Application for listing of medical devices under the Medical Device Administrative Control System (Class II/III/IV general medical devices)

Medical Device Control Office
Department of Health
18/09/2018

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Department of Health

Workshop

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This workshop introduces the latest listing requirements of general medical devices and traders under Medical Device Administrative Control System (MDACS)

For details, please refer to the MDCO website
https://www.mdco.gov.hk

Exercise

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Please return the completed exercise (Exercises 1 - 3) at the end of the workshop

Thank you!

Content

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- Medical Device Administrative Control System (MDACS)
- Listing of Traders
  - Local Responsible Person (LRP)
  - Local Manufacturer
  - Importer
  - Distributor
- **Short Break**
- Listing of General Medical Devices
  - Classification of General Medical Devices
  - Preparation of Application Documents
- Q&A

Medical Device Administrative Control System (MDACS)

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Background

No specific regulatory control on medical devices

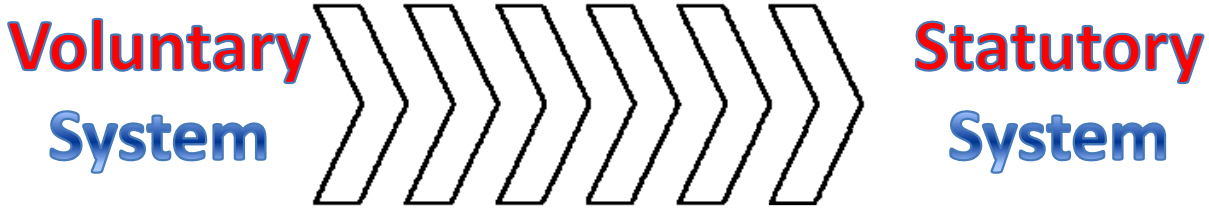
March 2004
LegCo Health Services Panel

Medical Device Bill in the future

July 2003
<<Regulation of Medical Devices>>
Consultation Document

July 2004
Medical Device Control Office
Nov 2004
Implementation of MDACS by phases

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**

Source: <<Regulation of Medical Devices>> Consultation Document (July 2003)

MDACS

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- Scope
  - Products fall within the definition of medical device
  - Some medical devices are EXEMPTED 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.

MDACS

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Medical Device Administrative Control System (MDACS)

Listing System	Conformity Assessment Body (CAB) Recognition Scheme	Medical Device Safety Alert System & Adverse Incidents Reporting System
(1) Medical Device ➢ General Medical Devices (Class II – IV) ➢ In Vitro Diagnostic(IVD) medical device (Class D) (2) Listing System of the Traders ➢ Local Responsible Person ➢ Local Manufacturer ➢ Importer ➢ Distributor		

MDACS

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Implementation Progress

1	Nov 2004	Listing of **Class IV** General Medical Devices
2	Nov 2005	Listing of **Classes II and III** General Medical Devices
3	Oct 2006	**Conformity Assessment Body** Recognition Scheme
4	Mar 2007	Listing of **Local Manufacturers**
5	Jul 2007	Listing of **Importers**
6	Dec 2009	Listing of **Class D** In Vitro Diagnostic Medical Devices
7	Apr 2015	Listing of **Distributors**

Brief Summary

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- MDACS will be eventually superseded by a statutory system

	MDACS	Medical Device Bill (Latest Proposal)
Pre-market Control	■Listing of Medical Devices	■ Registration of Medical Devices
		■ Listing of "Cosmetic Devices"
	■Listing of Traders ➢Local Responsible Person ➢Local Manufacturer/ Importer/Distributor	■Licensing of Traders ➢Authorised Representative ➢Local Manufacturer/ Importer/Distributor
	■CAB Recognition Scheme	■CAB Recognition Scheme
Post-market Control	■ Medical Device Safety Alert System and Adverse Incidents Reporting System	■Medical Device Safety Alert System and Adverse Incidents Reporting System

Listing of Traders

- Local Responsible Person (LRP)
- Local Manufacturer
- Importer
- Distributor

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Local Responsible Person (LRP)

