the medical device**	**Extent of invasiveness**	**Any drug or energy delivered to the patient**

***NOTE:**

Transient use: Intended for continuous use for less than 60mins

Short-term use: Intended for continuous use for between 60mins to 30days

Long-term use: Intended for continuous use for more than 30days

Basic Information of Classification

Classification of General Medical Devices

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- All classification rules in **Technical Reference TR-003** must be taken into consideration
- If more than one rules applies, the rule putting the device into the highest class prevails

Non-invasive Devices (Rules 1 to 4)	**Invasive Devices (Rules 5 to 8)**
Active Devices (Rules 9 to 12)	**Additional Rules (Rules 13 to 16)**

Classification of General Medical Devices

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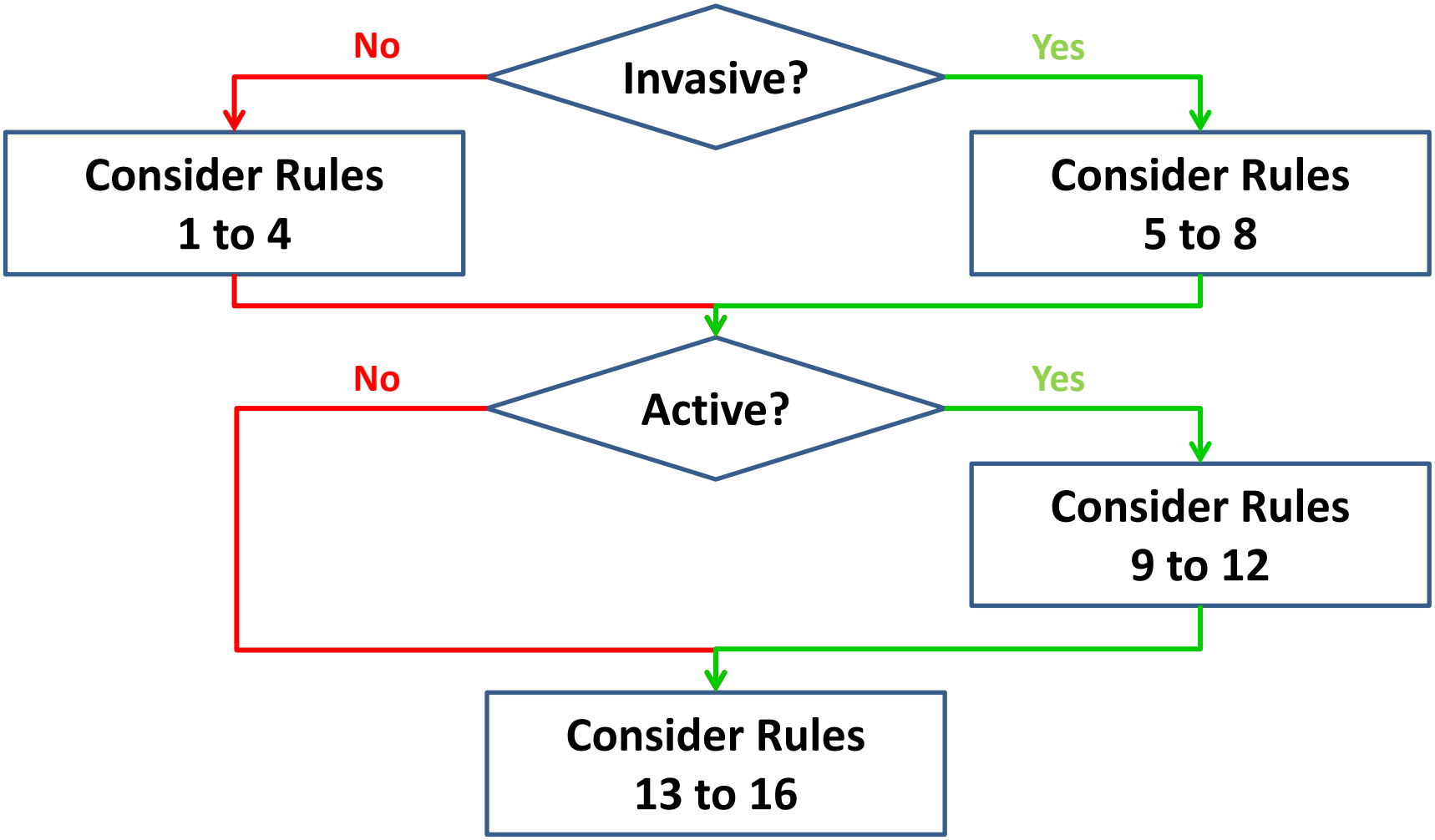

Classification Rules 1 to 4 (Non-invasive Medical Device)

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Device will come into contact with injured skin? — Yes → Rule 1 Applicable

No

Device for channeling or storing blood, body liquids or tissues, liquids or gases for eventual delivery into the body? — Yes → Rule 2 Applicable

No

Device modifies the biological or chemical composition of blood, other body liquids, or other liquids for infusion into the body? — Yes → Rule 3 Applicable

No

Rules 1, 2 and 3 applicable? — No → Rule 4 Applicable

Classification Rules 5 to 8 (Invasive Medical Device)

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Device is invasive with respect to body orifice? — **Yes** → Rule 5 Applicable

No *(i.e. device is surgically invasive)*

Device for transient use? — **Yes** → Rule 6 Applicable

No

Device for short-term use? — **Yes** → Rule 7 Applicable

No *(i.e. device is an implantable device or for long-term use)*

Rule 8 Applicable

Classification Rules 9 to 12 (Active Medical Device)

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Therapeutic device that administers or exchanges energy? — Yes → Rule 9(i) Applicable

No

Device controls/ monitors/directly influences performance of Class III active therapeutic devices? — Yes → Rule 9(ii) Applicable

No

Diagnostic device or emit ionization radiation? — Yes → Rule 10 Applicable

No

Device for administration and/or removal of medicines , body liquids or other substances to or from the body? — Yes → Rule 11 Applicable

No

Rules 9, 10 and 11 applicable? — No → Rule 12 Applicable

Classification Rules 13 to 16 (Additional Rules)

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Device incorporates medicinal products? — Yes → Rule 13 Applicable

No

Devices manufactured from or incorporates non-viable animal or human cell/tissues/derivatives? — Yes → Rule 14 Applicable

No

Device specifically for disinfecting or sterilizing medical devices? — Yes → Rule 15 Applicable

No

Device for contraception or the prevention of the transmission of sexually transmitted diseases? — Yes → Rule 16 Applicable

