

Briefing Seminar on Application for Listing Class II/III/IV General Medical Devices



Medical Device Division
Department of Health

Rev. 2023-11-30

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 - Classification
 - Classification exercise and break
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 - ◆ Listing of General Medical Devices (continued)
 - Preparation of Application Documents

Brief Introduction to Medical Device Administrative Control System (MDACS)



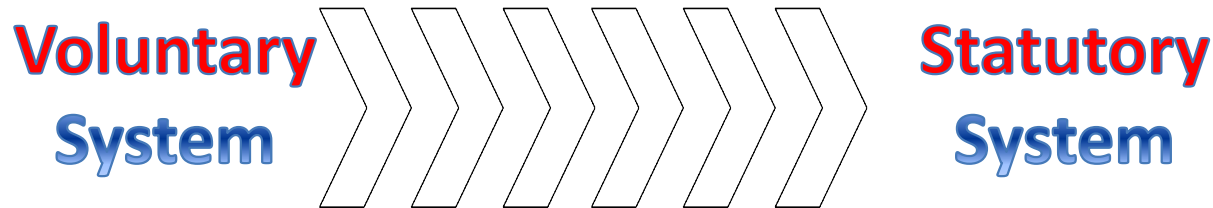
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MDACS



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■ 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)

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

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)



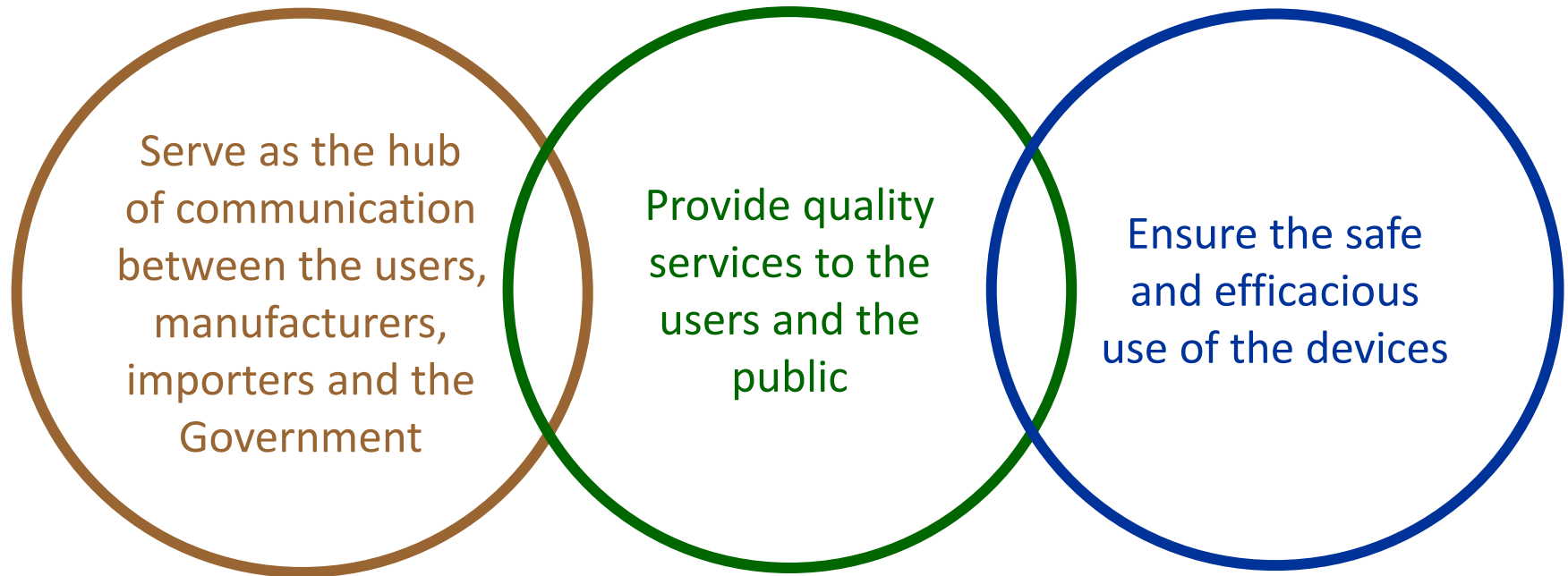
LRP



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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

■ The need for LRP



■ Requirements of LRP

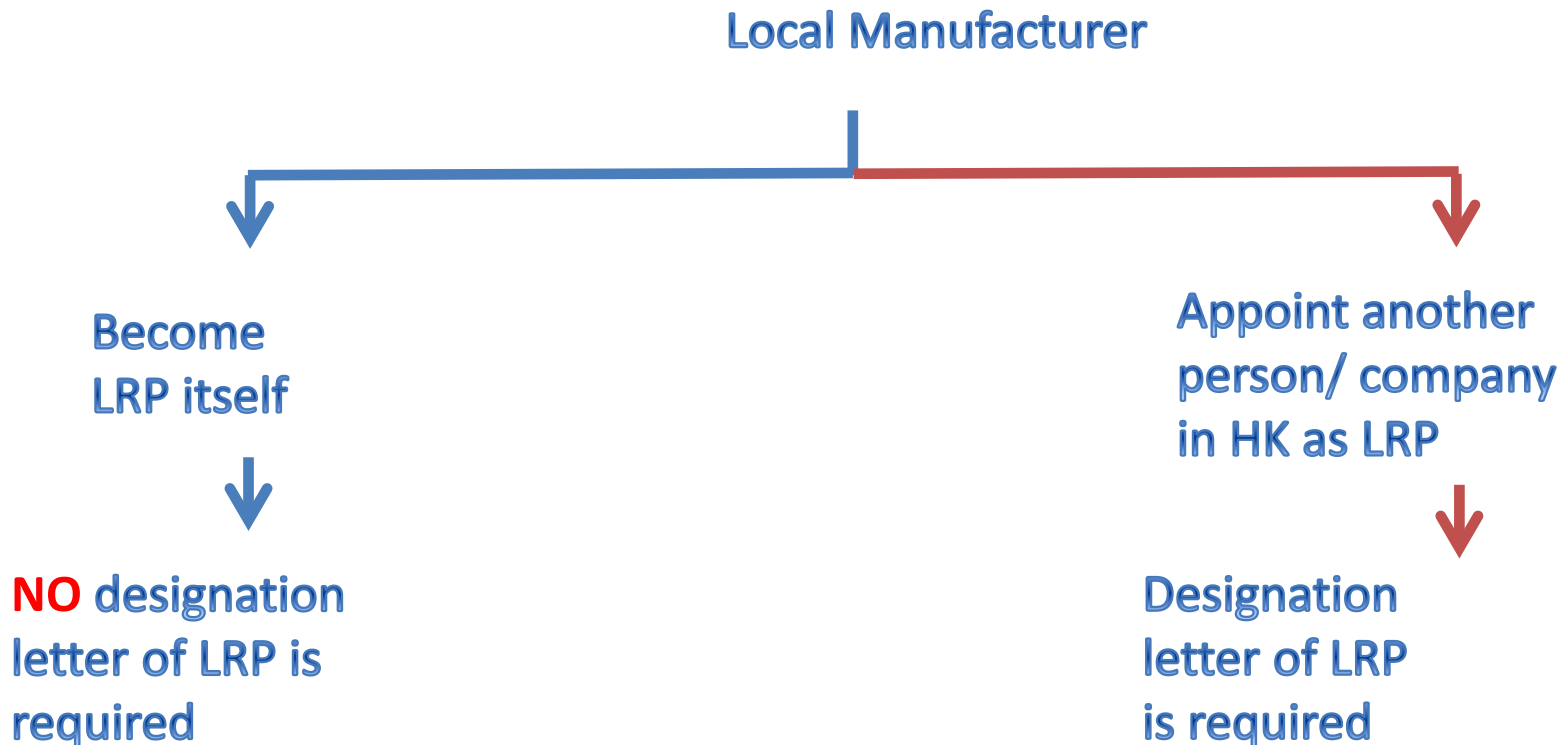
Either a legal person incorporated in Hong Kong,
Or
A natural or legal person with business registration in Hong Kong

Either the manufacturer of the device
or
supported by the manufacturer of the device to perform the obligations of an LRP for the device

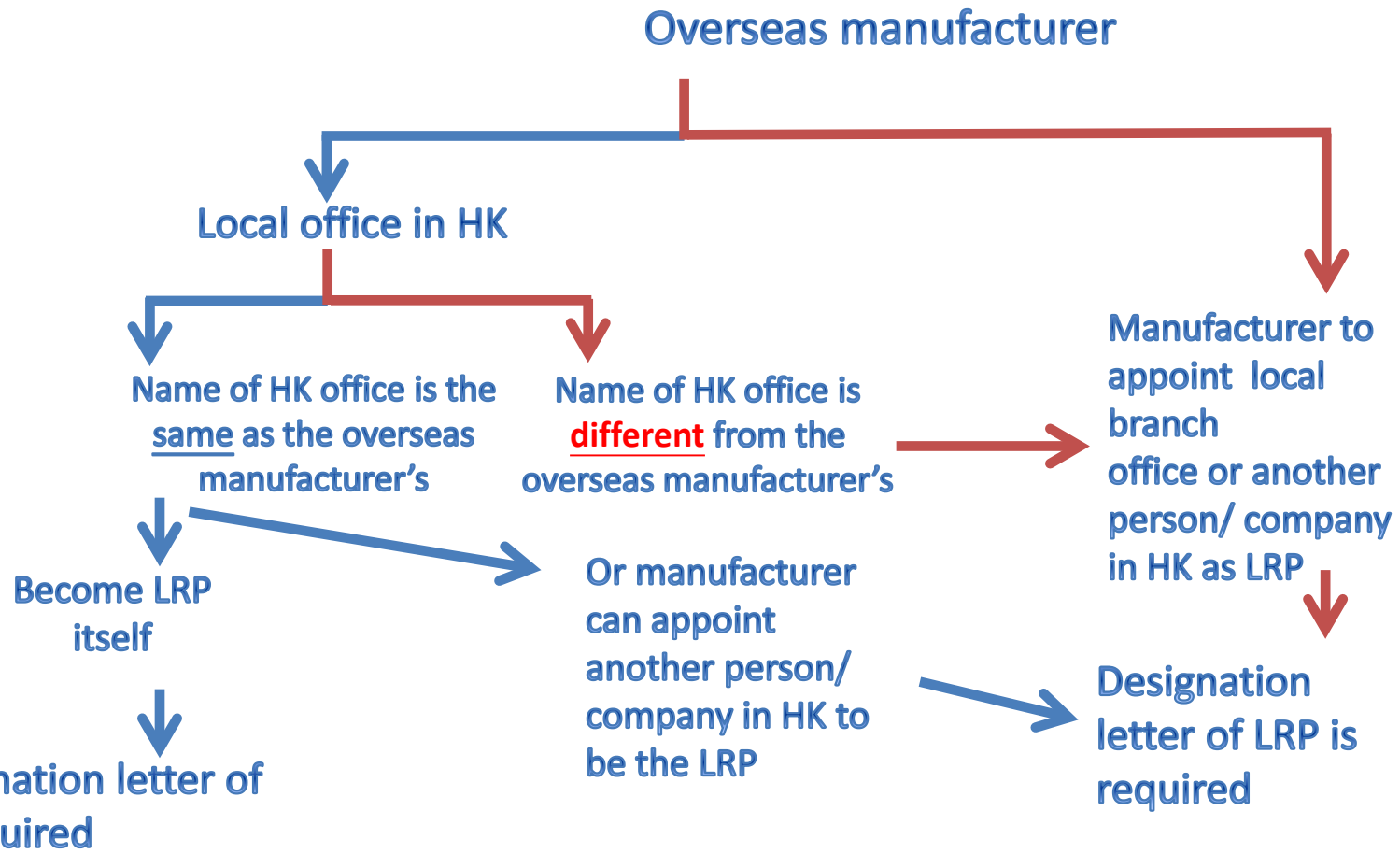
Submit the listing application to the Medical Device Division
(The application for listing of LRP is integrated with the application for listing of Medical Devices using the same application form)