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LRP

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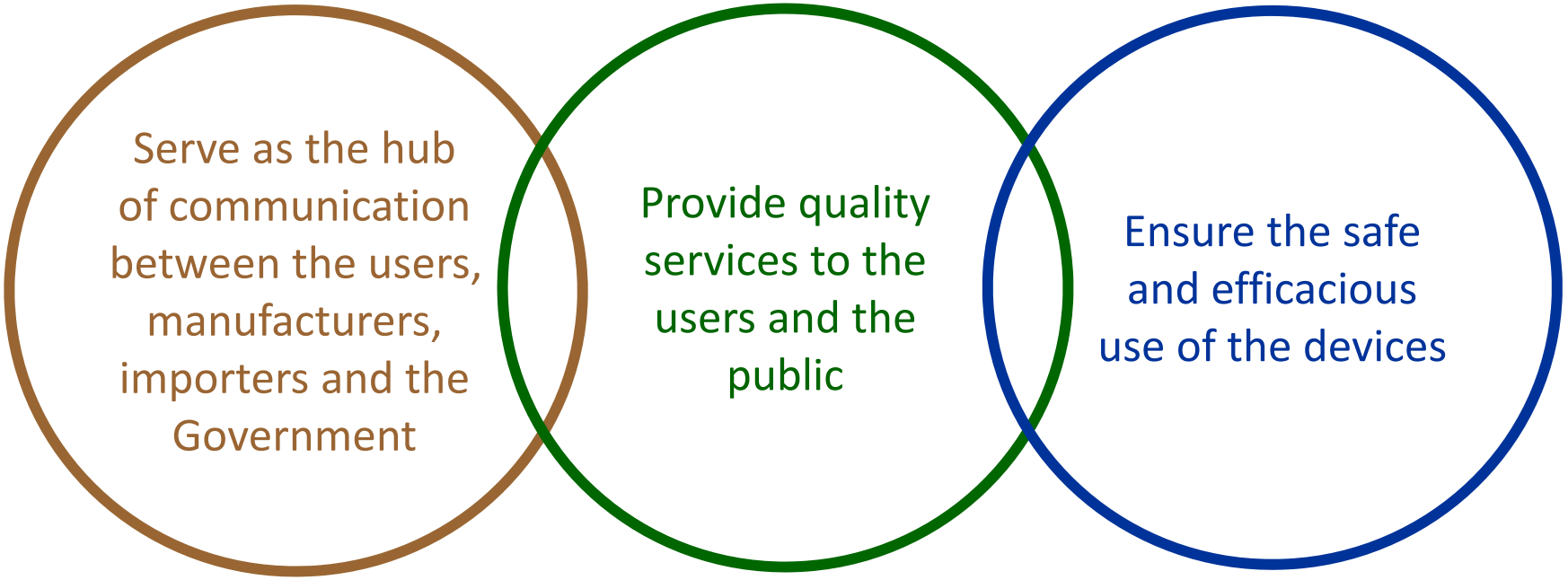
- What is LRP?
  - Local Responsible Person (LRP)
  - Authorized representative of the medical device manufacturer
  - The person responsible for placing the device on market
  - The person responsible for making the application of listing medical device under the MDACS and bears multiple responsibilities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