Classification of General Medical Devices

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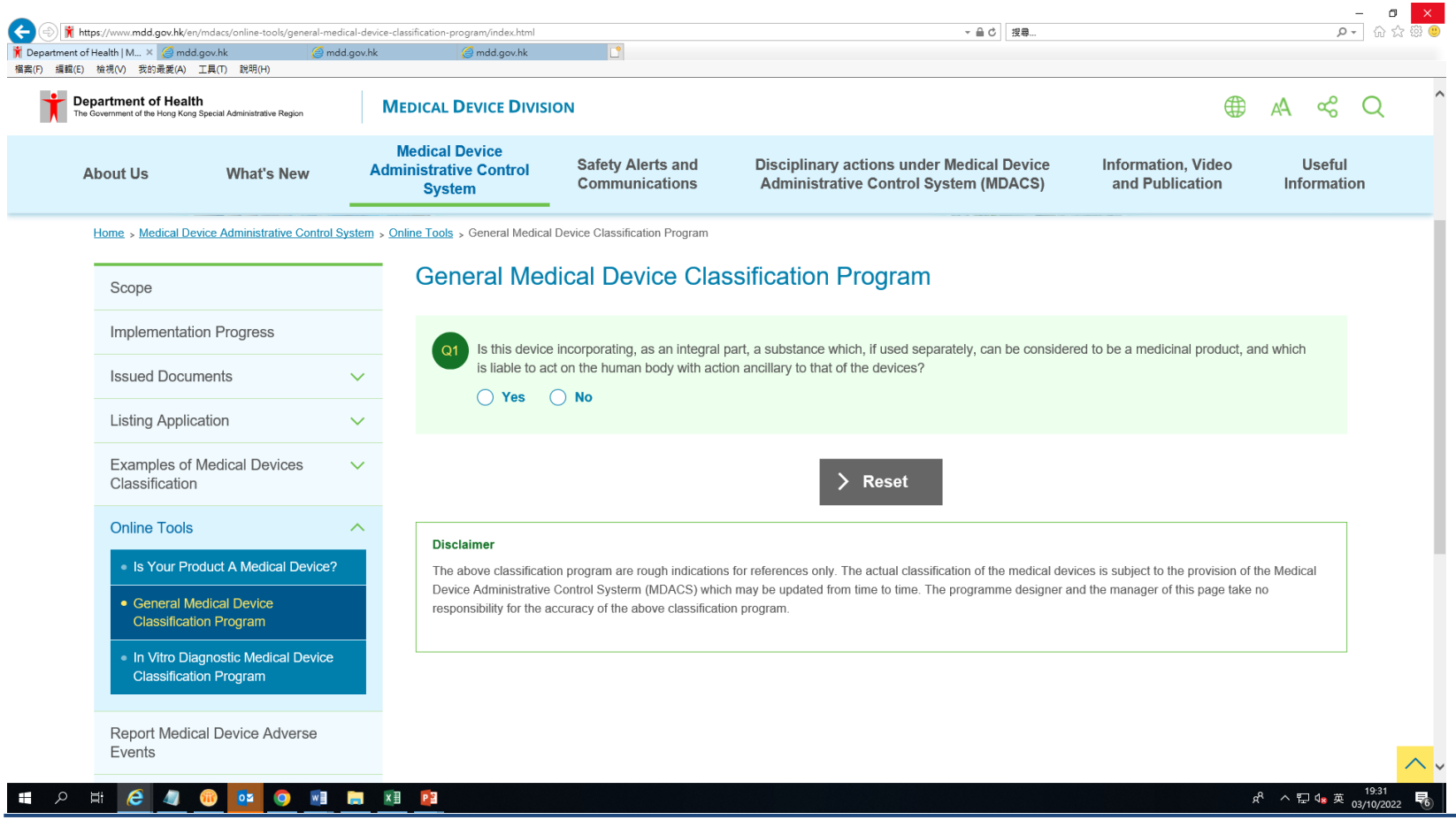
- Online classification program

https://www.mdd.gov.hk/en/mdacs/online-tools/general-medical-device-classification-program/index.html



Classification of General Medical Devices

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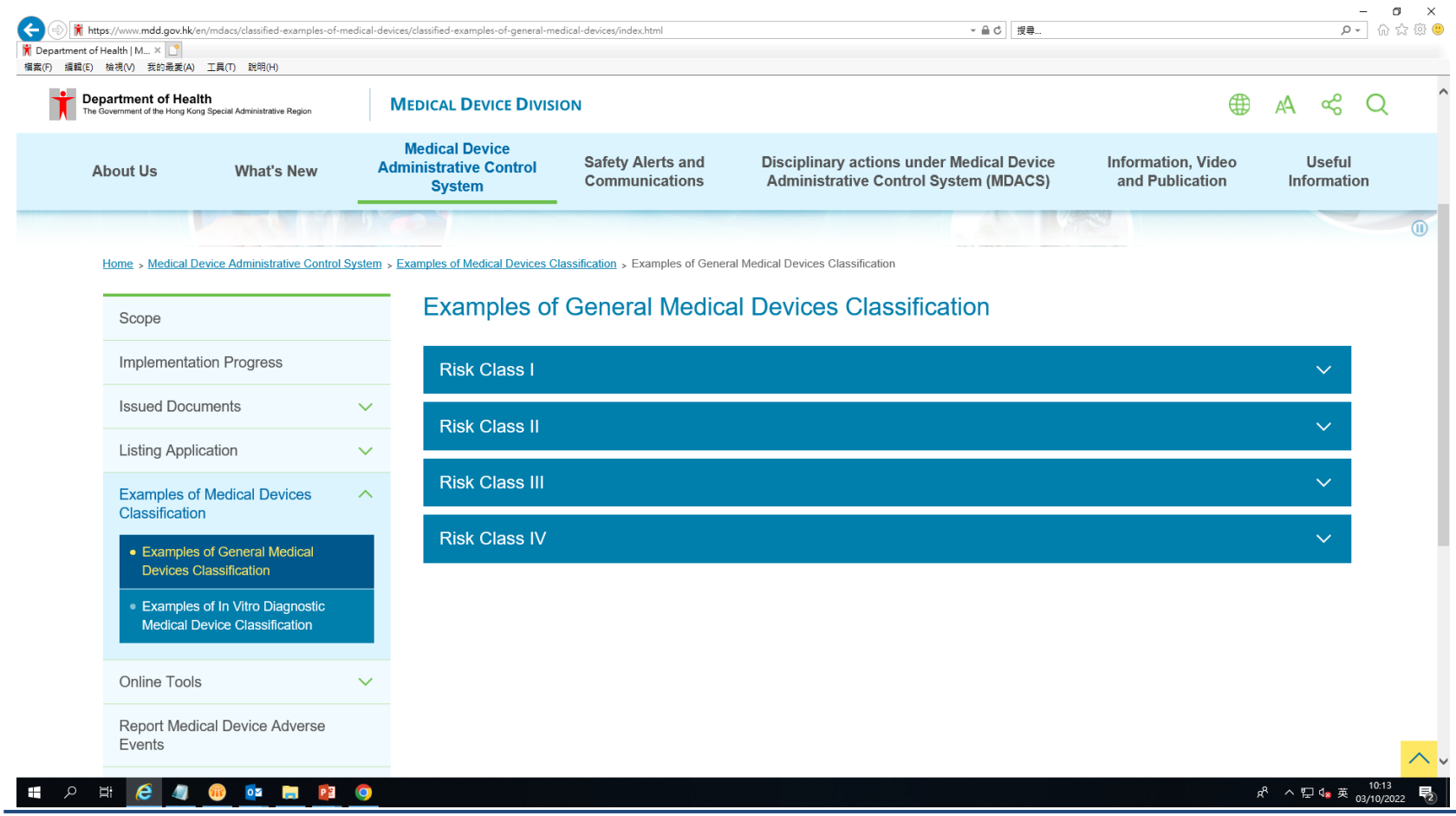
- **Examples of Classified General Medical Devices**

https://www.mdd.gov.hk/en/mdacs/classified-examples-of-medical-devices/classified-examples-of-general-medical-devices/index.html



Listing of IVD Medical Devices

Classification of IVD Medical Devices

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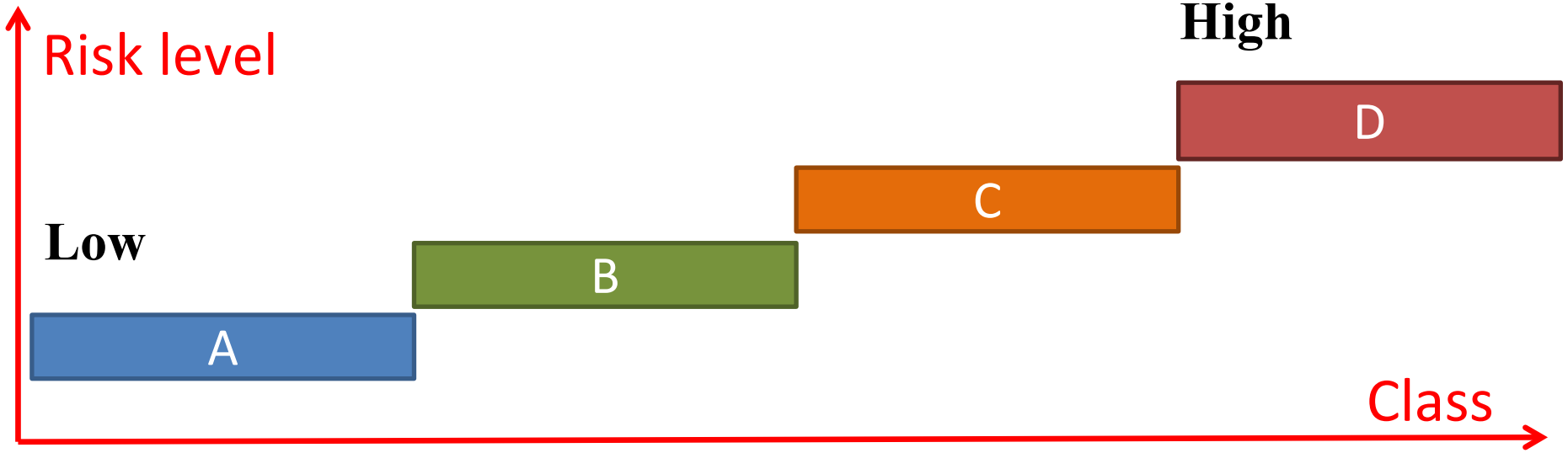
Classification of IVD Medical Device