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

■ Relationship between LRP and Local Manufacturer



■ Relationship between LRP and overseas manufacturer



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)

■ 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 **3 months** **(but no more than 1 year)** before the expiry of Listing **(5 years)**

■ 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 related to the business of the LRP or the listed medical devices as soon as possible and in no case later than 10 calendar days.



- **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	<u>Need</u> approval before implementation. Application for changes is required to get the approval from MDD.	<u>No need</u> 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 <u>before</u> 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	<ol style="list-style-type: none"> 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 <u>24 weeks</u> , 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

*We Build A Healthy Hong Kong And Aspire
To Be An Internationally Renowned Public
Health Authority*

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Original Change Application Form

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 <i>(Please provide a copy of valid Business Registration Certificate of LRP.)</i>	<input type="checkbox"/>	
	(b) LRP's name (in English / Chinese*)	<input type="checkbox"/>	
	(c) LRP's address in Hong Kong (in English / Chinese*)	<input type="checkbox"/>	
	(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.)	<input type="checkbox"/>	

Original Change Application Form



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

Original Change Application Form



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

New Change Application Form

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	<input type="checkbox"/>		_____
1.2	Addition/Removal/Change of manufacturing site	<input type="checkbox"/>		_____
1.3	Other changes in manufacturing processes, facility or Quality Management System (including Quality Control)	<input type="checkbox"/>	<input type="checkbox"/>	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	<input type="checkbox"/>		_____
2.2	Addition/Removal/Change of models or product codes	<input type="checkbox"/>	<input type="checkbox"/>	_____
2.3	Change to the design, or addition/removal/modification of a component	<input type="checkbox"/>	<input type="checkbox"/>	_____
2.4	Change in Magnetic Resonance (MR) safety or compatibility	<input type="checkbox"/>		_____
2.5	Other changes in design	<input type="checkbox"/>	<input type="checkbox"/>	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	<input type="checkbox"/>	<input type="checkbox"/>	_____
3.2	Change in sterilisation facilities	<input type="checkbox"/>	<input type="checkbox"/>	_____
3.3	Other changes to Sterilisation Facility and its Process or Quality Management System	<input type="checkbox"/>	<input type="checkbox"/>	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	<input type="checkbox"/>	<input type="checkbox"/>	_____
4.2	Enhancement of current features	<input type="checkbox"/>	<input type="checkbox"/>	_____
4.3	Other changes to software	<input type="checkbox"/>	<input type="checkbox"/>	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	<input type="checkbox"/>	<input type="checkbox"/>	Please specify: _____

New Change Application Form



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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	<input type="checkbox"/>	<input type="checkbox"/>	_____
6.2	Change in any warnings, precautions, contraindication and potential adverse events	<input type="checkbox"/>	<input type="checkbox"/>	_____
6.3	Change in shelf-life or storage conditions	<input type="checkbox"/>		_____
6.4	Change in the Special Listing Information (refer to GN-01)	<input type="checkbox"/>	<input type="checkbox"/>	_____
6.5	Addition/Removal of symbols	<input type="checkbox"/>	<input type="checkbox"/>	_____
6.6	Change in artwork/formatting of label, such as change of date format, addition of 2D barcodes		<input type="checkbox"/>	_____
6.7	Other changes in labelling	<input type="checkbox"/>	<input type="checkbox"/>	Please specify: _____
7.	Other changes that are not specified in above sections	<input type="checkbox"/>	<input type="checkbox"/>	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)	<input type="checkbox"/>		_____
8.2	Change of LRP's Address in Hong Kong	<input type="checkbox"/>		_____

New Change Application Form



(C)	Changes to Marketing approvals and/or essential principles Please specify: _____	<input type="checkbox"/>												
9	Proposed schedule for concurrent supply upon approval of Change Application (if applicable):	<input type="checkbox"/>												
	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)	<p>Submission of supporting documents regarding the changes in Parts A-C (if applicable)</p> <table border="0"> <tr> <td><input type="checkbox"/> ISO 13485 certificate</td> <td><input type="checkbox"/> Business Registration Certificate</td> <td><input type="checkbox"/> LRP Designation letter</td> </tr> <tr> <td><input type="checkbox"/> Instructions for Use (IFU)</td> <td><input type="checkbox"/> Device Label</td> <td><input type="checkbox"/> Special Listing Information</td> </tr> <tr> <td><input type="checkbox"/> Risk analysis/ management</td> <td><input type="checkbox"/> Clinical evaluation</td> <td><input type="checkbox"/> Others, e.g. test/study report</td> </tr> <tr> <td><input type="checkbox"/> Marketing approval(s)</td> <td><input type="checkbox"/> Essential Principles Conformity Checklist MD-CCL</td> <td><input type="checkbox"/> Essential Requirements Checklist / General Safety and Performance Requirements Checklist in accordance with relevant EU directives or regulations and Essential Principles Declaration of Conformity</td> </tr> </table>	<input type="checkbox"/> ISO 13485 certificate	<input type="checkbox"/> Business Registration Certificate	<input type="checkbox"/> LRP Designation letter	<input type="checkbox"/> Instructions for Use (IFU)	<input type="checkbox"/> Device Label	<input type="checkbox"/> Special Listing Information	<input type="checkbox"/> Risk analysis/ management	<input type="checkbox"/> Clinical evaluation	<input type="checkbox"/> Others, e.g. test/study report	<input type="checkbox"/> Marketing approval(s)	<input type="checkbox"/> Essential Principles Conformity Checklist MD-CCL	<input type="checkbox"/> Essential Requirements Checklist / General Safety and Performance Requirements Checklist in accordance with relevant EU directives or regulations and Essential Principles Declaration of Conformity	
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LRP



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Responsibilities in respect of advertisements

See GN-01, sec. 4.4.11

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.**

Tracking of specific medical devices

Have in place a tracking system that tracks those [specific high-risk devices \(see GN-01, Appendix 1\)](#) down to patient level or user-facility level.

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.

■ 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**

◆ 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

◆ 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

◆ 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>



- 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

[Home](#) > [Medical Device Administrative Control System](#) > Report Medical Device Adverse Events

Scope	
Implementation Progress	
Issued Documents	✓
Listing Application	✓
Examples of Medical Devices Classification	✓
Online Tools	✓
Report Medical Device Adverse Events	
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;

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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. (MDD Use Only)
I. ADMINISTRATIVE INFORMATION		
1. Report Type (select one):		
<input type="checkbox"/> Initial <input type="checkbox"/> Follow-up <input type="checkbox"/> Final <input type="checkbox"/> Trend		
2. Classification:		
<input type="checkbox"/> Serious Public Health Concern <input type="checkbox"/> Death <input type="checkbox"/> Serious Injury <input type="checkbox"/> Other Reportable Event		
3. Date of this report (dd-mm-yyyy)		
4. Date of adverse event (dd-mm-yyyy)		
5. LRP awareness date (dd-mm-yyyy)		
6. Expected date of next report (dd-mm-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:		
<input type="checkbox"/> Healthcare Professional <input type="checkbox"/> Patient <input type="checkbox"/> Other <input type="checkbox"/> None		
15. Usage of Device:		
<input type="checkbox"/> Initial Use <input type="checkbox"/> Reuse of Single-Use Device		
<input type="checkbox"/> Reuse of Reusable Device <input type="checkbox"/> Re-serviced / Refurbished		
<input type="checkbox"/> Other, please specify:		
16. Device Disposition / Current Location:		

Form-Eng AIR-LRP (2021 Edition)

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Page 2

V. RESULT OF MANUFACTURER'S INVESTIGATION		VI. INFORMATION OF PATIENT	
<u>1. Manufacturer's Device Analysis Results:</u>	1. Age at time of the adverse event (months, years)		
	2. Gender (M/F)		3. Weight (kg)
	<u>4. List of devices involved with the patient (see Section IV):</u>		
	<u>5. Corrective action taken relevant to the care of the patient:</u>		
	<u>6. Patient outcome:</u>		
VII. OTHER REPORTING INFORMATION			
Any other cases with this device with the same root cause?			
<input type="checkbox"/> Yes, please specify: _____ <input type="checkbox"/> 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.			
<u>2. Remedial Action / Corrective Action / Preventive Action:</u>			

Form-Eng AIR-LRP (2021 Edition)



- 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 *

The background of the slide is a blurred image of medical equipment, including a patient bed and a monitor displaying vital signs. The monitor shows a heart rate of 80, SpO2 of 99%, and other vital signs. The time on the monitor is 01:14:44.