LRP

- The need for LRP



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

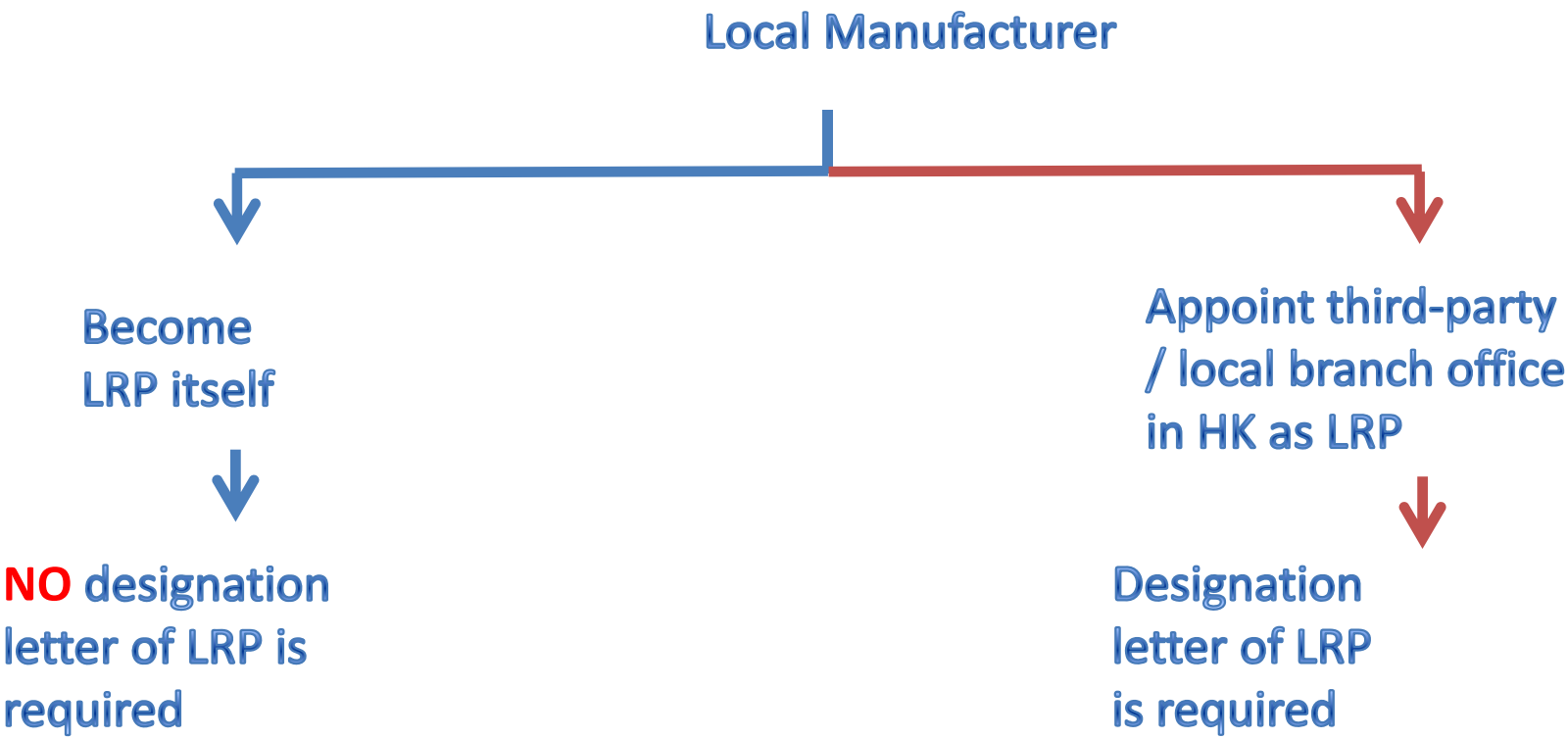
Submit the listing application to the Medical Device Control Office

(Applicant should submit completed application form and required information)

Establish documented procedures according to the requirements stipulated by the Medical Device Control Office