- 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 or any of their derivatives, in order to assess their suitability for transfusion or transplantation or cell administration, or**
- **To detect the presence of, or exposure to, a transmissible agent that causes a life-threatening, disease with a high or suspected high risk of propagation**
  - ◆Examples: Tests to detect infection by HCV, HIV, HTLV

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Rule 2

- **To be used for blood grouping, or to determine foeto-maternal blood group incompatibility, or tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissues or organs that are intended for transfusion or transplantation or cell administration are Class C (e.g. HLA),**

  except when intended to determine the presence of the antigen or antibody for any of the following markers:
  ABO system [A (ABO1), B (ABO2), AB (ABO3)], **Rhesus System** [RH1 (D), RH2 (C), RH3 (E), RH4 (c), RH5 (e), and weak or partial Rh (D)], **Kell System** [Kel1 (K)], **Kidd System** [JK1 (Jka), JK2 (Jkb)] **and Duffy System** [FY1 (Fya), FY2 (Fyb)], **in which case they are Class D.**

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Rule 3

- **IVDMDs 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.*
  - **in 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)

- **IVDMDs are Class C if they are intended for use:**
  - **in detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or severe disability to the individual, foetus or embryo being tested or to the individual's offspring**
    - Examples: Diagnostic assay for CMV, *Chlamydia pneumoniae*, Methycillin Resistant *Staphylococcus aureus*, Zika

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Rule 3 (continued)

- **IVDMDs are Class C if they are intended for use:**
  - **in determining infective disease status or immune status, and where there is a risk that an erroneous result will lead to a patient management decision resulting in an imminent life-threatening situation or severe disability for the patient or for the patient's offspring**
    - Examples: Enteroviruses, CMV and HSV in transplant patients

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Rule 3 (continued)

- **IVDMDs are Class C if they are intended for use:**
  - **in pre-natal screening of women in order to determine their immune status towards transmissible agents**
    - Examples: Immune status tests for Rubella or Toxoplasmosis
  - **in human genetic testing**
    - Examples: Huntington's Disease, Cystic Fibrosis

Rule 3 (continued)

- **IVDMDs are Class C if they are intended for use:**
  - **in screening for selection of patients for selective therapy and management as companion diagnostics (CDx)**
    - Examples: Devices intended to detect antibodies against a specific medicinal product during the course of treatment, Devices intended for the qualitative detection of ALK protein in FFPE NSCLC tissue, intended as an aid in identifying patients eligible for treatment with crizotinib or ceritinib, and Devices intended to identify defined EGFR mutations in order to administer the tyrosine-kinase inhibitor dacomitinib for the treatment of adult patients with locally advanced or metastatic NSCLC and EGFR-activating mutations

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Rule 3 (continued)

- **IVDMDs are Class C if they are intended for use:**
  - **to be used for disease staging, where there is a risk that an erroneous result would lead to a patient management decision resulting in a life-threatening situation for the patient or for the patient's offspring**
    - Examples: Brain type natriuretic peptide, and Devices intended for staging of ELF for detecting the following markers: hyaluronic acid, procollagen III amino terminal peptide, tissue inhibitor or metalloproteinase

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Rule 3 (continued)

- **IVDMDs are Class C if they are intended for use:**
  - **in screening, diagnosis or staging of cancer**
    - Examples: PSA, CEA, and CA 125
  - **to monitor levels of medicines, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in an immediate life-threatening situation for the patient or for the patient's offspring**
    - Examples: Troponin, Cyclosporin, Prothrombin time testing

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Rule 3 (continued)

- **IVDMDs are Class C if they are intended for use:**
  - **in the management of patients suffering from a life-threatening infectious disease**
    - Examples: HBV monitoring marker, HCV viral load, HIV Viral Load and HIV and HCV geno- and subtyping
  - **in screening for congenital disorders in the foetus or embryo**
    - Examples: Spina Bifida or Down Syndrome, Glucose-6-Phosphate Dehydrogenase Deficiency, and Tay-Sachs Disease

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Rule 3 (continued)

- **IVDMDs are Class C if they are intended for use:**
  - **in screening for congenital disorders in new-born babies where failure to detect and treat such disorders could lead to life-threatening situations or severe disabilities**
    - Examples: Beta-thalassaemia, Biotinidase Deficiency

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Rule 4

- **IVDMDs intended for self-testing or near patient testing are classified as Class C,**

except those devices from which the result is not determining a critical situation, in which case they are classified under Class B by Rule 6, and those devices which are classified under Class D by Rule 1 and/or Rule 2.

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

Rule 4 (continued)

- Example for self-testing Class C: Blood glucose monitoring.
- Example for near patient testing Class C: Blood glucose monitoring.
- Example for self-testing or near patient testing Class D: Rapid test for detection of HIV.
- Example for near patient testing Class D: Pre-transfusion ABO compatibility test card intended to be used at the recipients' bedside as precaution against ABO-incompatible transfusion.
- Examples for self-testing Class B: Pregnancy self-test, Fertility testing, Urine test strips.
- Example for near patient testing Class B: Quantitative test for haemoglobin as an aid in diagnosing iron deficiency.

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Rule 5 => Class A

- **The following IVDMDs are Class A:**
  - **Products for general laboratory use, or accessories which possess no critical characteristics, intended by the manufacturer to make them suitable for in vitro diagnostic procedures related to a specific examination**
    - Examples: Buffer solutions, Washing solutions, Histological stains
  - **Instruments intended by the manufacturer specifically to be used for in vitro diagnostic procedures**
    - Examples: Clinical chemistry analyser, Enzyme immunoassay analyser
  - **Specimen receptacles**
    - Examples: Plain urine cup, Microbiological specimen collection devices

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Rule 6 => Class B

- **IVDMDs not covered in Rules 1 through 5 are Class B**
  - Examples: Blood gases, Helicobacter pylori test, Physiological markers such as hormones, vitamins, enzymes, metabolic markers, Specific IgE assays, Coeliac disease markers, and Tests for Anti-Nuclear Antibody, SHBG, BUN, AST, ALP, Creatinine and HbA1c

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Rule 7 => Class B

- **IVDMDs that are controls without a quantitative or qualitative assigned value are Class B**
  - Examples: Urinalysis controls and Chemistry controls

Classification of IVD Medical Devices

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Recommendations (TR-006, sec. 5)

- 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

- Online classification program for IVD medical devices

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

Classification of IVD Medical Devices

- 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 Medical Devices

Preparation of Application Documents

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Preparation of Application Documents

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- **Requirements, application procedures, guidance** for completing the application form and information required for application for listing of MDs, you may refer to:
  - the Guidance Notes for Listing Class II/III/IV Medical Devices (GN-02)
  - the Guidance Notes for Listing Class B/C/D In Vitro Diagnostic Medical Device (GN-06)

- Application Forms:
  - MD101 (GMD) / MD102 (IVDMD)

    - 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				

* Manufacturer's name and address should be align with the information on ISO 13485 and marketing approval (s) (e.g. EC certificate).