- ◆ Listing of Traders (continued)
 - Local Manufacturer/ Importer/ Distributor



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 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 3 months before the expiry of Listing



Brief Summary



	*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-02	GN-08	GN-07	GN-09
Application Form	MD-C2&3&4	LM	MD-IP+D	MD-IP+D
Business Registration Certificate	✓	✓	✓	✓
Documented Procedures	✓	✓	✓	✓
Other Information	<ul style="list-style-type: none"> <input type="checkbox"/> Designation Letter <input type="checkbox"/> QMS certificate (if applicable) 	<ul style="list-style-type: none"> <input type="checkbox"/> ISO 13485 certificate or equivalent <input type="checkbox"/> List of medical device manufactured 	<ul style="list-style-type: none"> <input type="checkbox"/> List of medical devices imported <input type="checkbox"/> QMS certificate (if applicable) 	<ul style="list-style-type: none"> <input type="checkbox"/> List of medical devices distributed <input type="checkbox"/> QMS certificate (if applicable)

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



Brief Summary

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.

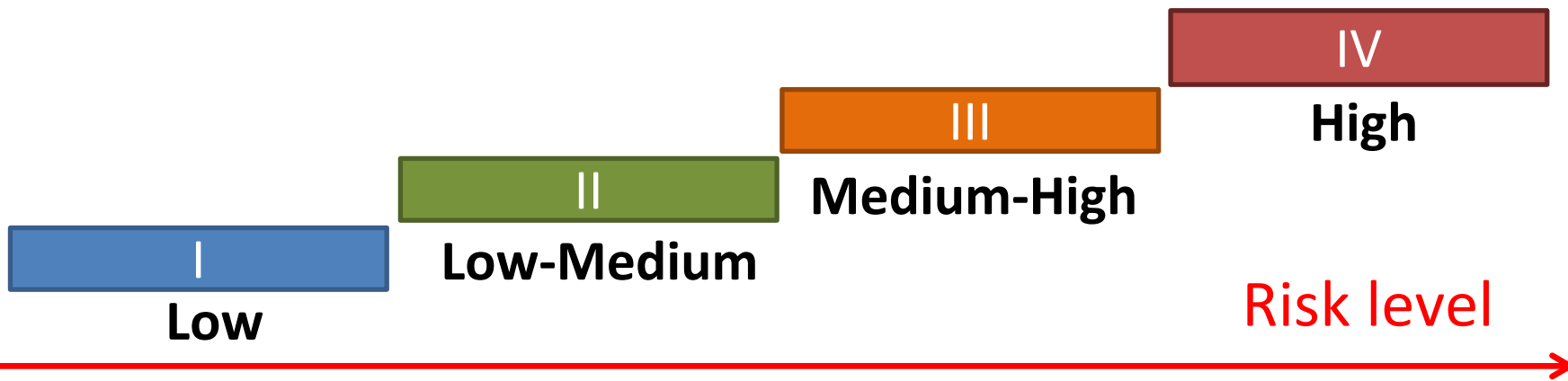


- ◆ Listing of General Medical Devices
 - Classification of General Medical Devices



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 <i>(including but not limited to)</i>			
Intended Use of the device	*<u>Duration of Contact</u> between Human Body and the medical device	Extent of <u>invasiveness</u>	Any <u>drug</u> or <u>energy</u> 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](#)

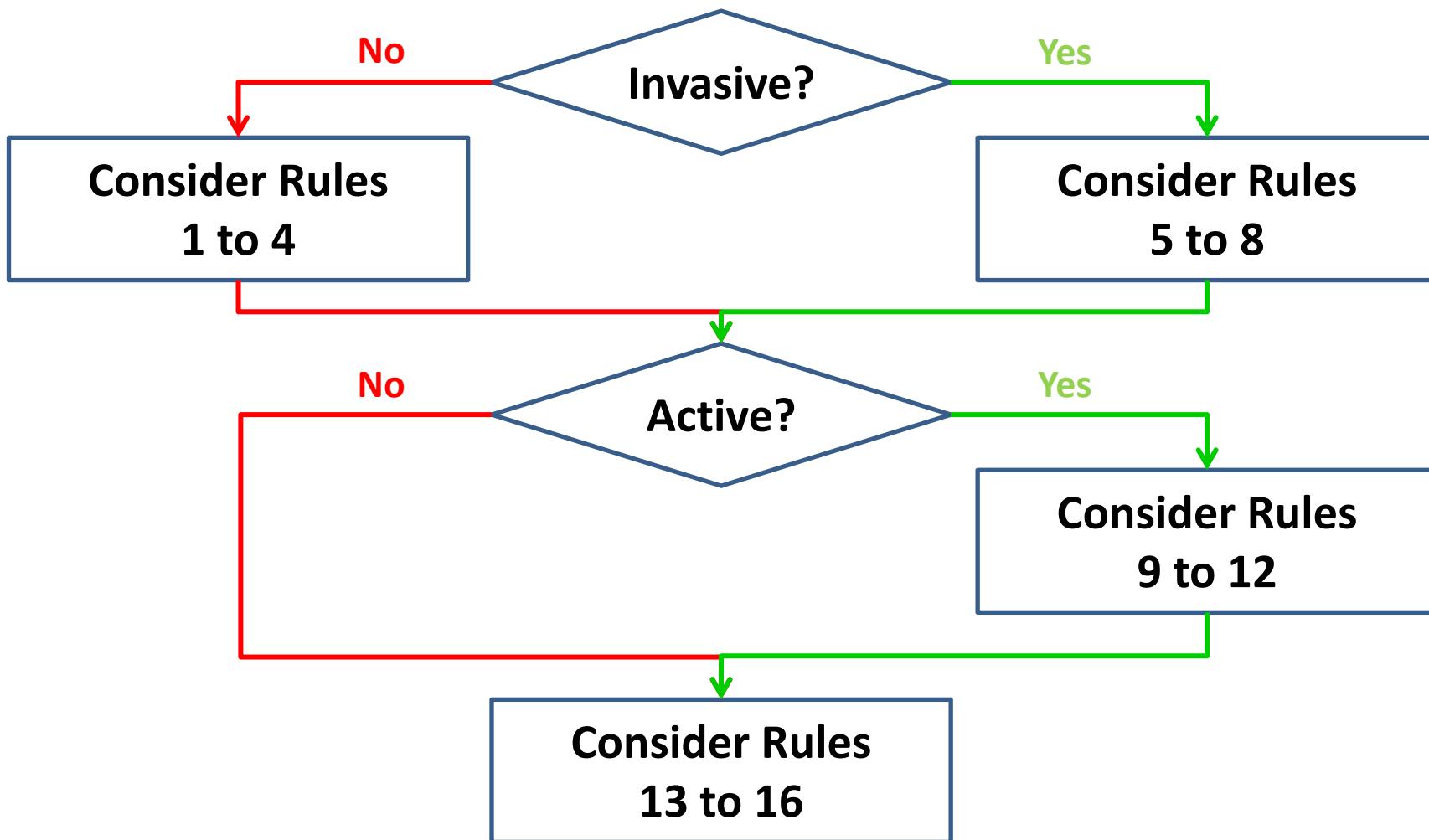
Classification of General Medical Devices



- 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**

<u>Non-invasive Devices</u> (Rules 1 to 4)	<u>Invasive Devices</u> (Rules 5 to 8)
<u>Active Devices</u> (Rules 9 to 12)	<u>Additional Rules</u> (Rules 13 to 16)

Classification of General Medical Devices



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

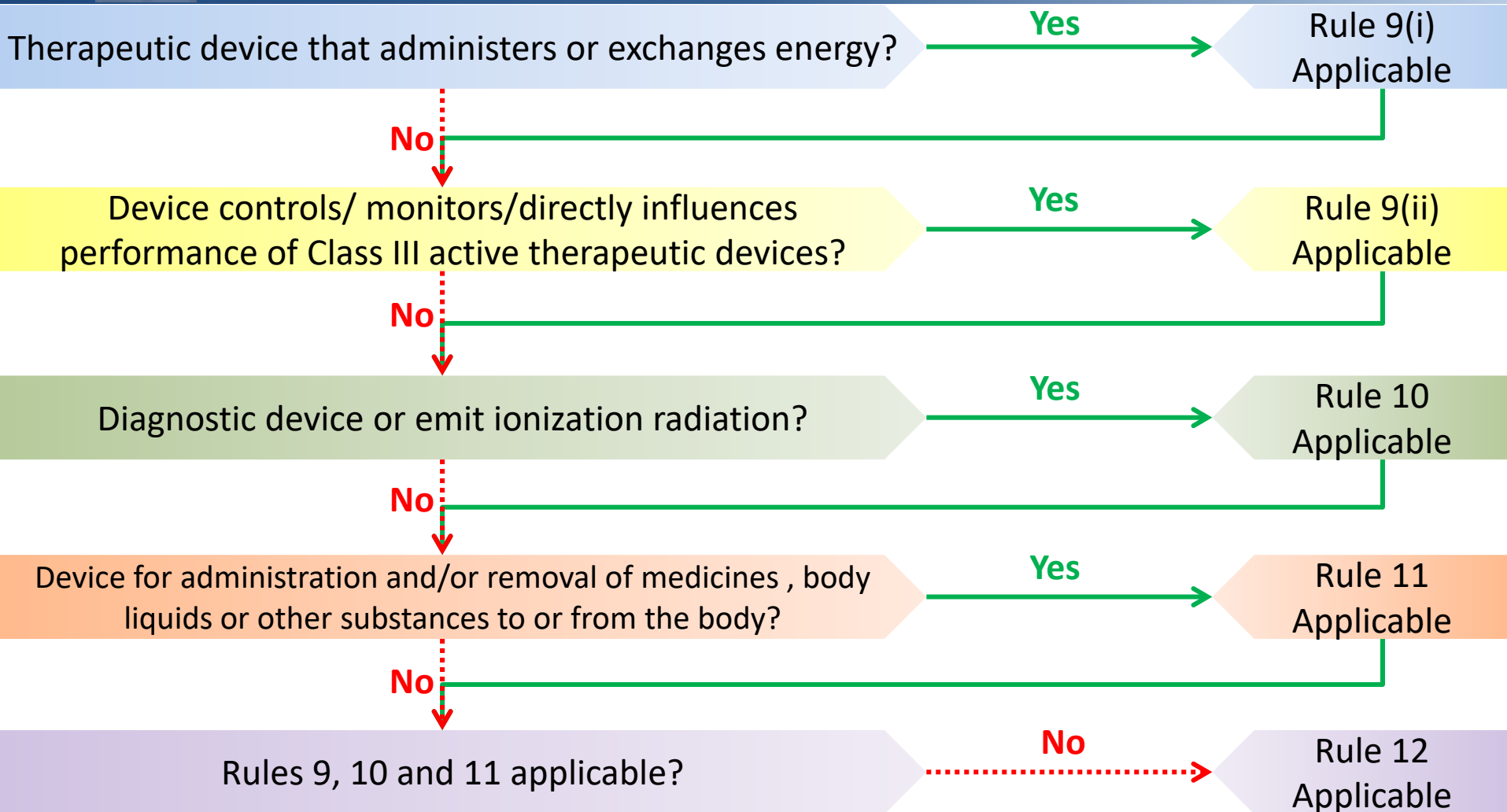
No (i.e. device is an implantable device
or for long-term use)