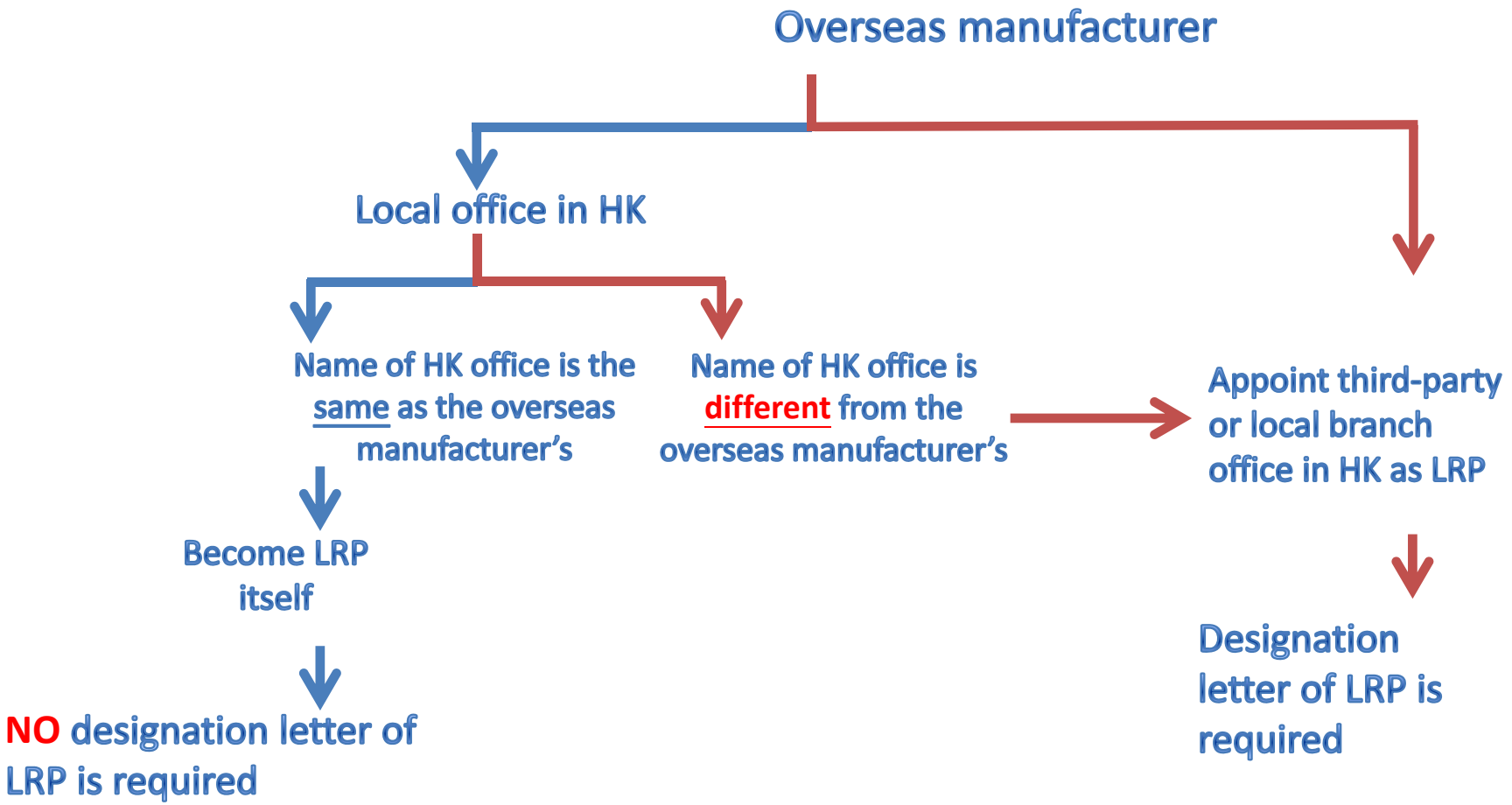
LRP

- Relationship between LRP and Local Manufacturer



LRP

- Relationship between LRP and overseas manufacturer



LRP

- Sample letter for designating a LRP

  (Source: GN-01 Annex 5)

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.