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:	E-mail:	
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: ☒ ISO13485:2003 or later edition (ISO13485: _____) ☒ 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 natural or 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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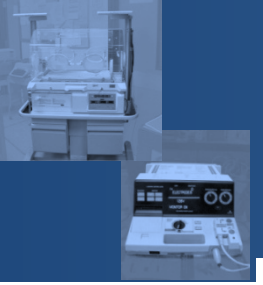
Note	Part B: Particulars of Local Responsible Person (LRP)			Encl.
B001	LRP's name*	*in English*	*CARDIO SUPPLIES LTD.*	(B1) ☒
		in Chinese	*心臟儀器供應有限公司*	
	Address in Hong Kong *(Please give the registered place of business, if any)**	*in English*	*32/F., METROPOLITAN CENTRE, 123 MERRY STREET, CAUSEWAY BAY, HONG KONG*	
		in Chinese	*香港銅鑼灣喜樂街123號都市中心32樓*	
	Contact person: *CHAN TAI-MAN*		Telephone: *2800 0000*	
	Position: *General Manager*		Email: *tchan@cardio.com.hk*	
	Contact telephone for public enquiries * : *2000 0000*		Fax : *2900 0000*	
	Mobile telephone for urgent use (24 hours) : *9000 0000*			
	Business Registration ☒ Copy of business registration certificate (with business registration number: *BR123467*) is enclosed ☐ Not applicable			
B002	Date designated as LRP by the manufacturer: *30 June 2010* ☒ Manufacturer's designation letter is enclosed			(B2) ☒
B003	Established Quality Management System ☒ ISO9001 ☐ ISO13485 ☐ None ☒ System certified by *ABC Agency* (certification body), and a copy of the certificate is enclosed			(B3) ☒

Part B: Particulars of Local Responsible Person



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B004	Documented Procedures Established and Maintained ☒ The applicant does not 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) Tracking of specific medical devices (if applicable) (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) ☒
B005	☒ The LRP is also an importer and/or distributor of the device named in Part C Listing No. of Importer (if applicable): IMP0123456 Listing No. of Distributor (if applicable): DIS0345678	
B006	☐ The device named in Part C is currently a listed device (under another LRP), with Listing No. _____.	

Part B: Particulars of Local Responsible Person

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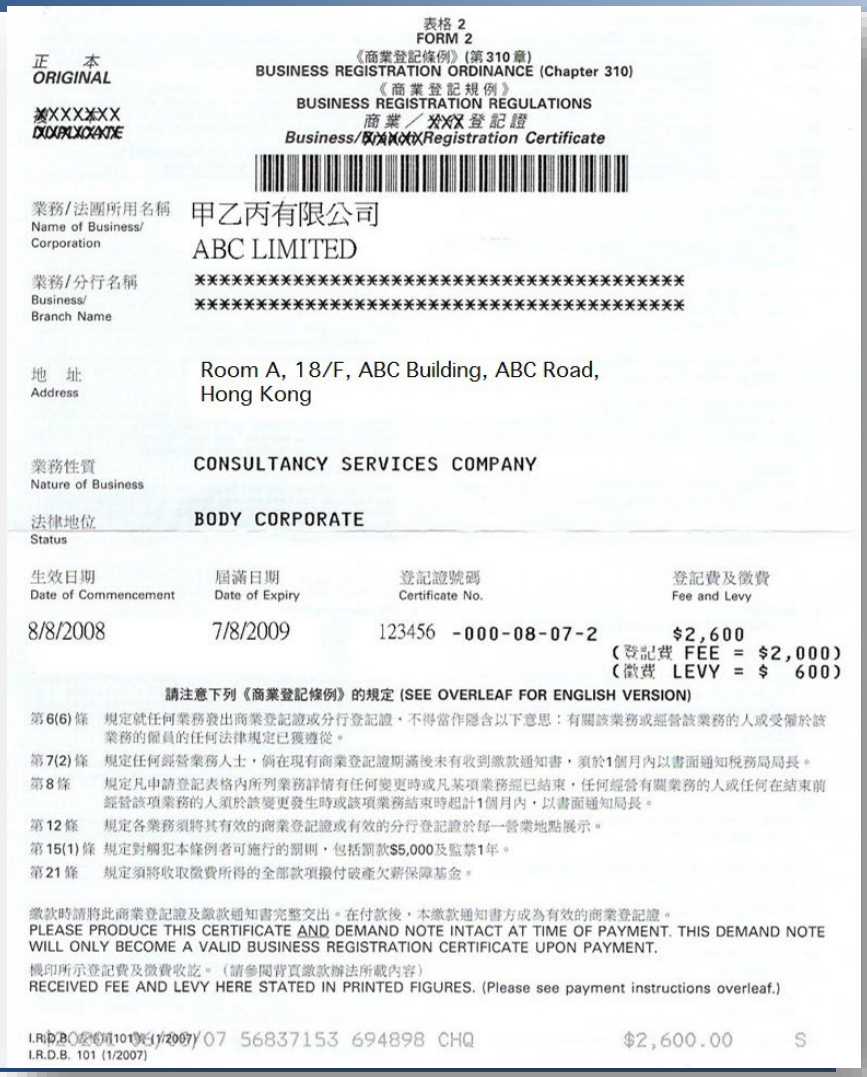
- Valid Business Registration Certificate of LRP

  (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／XXX登記證
Business/XXX 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
I.R.D.B. 101 (1/2007)

Part B: Particulars of Local Responsible Person

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Designation Letter

(Enclosure B2)

(GN-01 Appendix 5)

- ✓ Manufacturer's name and address
- ✓ LRP's name an 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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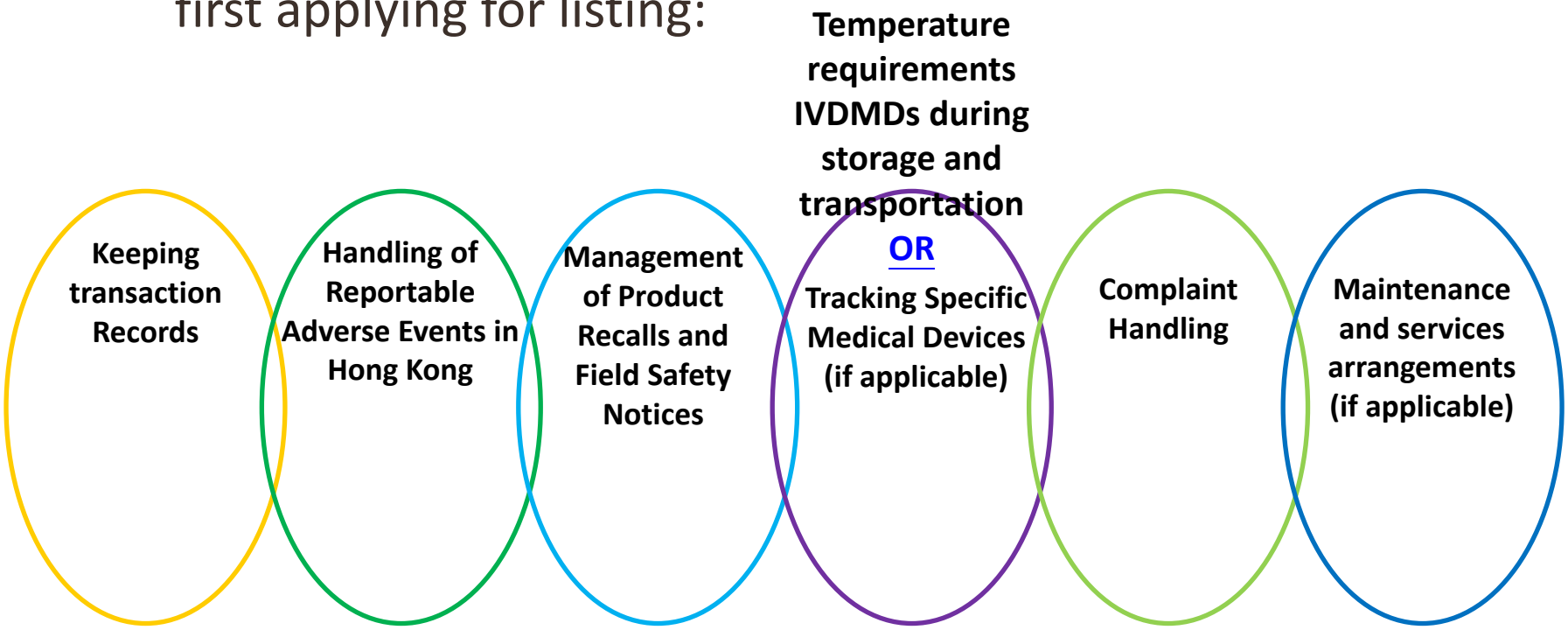
- Documented Procedure of LRP (Enclosure B4)
  - The documented procedures of LRP below [B004 items (i) to (vi)] must be submitted with the application form when first applying for listing:



Part C: Particulars of the Device

Note	Part C: Particulars of the Device			Encl.
C001	Make*	*in English*	ABC Medical	
		in Chinese	N/A	
	Brand Name*	*in English*	VGOOD	
		in Chinese	N/A	
	Model*	*in English*	PMS	
		in Chinese	N/A	
C002	☐ A single medical device ☐ A medical device family ☐ A medical device series ☒ A medical device system For a medical device family, medical device series or a medical device system, please provide the additional information required in a format similar to MDS-01. ☐ Additional information similar to MDS-01 attached			(C1) ☐
C003	Description of the device: *(Please enter the appropriate AMDNS term. If none of the terms in AMDNS appear appropriate, enter a short description of the device.)* MONITORING SYSTEMS, PHYSIOLOGIC			
	AMDNS Code: 12636			
	Other Codes *(Please enter if known):*			
C004	Other common descriptions of the device: PATIENT MONITORING SYSTEM			

See GN-02, Section 9

Please provide this information as far as possible

IVDMD (Form: MD102)

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. _____

Part C: Particulars of the Device

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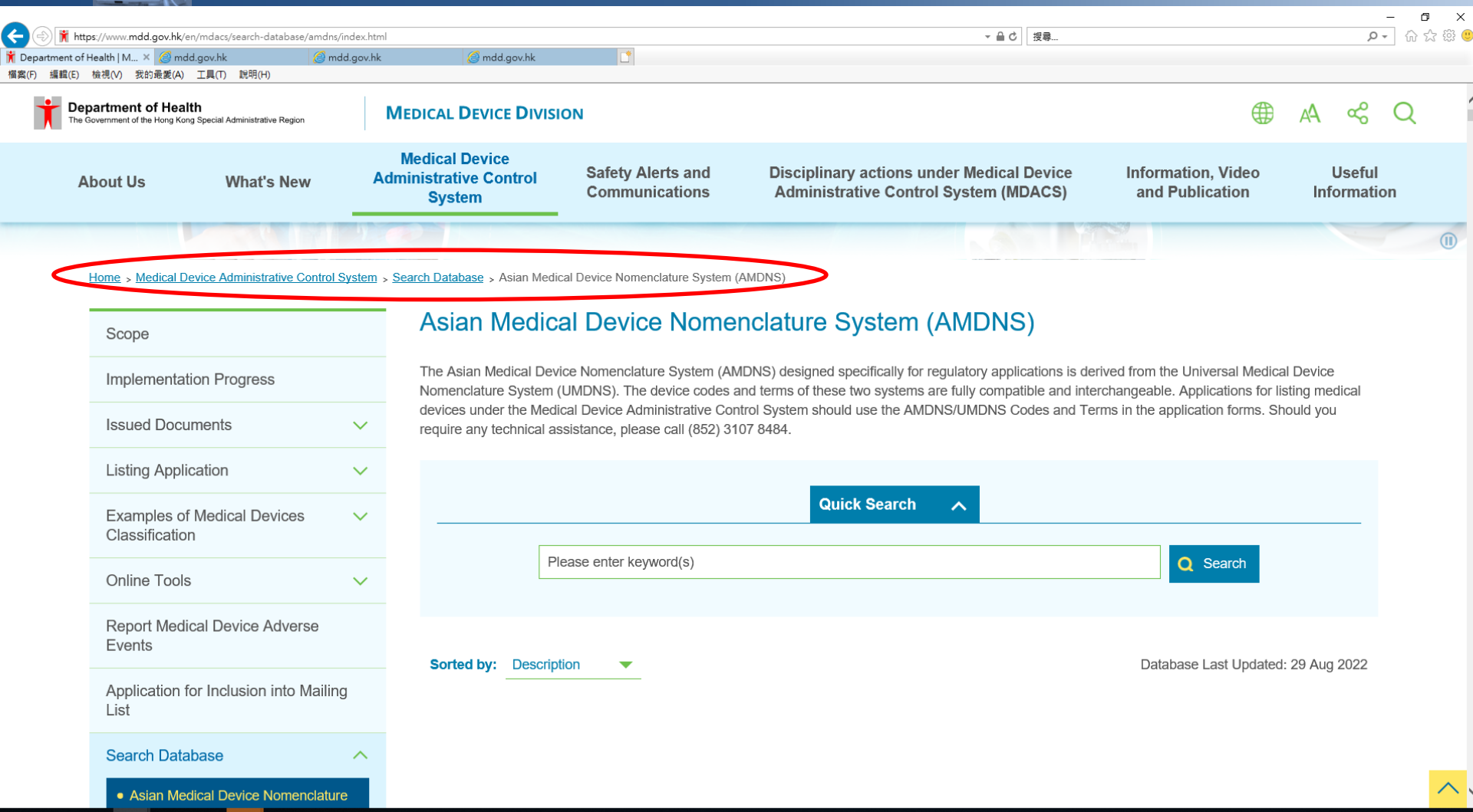

Part C: Particulars of the Device

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

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

- Online Tools
- Report Medical Device Adverse Events
- Application for Inclusion into Mailing List
- Search Database
  - Asian Medical Device Nomenclature System (AMDNS)
  - The List of Medical Devices
  - The List of Local Responsible Person (LRP)
  - The List of Importers
  - 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

Back

19:39
03/10/2022

Part C: Particulars of the Device

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C005	Intended use of the device*	*in English*	A physiologic monitoring system intended for monioring, recording and alarming of multiple physiological parameters depending on which modules are equipped. It is indicated for use in acute care settings in health care facilities by health care professionals whenever there is a need for monitoring physiological parameters of adult, paediatric or neonatal patients.	
		in Chinese	病人監護儀用以監察及記錄病人的多項生理參數（視乎裝設哪些元件而定），並在適當時發出警報。醫護人員在醫護設施的急症護理環境中，如需監護病患成年人, 兒童或初生嬰兒的生理參數，版刻使用該監護儀	

Part C: Particulars of the Device

C006	Accessories and parts covered by the Marketing Approvals and Essential Principles Conformity Checklist under Note D001 of Part D. *Please provide its identifier(s) (e.g. part number) and description using a format similar to MDS-02.* ☒ Additional information similar to MDS-02 attached	(C1) ☒
C007	1. The device Yes No ☐ ☒ incorporates, as an integral part, a medicinal product which could act on the human body with action ancillary to that of the device ☐ ☒ is manufactured from or incorporating human cells/tissues/derivatives ☐ ☒ is manufactured from or incorporating animal cells/tissues/derivatives	
	2. The device ☐ is a **non-active device** *(please go to section 3)* ☒ is an **active device** ☐ intended to control or monitor the performance of devices in Class III, or intended directly to influen of such devices ☒ intended for monitoring of vital physiological par nature of variations is such that it could result in in the patient ☒ intended for diagnosing in clinical situations whe immediate danger ☐ intended to administer or exchange energy to or fro potentially hazardous way including ionizing radiat ☐ none of the above	

IVDMD (Form: MD102)

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)*:
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.