Rule 8
Applicable

Classification Rules 9 to 12 (Active Medical Device)



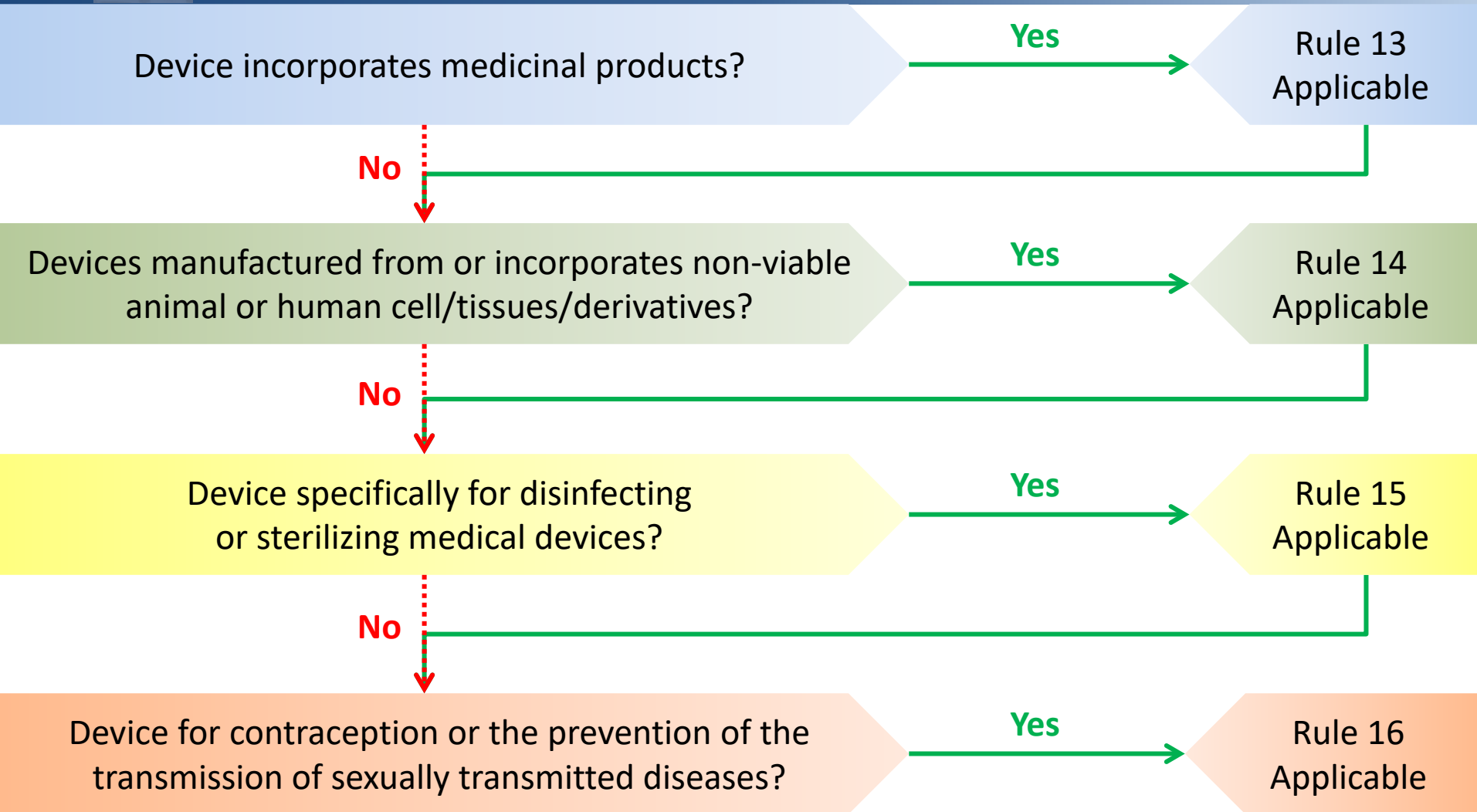
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Classification Rules 13 to 16 (Additional Rules)



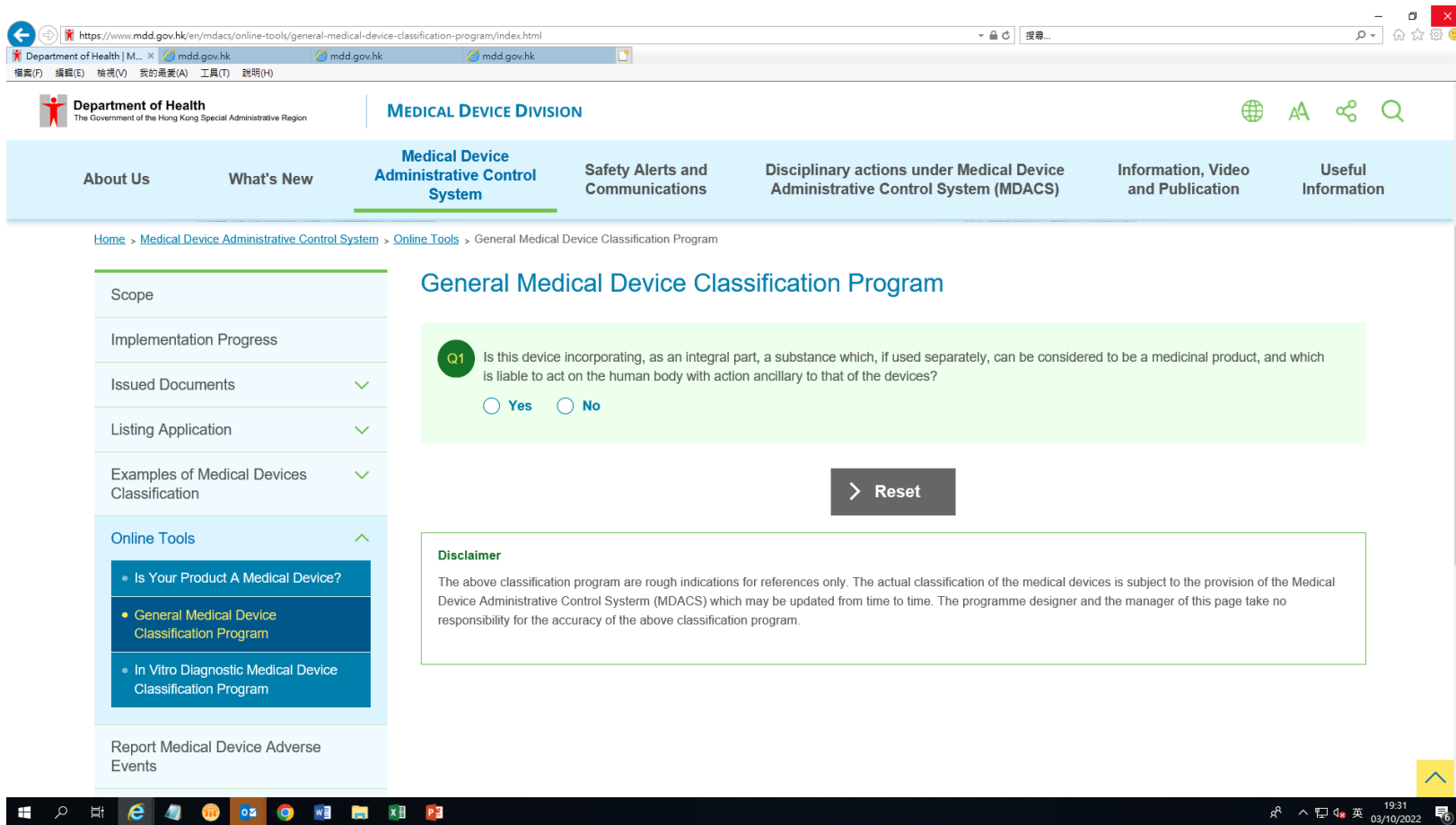
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Classification of General Medical Devices

Online classification program

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

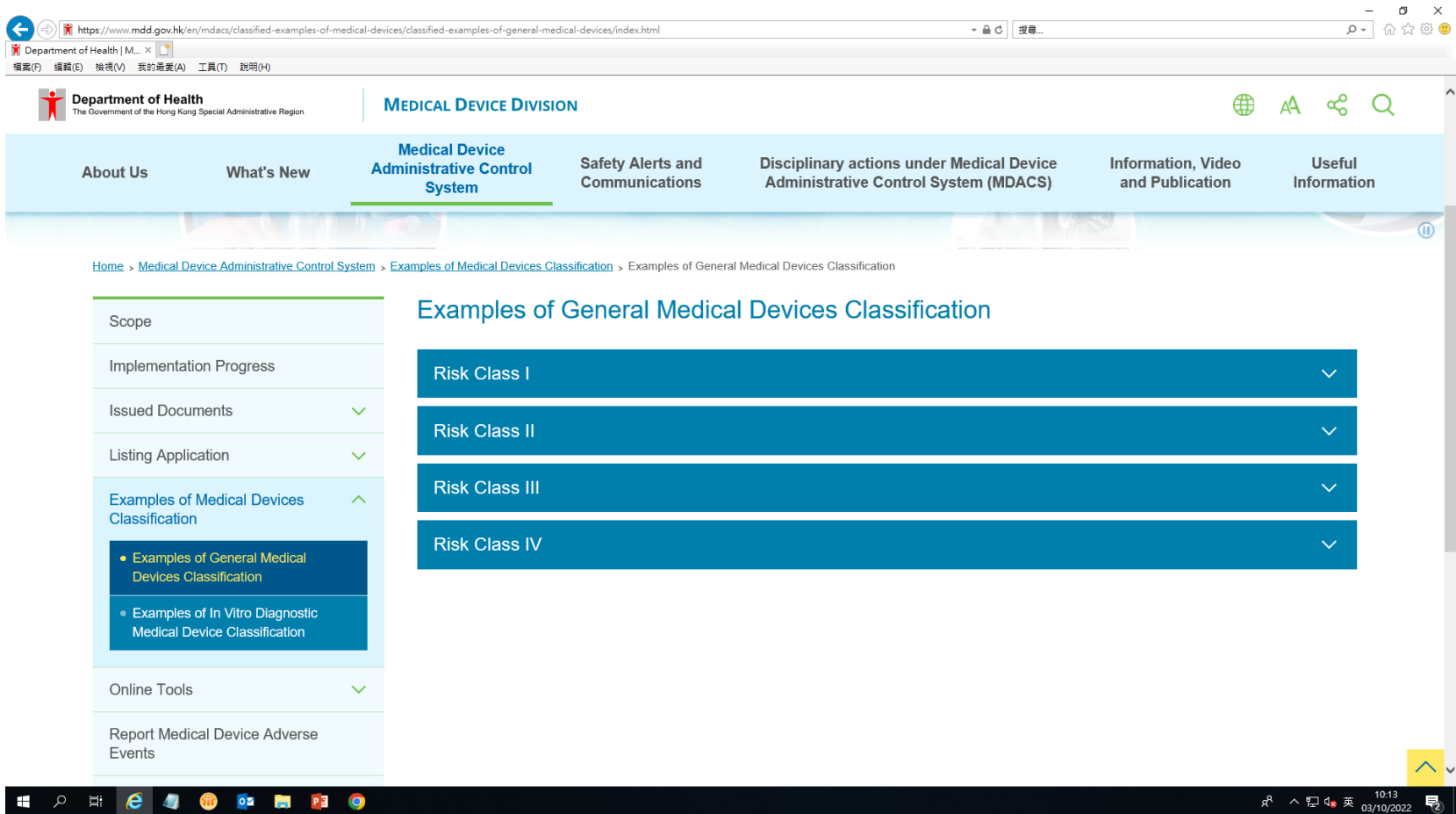


The screenshot shows a web browser displaying the Department of Health's Medical Device Division website. The page is titled "General Medical Device Classification Program". On the left, there is a navigation menu with options like "About Us", "What's New", "Medical Device Administrative Control System", "Safety Alerts and Communications", "Disciplinary actions under Medical Device Administrative Control System (MDACS)", "Information, Video and Publication", and "Useful Information". The main content area features a question: "Q1 Is this device incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, and which is liable to act on the human body with action ancillary to that of the devices?". Below the question are radio buttons for "Yes" and "No". A "Reset" button is also visible. A disclaimer box at the bottom states: "The above classification program are rough indications for references only. The actual classification of the medical devices is subject to the provision of the Medical Device Administrative Control System (MDACS) which may be updated from time to time. The programme designer and the manager of this page take no responsibility for the accuracy of the above classification program."

Classification of General Medical Devices

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>



The screenshot shows a web browser displaying the MDD website. The page title is "MEDICAL DEVICE DIVISION". The navigation menu includes "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", and "Useful Information". The breadcrumb trail is: Home > Medical Device Administrative Control System > Examples of Medical Devices Classification > Examples of General Medical Devices Classification. The main content area is titled "Examples of General Medical Devices Classification" and lists four risk classes: Risk Class I, Risk Class II, Risk Class III, and Risk Class IV. A left sidebar contains a table of contents with items like "Scope", "Implementation Progress", "Issued Documents", "Listing Application", "Examples of Medical Devices Classification", "Online Tools", and "Report Medical Device Adverse Events".



◆ Listing of General Medical Devices (continued)

□ Preparation of Application Documents



Preparation of Application Documents



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- Guidance Notes GN-02
 - **Appendix 1:** sample completed application form
- Application Form
 - <https://www.mdd.gov.hk/en/useful-information/forms/index.html>

Preparation of Application Documents



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

MEDICAL DEVICE DIVISION

Medical Device Administrative Control System | Safety Alerts and Communications | Disciplinary actions under Medical Device Administrative Control System (MDACS) | Information, Video and Publication | **Useful Information**

Home > Useful Information > Forms

Frequently Asked Questions

Issued Documents under Medical Device Administrative Control System (MDACS)

Forms

Useful Sites

(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) (MD-IVD)
- Application for the Listing of Local Manufacturers (LM)
- Application for the Listing of Class III/III/IV General Medical Devices (MD-C2&3&4)**
- Application Form for Certificate to National Medical Products Administration
- Change Form for Listed Medical Devices
- Essential Principles Conformity Checklist (MD-CCL)

Preparation of Application Documents



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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

▶ 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)



Preparation of Application Documents



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- Application Form
 - 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

Note	Part A: Particulars of Manufacturer		Encl.
A001	Manufacturer's name*	<i>in English</i>	ABC Medical limited
		<i>in Chinese</i>	N/A
	Address of Head Office*:	<i>in English</i>	1342N, Derby Road, Arlington VA, USA
		<i>in Chinese</i>	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



A002	<input type="checkbox"/> Registered place of business in Hong Kong:		(A1) <input type="checkbox"/>
	<input type="checkbox"/> Copy of business registration certificate (with business registration number _____) is enclosed		
	Contact person:	Telephone:	
	Fax:	E-mail:	
A003	<u>Established Quality Management System</u> <input checked="" type="checkbox"/> Full quality management system covering device design, production, and post-production processes <input type="checkbox"/> Partial quality management system covering processes: _____		(A2) <input checked="" type="checkbox"/>
	Standards with which the system complies: <input checked="" type="checkbox"/> ISO13485:2003 or later edition (ISO13485: _____) <input checked="" type="checkbox"/> System certified by <u>CAB SYSTEMS LTD</u> (certification body), and a copy of the certificate is enclosed		
A004	Has the manufacturer designated any Local Responsible Person (LRP)? <i>(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.)</i> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> 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*	<i>in English</i>	CARDIO SUPPLIES LTD.	(B1) <input checked="" type="checkbox"/>	
		<i>in Chinese</i>	心臟儀器供應有限公司		
	Address in Hong Kong (Please give the registered place of business, if any)*	<i>in English</i>	32/F., METROPOLITAN CENTRE, 123 MERRY STREET, CAUSEWAY BAY, HONG KONG		
		<i>in Chinese</i>	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					
<u>Business Registration</u>					
<input checked="" type="checkbox"/> Copy of business registration certificate (with business registration number: <u>BR123467</u>) is enclosed					
<input type="checkbox"/> Not applicable					
B002	Date designated as LRP by the manufacturer: <u>30 June 2010</u>			(B2) <input checked="" type="checkbox"/>	
	<input checked="" type="checkbox"/> Manufacturer's designation letter is enclosed				
B003	<u>Established Quality Management System</u>			(B3) <input checked="" type="checkbox"/>	
	<input checked="" type="checkbox"/> ISO9001 <input type="checkbox"/> ISO13485 <input type="checkbox"/> None <input checked="" type="checkbox"/> System certified by <u>ABC Agency</u> (certification body), and a copy of the certificate is enclosed				

Part B: Particulars of Local Responsible Person




B004	<p><u>Documented Procedures Established and Maintained</u></p> <p><input checked="" type="checkbox"/> The applicant <u>does not</u> have any medical device listed under the Medical Device Administrative Control System</p> <p><input checked="" type="checkbox"/> The procedures indicated in items (i) to (vi) below are enclosed</p> <p>(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)</p> <p><input type="checkbox"/> The applicant already has one or more medical device listed under the Medical Device Administrative Control System (LRP number: _____)</p> <p><input type="checkbox"/> There is no change to the procedures indicated in items (i) to (vi). (<i>Please go to B005</i>); OR</p> <p><input type="checkbox"/> The procedures indicated in items (i) to (vi) have been updated and enclosed.</p>	(B4) <input checked="" type="checkbox"/>
B005	<p><input checked="" type="checkbox"/> The LRP is also an importer and/or distributor of the device named in Part C</p> <p>Listing No. of Importer (if applicable): <u>IMP0123456</u></p> <p>Listing No. of Distributor (if applicable): <u>DIS0345678</u></p>	
B006	<p><input type="checkbox"/> The device named in Part C is currently a listed device (under another LRP), with Listing No. _____.</p>	

Part B: Particulars of Local Responsible Person

Valid Business Registration Certificate of LRP (Enclosure B1)

表格 2
FORM 2
《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 / ~~XXXXXX~~ 登記證
Business / ~~XXXXXX~~ Registration Certificate

~~XXXXXXXXXX~~
~~XXXXXXXXXX~~



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雇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 and address
- ✓ Descriptions of the device(s)
- ✓ Manufacturer's signature and official stamp (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)

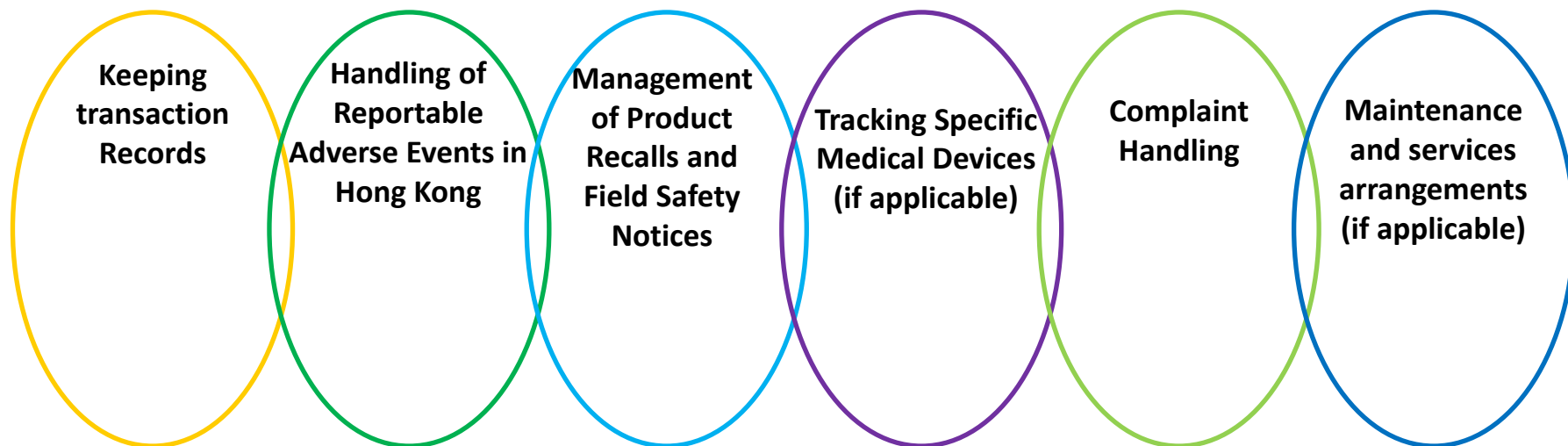
(official chop (if any) of the manufacturer)