Part C: Particulars of the Device

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C007	3. The device ☒ is a **non-invasive device** ☐ comes into contact with injured skin (e.g. wound dressings) *(please complete section 4)* ☒ connected to an active medical device in Class II or a higher class ☐ intended for channelling blood, or storing or channelling other body liquids, or for storing organs, parts of organs or body tissues ☐ intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body ☐ none of the above ☐ is an **invasive device** ☐ invasive with respect to body orifices (other than those surgically invasive) ☐ intended to be connected to an active medical device in Class II or a higher class ☐ intended for use in oral cavity, ear canal or nasal cavity ☐ intended to supply energy in the form of ionizing radiation ☐ intended to have biological effect or be wholly or mainly absorbed ☐ intended to administer medicinal products by means of a delivery system and is potentially hazardous ☐ intended for use in direct contact with the central nervous system or to diagnose, monitor or correct a defect of the heart of central circulatory system through direct contact ☐ intended to undergo chemical change in the body ☐ none of the above and is intended for *(please check the applicable item only)* ☐ transient use (< 60 mins) ☐ short-term use (between 60 mins and 30 days) ☐ long-term use (> 30 days)

Part C: Particulars of the Device

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	4. The device is a wound dressing ☐ intended to be used as a mechanical barrier, for compression of wounds or for absorption of exudates (e.g. simple wound dressing; cotton wool) ☐ intended to manage the microenvironment of wounds (e.g. non-medicated impregnated gauze dressings) ☐ intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent (e.g. dressings for chronic ulcerated wounds). ☐ impregnated with medicinal products (e.g. medicated gauze dressings)	
C008	Class of the medical device: ☐ Class II ☒ Class III ☐ Class IV	
	Reasons for classifying the device as Class II/III/IV device: *It is an active device intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient (Rule 10(i))*	
C009	Manufacturing Site(s) *(Use separate sheet if required)*: *(1) 1324N, Derby Road, Arlington, VA 12345-6789, USA* *(2) 1000 Butler Road, Plymouth Place, PA 12486-1248, USA*	(C1) ☒

IVDMD (Form: MD102)

C008	Class of the IVDMD: ☐ Class B ☐ Class C ☐ Class D
	Reasons for the classification:
C009	Manufacturing site(s) *(Use separate sheet if required)*:

Part C: Particulars of the Device

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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 device is for single use ☐ The device 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 and Servicing ☒ The device 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	

IVDMD (Form: MD102)

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

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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: *https://www.abcmedical.com/vgood* ☒ Sample of Special Listing Information is enclosed Please indicate where in the labelling the following information is given: (1) Indications for use of the device: *Pages 4 – 8 of the operator's manual* (2) Contraindications against use of the device: *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) ☒
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) ☐

Part C: Particulars of the Device

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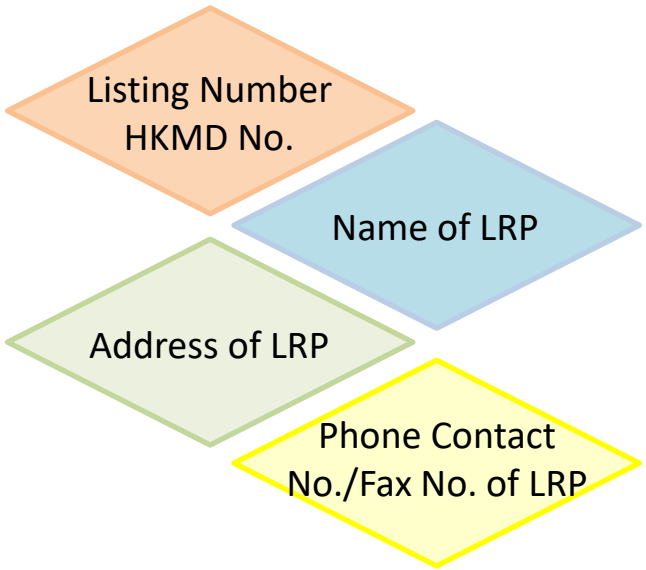
- C013: Special Listing Information **(See GN-01, sec. 4.4.13)**

- Special Listing Information Includes:



The Special Listing Information shall be provided on:

(1) the outer packaging of the medical device, and/or

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

Part C: Particulars of the Device

C015	Conformity Assessment ☐ MDACS Conformity Assessment Certificate issued by one of the Conformity Assessment Bodies recognized by MDD MDACS Conformity Assessment Body number: _____	(C5) ☐
C016	Safety and Risk Analysis International or national safety standards with which the device complies: *(1) IEC 60601-1:2005; (2) IEC 60601-1-2:2014; (3) IEC60601-1-8:2006; (4) IEC 60601-2-49:2011* ☒ Risk analysis conducted: report or summary is enclosed ☒ Type test performed: report or test certificate is enclosed	(C6) ☒
C017	Clinical Evaluation ☒ Clinical investigation report of the device is enclosed ☐ Demonstration of equivalence to another device (equivalent device) where safety and efficacy of which are well established: ☐ Clinical investigation report of the equivalent device and a report of demonstration of equivalence are enclosed ☐ Report demonstrating full equivalence to a well established product is enclosed	

IVDMD (Form: MD102)

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) ☐

Part C: Particulars of the Device

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- C015: Conformity Assessment Certificate (Appendix C5)
  - **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 CABs:
    - ✓ BSI Assurance UK Limited (c/o BSI Pacific Limited)
    - ✓ SGS United Kingdom Limited (c/o SGS Hong Kong Limited)
    - ✓ TÜV SÜD Product Service GmbH (c/o TÜV SÜD Hong Kong)

Part C: Particulars of the Device

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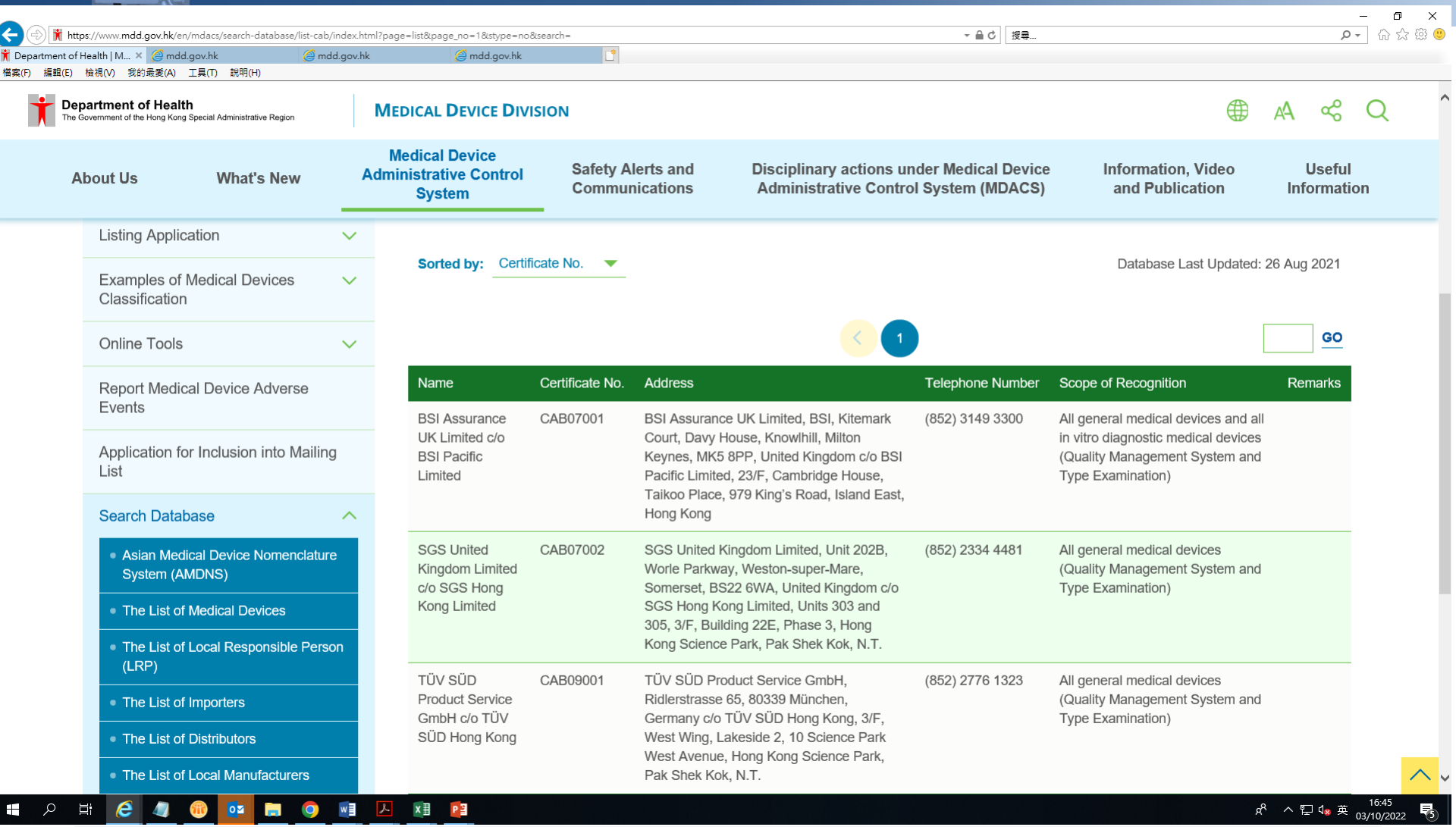

Name	Certificate No.	Address	Telephone Number	Scope of Recognition	Remarks
BSI Assurance UK Limited c/o BSI Pacific Limited	CAB07001	BSI Assurance UK Limited, BSI, Kitemark Court, Davy House, Knowlhill, Milton Keynes, MK5 8PP, United Kingdom c/o BSI Pacific Limited, 23/F, Cambridge House, Taikoo Place, 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)	

Part C: Particulars of the Device

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Conformity Assessment Routes

C015:
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 Medical Device** through **valid marketing approvals of the medical device obtained in specified countries/region***

*China, Australia, Canada, European Union, Japan, United States of America and/or Korea (trial scheme)

Part D: Marketing Approvals & Essential Principles

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Note	Part D: Marketing Approvals and Essential Principles	Encl.
D001	Marketing Approvals in Mainland China and/or Foreign Countries ☑ Approval(s) obtained for the medical device (with same make and model) to be placed on the market of the following countries: ☑ Mainland China (National Medical Products Administration) ☐ 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) ☐ Korea (Ministry of Food and Drug Safety) ☐ 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 MD-CCL is enclosed; OR ☐ Essential Requirements Checklist / General Safety and Performance Requirements Checklist in accordance with relevant EU directives or regulations and Essential Principles Declaration of Conformity are enclosed	(D1) ☑

Part D: Marketing Approvals

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Marketing approvals (GMDs and IVDMDs)

Starting from 1st January 2024,

✓ MDD accepts marketing approvals in Mainland China, South Korea and/or other five Global Harmonization Task Force (GHTF) founding member's countries, including Australia, Canada, member countries of European Union, Japan and United States of America.

Starting from 2nd April 2024:

✓ MDD accepts the marketing approval in Singapore.

Marketing Approvals

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Countries	Marketing Approvals
China	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 93/42/EEC (MDD) • Directive 90/385/EEC (AIMD) • Regulation (EU) 2017/745 (MDR)
Korea	•Medical Equipment Import Permit or Certificate of Free Sales
Singapore	•Health Sciences Authority (HSA) (SINGAPORE MEDICAL DEVICE REGISTER (SMDR))

Part D: Marketing Approvals & Essential Principles

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- **GMD:**
  - Marketing Approvals (Appendix D1)- Conformity to the Essential Principles
    - If recognized marketing approvals were obtained on or after 1st January, 2005, then the applicant has to provide:
      - Essential Principles Conformity Checklist (MD-CCL); or
      - (i) Essential Requirements Checklist prepared according to the European Medical Device Directives or General Safety and Performance Requirements (GSPR) Checklist prepared according to the European Medical Device Regulation and
      - (ii) the Hong Kong Essential Principles Declaration of Conformity (GN-02, Appendix I)

IVDMD:

- 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 I)

Essential Principles Conformity Checklist (MD-CCL)

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Appendix 2

Medical Device Control Office
Department of Health

Medical Device Administrative Control System
Essential Principles Conformity Checklist

Make: *ABC Medical*
Brand Name and Model: *VGOOD PMS-123*

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 of intended users, they will 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 ISO 13485 and presently certified* 2. *The patient monitor is tested to comply with IEC 60601-1, IEC 60601-1-2, IEC 60601-1-8 and IEC 60601-2-49 standards.* 3. *Risk analysis has been performed in accordance with ISO 14971. 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. *ISO 13485 Certificate No. 012345* 2. *Type Test Certificate No. 123456 to show compliance with ISO IEC 60601-1 standard* 3. *Type Test Certificate No. 23456 to show compliance with IEC 60601-1-2 standard* 4. *Type Test Certificate No. 34567 to show compliance with IEC 60601-1-8 standard* 5. *Type Test Certificate No. 45678 to show compliance with IEC 60601-2-49 standard* 6. *Risk Analysis Report RAR-001*

Essential Principles Conformity Checklist (MD-CCL)

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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): CARDIO SUPPLIES LTD
Date: 31 Jul 2011

Essential Principles Declaration of Conformity (GN-02 / GN-06, Appendix I)

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GMD:

GN-02:2024(E)

11. Appendix I

<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 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>

IVDMD:

GN-06:2024(E)

9. Appendix I

<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>

Supplementary Information Sheet for Medical Devices Procured by the Hospital Authority (MD111)

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- ✓ Applicable to listing application containing medical device(s) procured by the Hospital Authority in the past twelve months
- ✓ The applicant should include the duly completed Supplementary Information Sheet along with the relevant listing application forms and required documents
- ✓ **Not applicable** to change application and renewal application
- ✓ The Supplementary Information Sheet need not be submitted if there is no relevant information on medical device(s) being procured by the Hospital Authority

Supplementary Information Sheet for Medical Devices Procured by the Hospital Authority (MD111)

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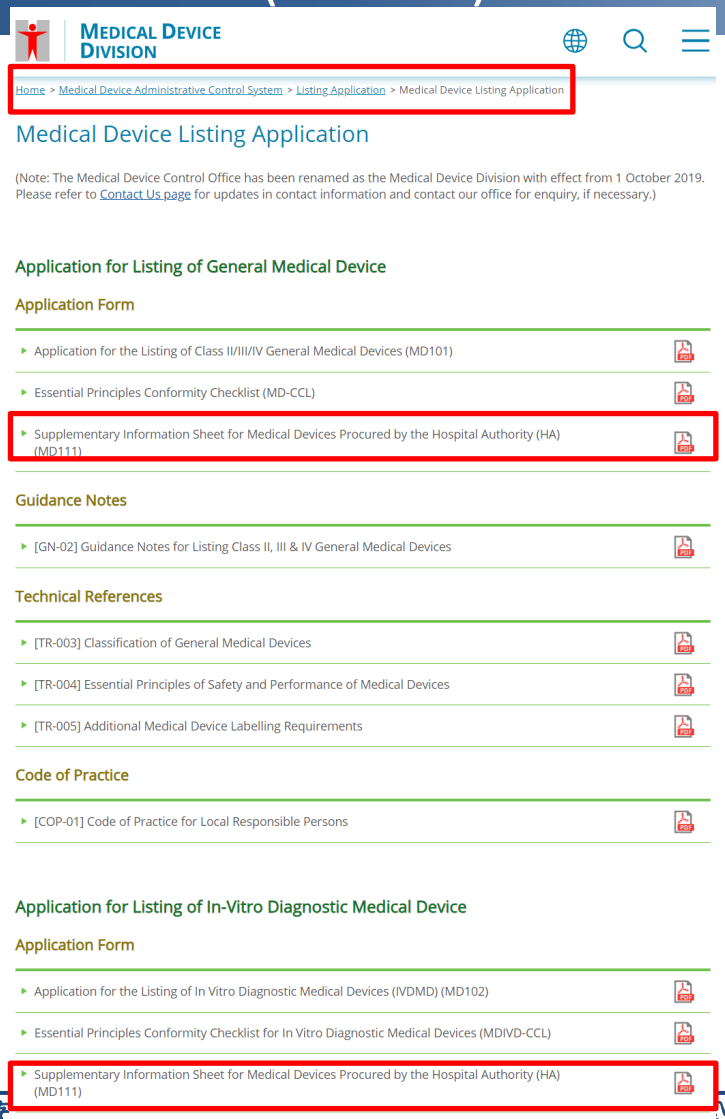

MEDICAL DEVICE DIVISION

Home > Medical Device Administrative Control System > Listing Application > Medical Device Listing Application

Medical Device Listing Application

(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.)