Part B: Particulars of Local Responsible Person



■ 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:



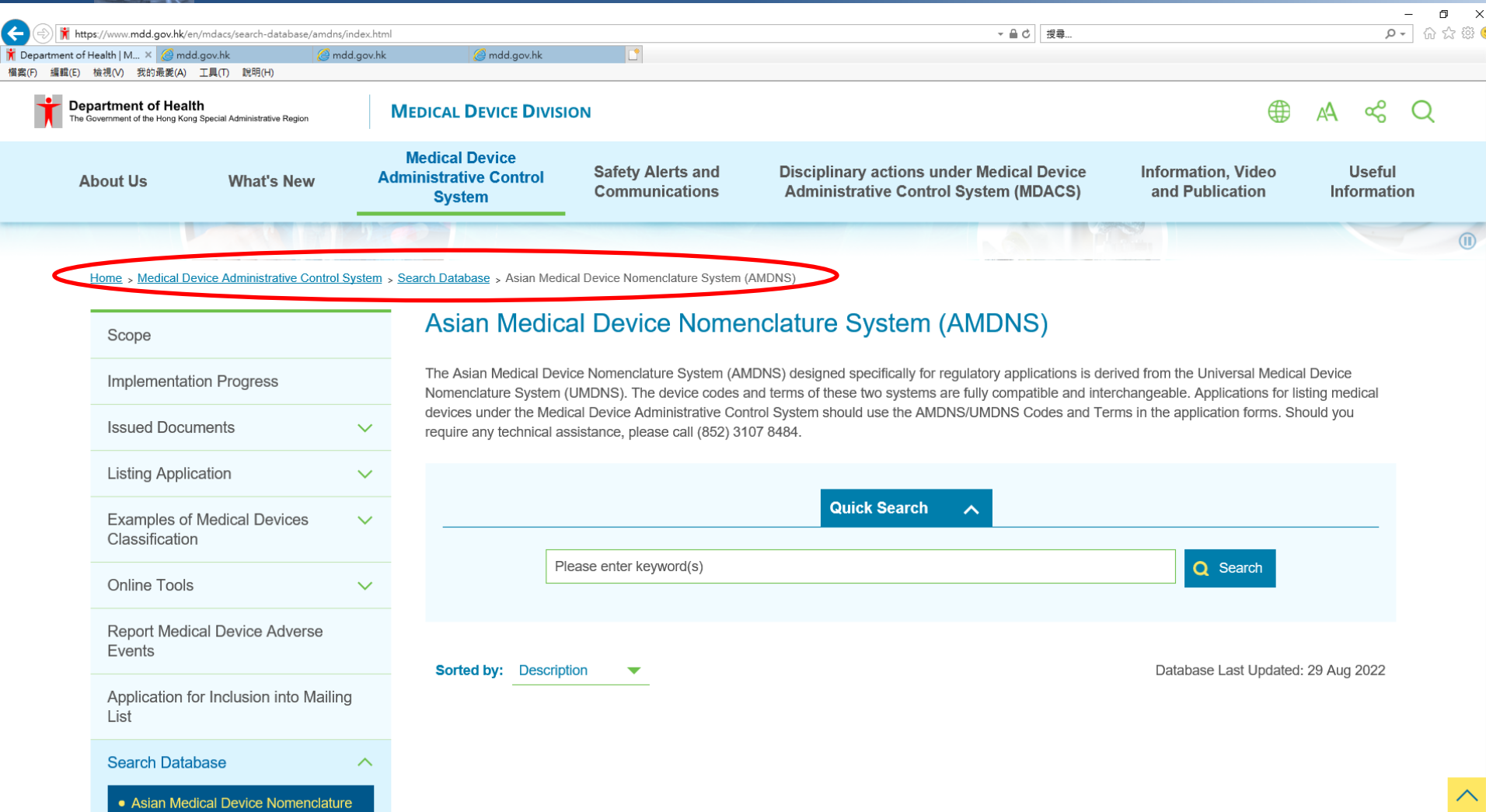
Part C: Particulars of the Device

Note	Part C: Particulars of the Device		Encl.	
C001	Make*	<i>in English</i>	ABC Medical	
		<i>in Chinese</i>	N/A	
	Brand Name*	<i>in English</i>	VGOOD	
		<i>in Chinese</i>	N/A	
	Model*	<i>in English</i>	PMS	
		<i>in Chinese</i>	N/A	
C002	<input type="checkbox"/> A single medical device <input type="checkbox"/> A medical device family <input type="checkbox"/> A medical device series <input checked="" type="checkbox"/> 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. <input type="checkbox"/> Additional information similar to <u>MDS-01</u> attached		(C1) <input type="checkbox"/>	
C003	Description of the device: <i>(Please enter the appropriate AMDNS term. If none of the terms in AMDNS appear appropriate, enter a short description of the device.)</i> MONITORING SYSTEMS, PHYSIOLOGIC			
	AMDNS Code: 12636			
	Other Codes <i>(Please enter if known):</i>			
C004	Other common descriptions of the device: PATIENT MONITORING SYSTEM			

See GN-02, Appendix 1

Please provide this information as far as possible

Part C: Particulars of the Device



The screenshot shows a web browser displaying the Medical Device Administrative Control System (MDACS) search database. The breadcrumb navigation path is circled in red: [Home](#) > [Medical Device Administrative Control System](#) > [Search Database](#) > Asian Medical Device Nomenclature System (AMDNS). The main heading is "Asian Medical Device Nomenclature System (AMDNS)". Below the heading is a paragraph explaining that the AMDNS is derived from the Universal Medical Device Nomenclature System (UMDNS) and is designed for regulatory applications. A search bar with a "Quick Search" button and a "Search" button is present. The "Sorted by" dropdown is set to "Description". The database was last updated on 29 Aug 2022. The left sidebar contains a list of navigation options, with "Search Database" highlighted.

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Asian Medical Device Nomenclature System (AMDNS)

The Asian Medical Device Nomenclature System (AMDNS) designed specifically for regulatory applications is derived from the Universal Medical Device Nomenclature System (UMDNS). The device codes and terms of these two systems are fully compatible and interchangeable. Applications for listing medical devices under the Medical Device Administrative Control System should use the AMDNS/UMDNS Codes and Terms in the application forms. Should you require any technical assistance, please call (852) 3107 8484.

Quick Search

Please enter keyword(s) Search

Sorted by: [Description](#)

Database Last Updated: 29 Aug 2022

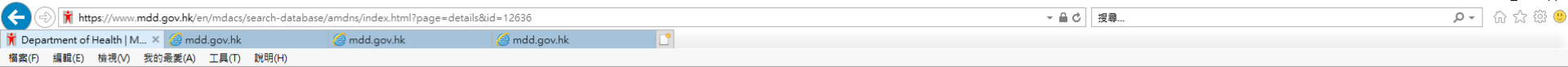
Search Database

- Asian Medical Device Nomenclature

Part C: Particulars of the Device



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(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

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Part C: Particulars of the Device



C005	Intended use of the device*	<i>in English</i>	A physiologic monitoring system intended for monitoring, 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.
		<i>in Chinese</i>	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	<p>Accessories and parts covered by the Marketing Approvals and Essential Principles Conformity Checklist under Note D001 of Part D. <i>Please provide its identifier(s) (e.g. part number) and description using a format similar to MDS-02.</i></p> <p><input checked="" type="checkbox"/> Additional information similar to MDS-02 attached</p>	(C1) <input checked="" type="checkbox"/>
C007	<p>1. The device</p> <p>Yes No</p> <p><input type="checkbox"/> <input checked="" type="checkbox"/> incorporates, as an integral part, a medicinal product which could act on the human body with action ancillary to that of the device</p> <p><input type="checkbox"/> <input checked="" type="checkbox"/> is manufactured from or incorporating human cells/tissues/derivatives</p> <p><input type="checkbox"/> <input checked="" type="checkbox"/> is manufactured from or incorporating animal cells/tissues/derivatives</p>	
	<p>2. The device</p> <p><input type="checkbox"/> is a non-active device (<i>please go to section 3</i>)</p> <p><input checked="" type="checkbox"/> is an active device</p> <p><input type="checkbox"/> intended to control or monitor the performance of active therapeutic devices in Class III, or intended directly to influence the performance of such devices</p> <p><input checked="" type="checkbox"/> intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient</p> <p><input checked="" type="checkbox"/> intended for diagnosing in clinical situations where the patient is in immediate danger</p> <p><input type="checkbox"/> intended to administer or exchange energy to or from human body in a potentially hazardous way including ionizing radiation</p> <p><input type="checkbox"/> none of the above</p>	

Part C: Particulars of the Device



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

Part C: Particulars of the Device



	<p>4. The device is a wound dressing</p> <ul style="list-style-type: none"> <input type="checkbox"/> intended to be used as a mechanical barrier, for compression of wounds or for absorption of exudates (e.g. simple wound dressing; cotton wool) <input type="checkbox"/> intended to manage the microenvironment of wounds (e.g. non-medicated impregnated gauze dressings) <input type="checkbox"/> 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). <input type="checkbox"/> impregnated with medicinal products (e.g. medicated gauze dressings) 	
C008	<p>Class of the medical device: <input type="checkbox"/> Class II <input checked="" type="checkbox"/> Class III <input type="checkbox"/> Class IV</p> <p>Reasons for classifying the device as Class II/III/IV device: <i>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))</i></p>	
C009	<p><u>Manufacturing Site(s) (Use separate sheet if required):</u> (1) 1324N, Derby Road, Arlington, VA 12345-6789, USA (2) 1000 Butler Road, Plymouth Place, PA 12486-1248, USA</p>	(C1) <input checked="" type="checkbox"/>