Application for Listing of General Medical Device

Application Form

- Application for the Listing of Class II/III/IV General Medical Devices (MD101)
- Essential Principles Conformity Checklist (MD-CCL)
- Supplementary Information Sheet for Medical Devices Procured by the Hospital Authority (HA) (MD111)

Guidance Notes

- [GN-02] Guidance Notes for Listing Class II, III & IV General Medical Devices

Technical References

- [TR-003] Classification of General Medical Devices
- [TR-004] Essential Principles of Safety and Performance of Medical Devices
- [TR-005] Additional Medical Device Labelling Requirements

Code of Practice

- [COP-01] Code of Practice for Local Responsible Persons

Application for Listing of In-Vitro Diagnostic Medical Device

Application Form

- Application for the Listing of In Vitro Diagnostic Medical Devices (IVDMD) (MD102)
- Essential Principles Conformity Checklist for In Vitro Diagnostic Medical Devices (MDIVD-CCL)
- Supplementary Information Sheet for Medical Devices Procured by the Hospital Authority (HA) (MD111)

Supplementary Information Sheet for Medical Devices Procured by the Hospital Authority (MD111)

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Home > Useful Information > Forms

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

Forms

(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.)

Forms are available in pdf and/or Word formats:

- Application for Inclusion on the List of Importers/ Distributors (MD-IP+D)
- Application for Recognition (or Change of Scope of Recognition) Under the Conformity Assessment Body Recognition Scheme of the MDACS (CAB-AA)
- Application for the Listing of In Vitro Diagnostic Medical Devices (IVDMD) (MD102)
- Application for the Listing of Local Manufacturers (LM)
- Application for the Listing of Class II/III/IV General Medical Devices (MD101)
- Application Form for Certificate to National Medical Products Administration
- Change Application Form for Listed Medical Devices (MD105)
- Essential Principles Conformity Checklist (MD-CCL)
- 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 (MD108)
- Renewal and Change Application Form for Listed Importers/Distributors (MD203)
- Renewal / Change Form for Listed Local Manufacturers
- Renewal Form for Listed Medical Devices
- Supplementary Information Sheet for Medical Devices Procured by the Hospital Authority (HA)(MD111)

Frequently asked questions

1) What is the existing legislative control of MDs?

- Currently, there is no specific legislation that regulates the *manufacture, import, export and sale* of MDs in Hong Kong. However, depending on the nature and characteristics of the products concerned, some products may be regulated by existing pieces of legislation

2) How to distinguish or classify MDs?

- Depend on the claims made by the manufacturer, generally its intended use and the principle of design, which usually could be observed from technical documents or labelling of the product
- Definition of MD under MDACS (GN-00) ; Classification of GMDs (TR-003) ; Classification of IVDMDs (TR-006)
- Online Tools (https://www.mdd.gov.hk/en/mdacs/online-tools/index.html)
- Examples of MDs Classification (https://www.mdd.gov.hk/en/mdacs/classified-examples-of-medical-devices/index.html)

3) Does MDD issues Free Sale Certificate?

- At present, Free Sale Certificate / letter to foreign government is not available under the Medical Device Administrative Control System

4) What kind of changes of listed MDs do LRPs need to be submit/notify MDD?

- The LRP has the responsibility to timely inform MDD of any change to the listed MD (including major and minor change)

5) How to distinguish major and minor changes?

- Refer Section 2 of GN-10 to know the definition of major an minor changes
- Refer to the Flowchart in Guidance Notes: GN-10 for reference to distinguish major change and minor change of MDs

Preparation of Application Documents

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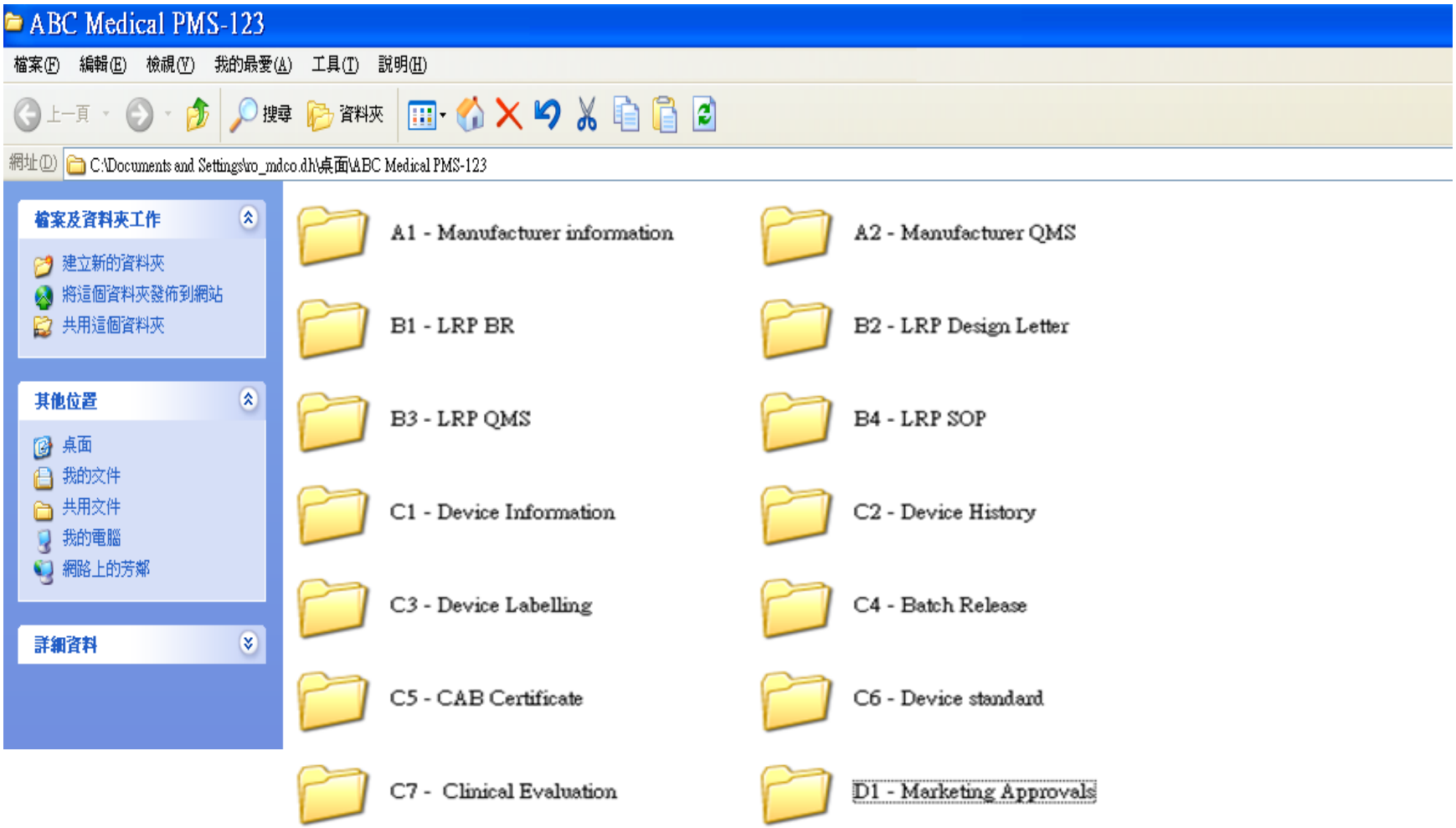

Further Information

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- Online Resources(www.mdd.gov.hk)
  - Related Guidance notes, Technical References and Codes of Practice https://www.mdd.gov.hk/en/useful-information/issued-documents-under-mdacs/index.html
  - List of Medical Device https://www.mdd.gov.hk/en/mdacs/search-database/list-md/index.html

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
Guidance Notes for Changes of Listed Medical Devices	GN-10

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
Software Medical Devices and Cybersecurity	TR-007
Artificial Intelligence Medical Devices (AI-MD)	TR-008

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
Code of Practice for Listed Distributors of Medical Devices	COP-05

Contact Us

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Department of Health

Department of Health
Medical Device Division (MDD)

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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