Part C: Particulars of the Device



C010	<p><u>History of previous recalls, reportable adverse incidents, banning in other countries or post-market surveillance studies</u></p> <p><input type="checkbox"/> No</p> <p><input checked="" type="checkbox"/> Yes (Please check the appropriate boxes and provide details):</p> <p><input type="checkbox"/> Recalls completed or in progress</p> <p><input checked="" type="checkbox"/> Reportable adverse incidents bearing implications to the device</p> <p><input type="checkbox"/> The device banned previously in other countries</p> <p><input type="checkbox"/> Proactive post-market surveillance studies</p>	(C2) <input checked="" type="checkbox"/>
C011	<p><u>Usage</u></p> <p><input type="checkbox"/> The device is for single use</p> <p><input type="checkbox"/> The device is supplied as sterile product</p> <p><input type="checkbox"/> Disposal of used device or any part thereof (including any used accessories or consumables) requires special precautions.</p> <p><input type="checkbox"/> The device is intended to be used/operated by healthcare professionals only</p> <p><input type="checkbox"/> The device is intended to be used/operated by laypersons</p> <p><input type="checkbox"/> It is intended for self-use</p>	
C012	<p><u>Repair and Servicing</u></p> <p><input checked="" type="checkbox"/> The device requires regular servicing/testing/checking/calibration</p> <p><input checked="" type="checkbox"/> Repairs and servicing provided by the LRP or appointed party in Hong Kong</p> <p><input type="checkbox"/> All repairs and servicing performed in Hong Kong</p> <p><input checked="" type="checkbox"/> Part of the repairs and servicing performed in Hong Kong</p> <p><input checked="" type="checkbox"/> Technical support provided by the manufacturer</p>	

Part C: Particulars of the Device



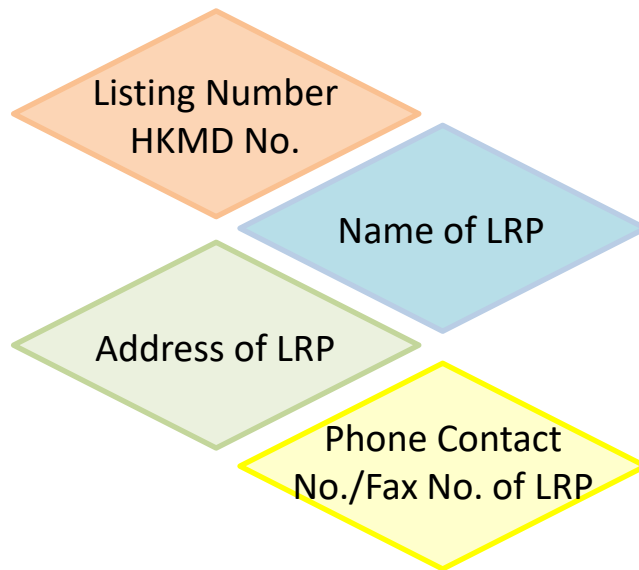
C013	<p>Labelling Requirements</p> <p>Instructions for use are available (Note: <u>Devices intended for self-use by consumers must be accompanied by instructions for use written in both English and Chinese</u>):</p> <p><input checked="" type="checkbox"/> in English <input type="checkbox"/> in Chinese</p> <p><input checked="" type="checkbox"/> A set of copies of device labelling is enclosed</p> <p><input checked="" type="checkbox"/> Electronic labelling is available: https://www.abcmedical.com/vgood</p> <p><input checked="" type="checkbox"/> Sample of Special Listing Information is enclosed</p> <p>Please indicate where in the labelling the following information is given:</p> <p>(1) Indications for use of the device: <u>Pages 4 – 8 of the operator's manual</u></p> <p>(2) Contraindications against use of the device: <u>Pages 9 – 11 of the operator's manual</u></p> <p>(3) Cleaning, disinfection and/or sterilization procedures: <u>Pages 45 of the operator's manual</u></p> <p>(4) User precautions: <u>Pages 24 – 28 of the operator's manual</u></p> <p>(5) Disposal precautions: <u>N.A.</u></p>	(C3) <input checked="" type="checkbox"/>
C014	<p>Licensing Requirements</p> <p>The device is subject to provisions under the following ordinances and a copy of the required licence(s) is/are enclosed:</p> <p>Yes No</p> <p><input type="checkbox"/> <input checked="" type="checkbox"/> Radiation Ordinance (Cap. 303)</p> <p><input type="checkbox"/> <input checked="" type="checkbox"/> Pharmacy and Poisons Ordinance (Cap. 138)</p> <p><input type="checkbox"/> <input checked="" type="checkbox"/> Antibiotics Ordinance (Cap. 137)</p> <p><input type="checkbox"/> <input checked="" type="checkbox"/> Dangerous Drugs Ordinance (Cap. 134)</p>	(C4) <input type="checkbox"/>

Part C: Particulars of the Device



■ 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	<p><u>Conformity Assessment</u></p> <p><input type="checkbox"/> MDACS Conformity Assessment Certificate issued by one of the Conformity Assessment Bodies recognized by MDD</p> <p>MDACS Conformity Assessment Body number: _____</p>	(C5) <input type="checkbox"/>
C016	<p><u>Safety and Risk Analysis</u></p> <p>International or national safety standards with which the device complies: <u>(1) IEC 60601-1:2005; (2) IEC 60601-1-2:2014; (3) IEC60601-1-8:2006;</u> <u>(4) IEC 60601-2-49:2011</u></p> <p><input checked="" type="checkbox"/> Risk analysis conducted: report or summary is enclosed</p> <p><input checked="" type="checkbox"/> Type test performed: report or test certificate is enclosed</p>	(C6) <input checked="" type="checkbox"/>
C017	<p><u>Clinical Evaluation</u></p> <p><input checked="" type="checkbox"/> Clinical investigation report of the device is enclosed</p> <p><input type="checkbox"/> Demonstration of equivalence to another device (equivalent device) where safety and efficacy of which are well established:</p> <p><input type="checkbox"/> Clinical investigation report of the equivalent device and a report of demonstration of equivalence are enclosed</p> <p><input type="checkbox"/> Report demonstrating full equivalence to a well established product is enclosed</p>	(C7) <input checked="" type="checkbox"/>

Part C: Particulars of the Device

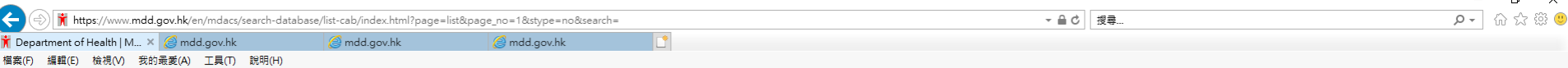


- C015: Conformity Assessment Certificate (Appendix C5)
 - **Conformity Assessment Body (CAB)** means a body recognized by the MDD to engage in the performance of procedures for determining whether the device fulfills the relevant MDACS requirements
 - Recognized CABs:
 - ✓ BSI Assurance UK Limited (c/o BSI Pacific Limited)
 - ✓ SGS United Kingdom Limited (c/o SGS Hong Kong Limited)
 - ✓ TÜV SÜD Product Service GmbH (c/o TÜV SÜD Hong Kong)

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Classification



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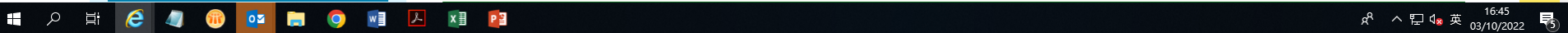
- Asian Medical Device Nomenclature System (AMDNS)
- The List of Medical Devices
- The List of Local Responsible Person (LRP)
- The List of Importers
- The List of Distributors
- The List of Local Manufacturers

Sorted by: Certificate No.

Database Last Updated: 26 Aug 2021

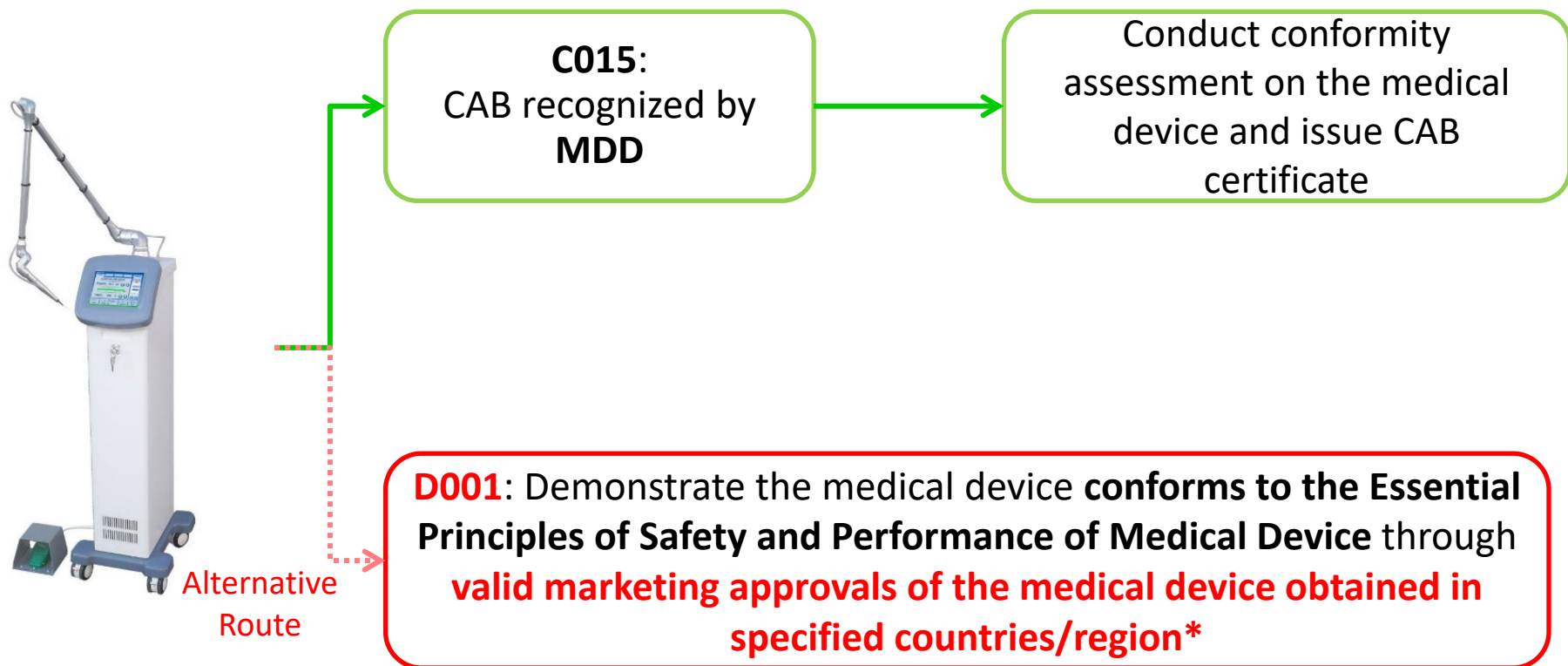


Name	Certificate No.	Address	Telephone Number	Scope of Recognition	Remarks
BSI Assurance UK Limited c/o BSI Pacific Limited	CAB07001	BSI Assurance UK Limited, BSI, Kitemark Court, Davy House, Knowhill, Milton Keynes, MK5 8PP, United Kingdom c/o BSI Pacific Limited, 23/F, Cambridge House, Talkoo Place,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

Conformity Assessment Routes

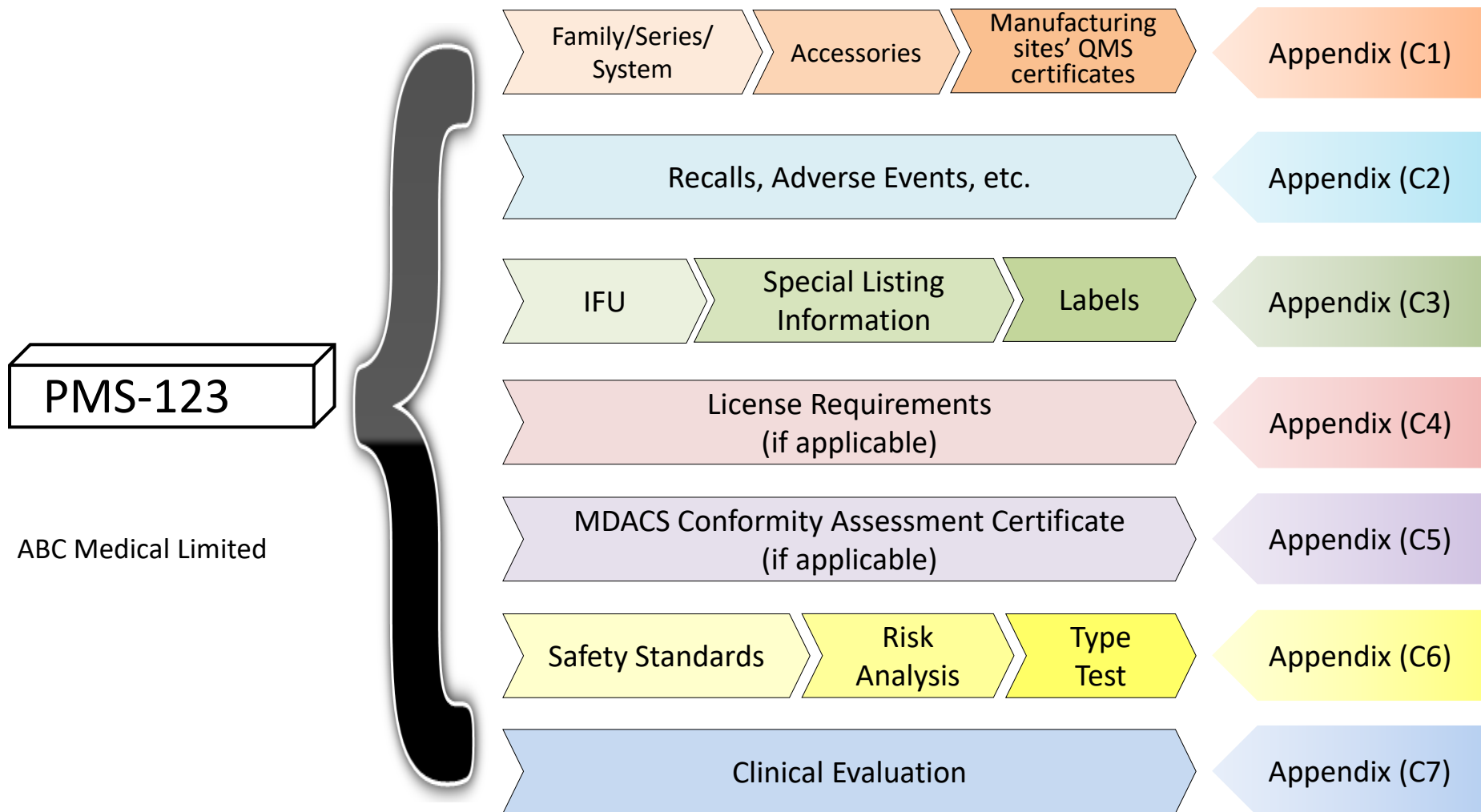


*China, Australia, Canada, European Union, Japan, United States of America and/or Korea (trial scheme)

Part C: Particulars of the Device



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Part D: Marketing Approvals & Essential Principles



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Note	Part D: Marketing Approvals and Essential Principles	Encl.
D001	<p><u>Marketing Approvals in Mainland China and/or Foreign Countries</u></p> <p><input checked="" type="checkbox"/> Approval(s) obtained for the medical device (with same make and model) to be placed on the market of the following countries:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Mainland China (National Medical Products Administration) <input type="checkbox"/> Australia (The Therapeutic Goods Administration) <input type="checkbox"/> Canada (Health Canada) <input checked="" type="checkbox"/> Member countries of European Union that have implemented relevant EU directives or regulations and a copy of the EC Declaration of Conformity is enclosed <input type="checkbox"/> Japan (Ministry of Health, Labour and Welfare) <input type="checkbox"/> United States of America (U.S. Food and Drug Administration) <p><u>Essential Principles</u></p> <ul style="list-style-type: none"> <input type="checkbox"/> Earliest approval obtained on or before 31 December 2004 <input checked="" type="checkbox"/> Earliest approval obtained on or after 1 January 2005 <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Essential Principles Conformity Checklist MD-CCL is enclosed; OR <input type="checkbox"/> 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) <input checked="" type="checkbox"/>

Part D: Marketing Approvals & Essential Principles



Note	Part D: Marketing Approvals and Essential Principles	Encl.
D001	<p><u>Marketing Approvals in Mainland China and/or Foreign Countries</u></p> <p><input type="checkbox"/> Approval(s) obtained for the medical device (with same make and model) to be placed on the market of the following countries:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Korea (Ministry of Food and Drug Safety) Trial scheme <input type="checkbox"/> Mainland China (National Medical Products Administration) <input type="checkbox"/> Australia (The Therapeutic Goods Administration) <input type="checkbox"/> Canada (Health Canada) <input type="checkbox"/> Member countries of European Union that have implemented relevant EU directives or regulations and a copy of the EC Declaration of Conformity is enclosed <input type="checkbox"/> Japan (Ministry of Health, Labour and Welfare) <input type="checkbox"/> United States of America (U.S. Food and Drug Administration) <p><u>Essential Principles</u></p> <ul style="list-style-type: none"> <input type="checkbox"/> Earliest approval obtained on or before 31 December 2004 <input type="checkbox"/> Earliest approval obtained on or after 1 January 2005 <ul style="list-style-type: none"> <input type="checkbox"/> Essential Principles Conformity Checklist MD-CCL is enclosed; OR <input type="checkbox"/> 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) <input type="checkbox"/>

Part D: Marketing Approvals & Essential Principles



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■ 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 3)

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	<ol style="list-style-type: none"> The devices are designed and manufactured under a full quality management system in accordance with ISO 13485 and presently certified 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. 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. 	<ol style="list-style-type: none"> ISO 13485 Certificate No. 012345 Type Test Certificate No. 123456 to show compliance with ISO IEC 60601-1 standard Type Test Certificate No. 23456 to show compliance with IEC 60601-1-2 standard Type Test Certificate No. 34567 to show compliance with IEC 60601-1-8 standard Type Test Certificate No. 45678 to show compliance with IEC 60601-2-49 standard 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, Appendix 3)



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Appendix 3

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

Medical Device Control Office,
Department of Health,
Room 3101, 31/F., Hopewell Centre,
183 Queen's Road East,
Wan Chai,
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>

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 Certificates: <ul style="list-style-type: none">• Directive 93/42/EEC (MDD)• Directive 90/385/EEC (AIMD)• Regulation (EU) 2017/745 (MDR)

EU

Marketing Approval (by EU NB)



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EC Certificates	Directive 93/42/EEC (MDD)	Directive 90/385/EEC (AIMD)
Full Quality Assurance System Approval Certificate	Annex II	Annex 2
EC Design–Examination Certificate	Annex II, Section 4	Annex 2, Section 4
EC Type Examination Certificate	Annex III	Annex 3
EC Verification Certificate	Annex IV	Annex 4
Production Quality Assurance System Approval Certificate	Annex V	Annex 5
Product Quality Assurance System Approval Certificate	Annex VI	-

The top-left corner of the slide features two overlapping images of medical equipment. The top image shows a white medical machine, possibly a ventilator or a specialized monitor, with various tubes and components. The bottom image shows a white ultrasound machine with a control panel and a screen.

EU

Marketing Approval (by EU NB)



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Regulation (EU) 2017/745 (MDR)

For example:

- EU Quality Management System Certificate
- EU Technical Documentation Assessment Certificate

Preparation of Application Documents



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The screenshot shows a Windows Explorer window titled 'ABC Medical PMS-123'. The address bar indicates the path: 'C:\Documents and Settings\vo_mdco.dh\桌面\ABC Medical PMS-123'. The main area displays a grid of folders:

A1 - Manufacturer information	A2 - Manufacturer QMS
B1 - LRP BR	B2 - LRP Design Letter
B3 - LRP QMS	B4 - LRP SOP
C1 - Device Information	C2 - Device History
C3 - Device Labelling	C4 - Batch Release
C5 - CAB Certificate	C6 - Device standard
C7 - Clinical Evaluation	<u>D1 - Marketing Approvals</u>

The folder 'D1 - Marketing Approvals' is highlighted with a dashed border. The left sidebar shows navigation options under '檔案及資料夾工作' and '其他位置'.

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

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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