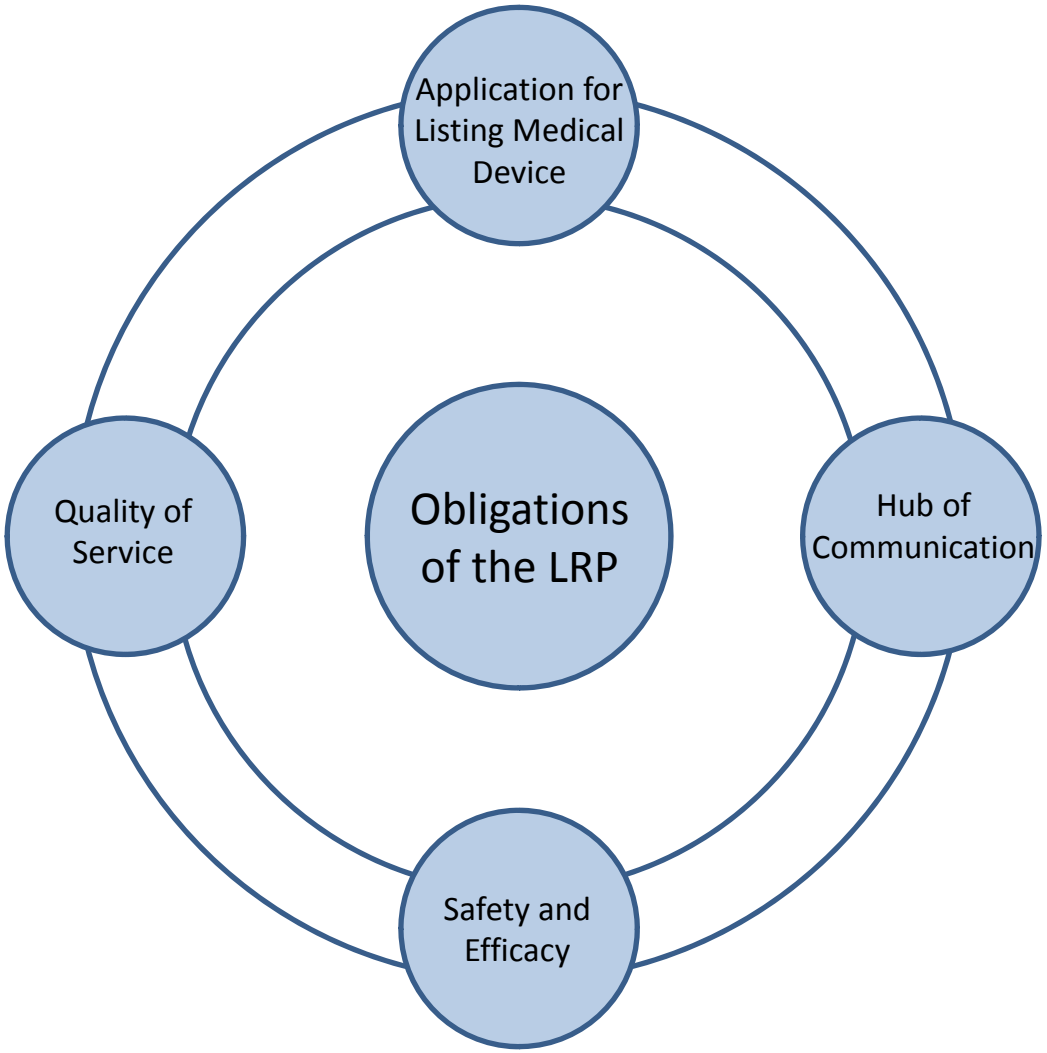
Yours faithfully,

(signature)

(name and title of official signing this letter)

(official chop (if any) of the manufacturer)

LRP



LRP

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- Application for listing medical device
  - Submit the documents, data and samples 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 MDCO at least 3 months before the expiry of Listing (5 years)

LRP

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Hub of Communication

Efficient Communication Channels

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

Making Records Available for Inspection

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

Transaction Records

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

Reporting Changes

Inform the MDCO 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.

LRP

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Safety and Efficacy

Managing Reportable Adverse Incidents in Hong Kong

Observe the adverse incident reporting requirements of the Guidance Notes GN-03 and report all reportable adverse incidents to the MDCO.

Product alerts, modifications and recalls

Inform the MDCO 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 down to patient level or user-facility level. (Appendix 4 of GN-01 refers)

LRP

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Quality of Services

Maintenance and Services Arrangements

Offer or arrange other parties to provide **preventive and corrective maintenance**

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.

Moreover, the LRP should provide "**Special Listing Information**" ,
(1) on the outer packaging of the medical device, or on a document delivered together with the medical device; or
(2) on a document which the "Special Listing Information" is printed, such as a receipt

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 or natural person **who brings or causes to be brought into Hong Kong** any medical devices falling within the scope of the MDACS for **supply in Hong Kong** (Note 1)

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. (Note 2)

Note 1 : **does not include** any person who is employed or engaged by such person to carry such products into Hong Kong

Note 2 : **does not include** (i) A person who purchases or receives medical device(s) exclusively for one's own personal use; (ii) Retailer who supplies a medical device, or provides a service utilising a medical device, solely and directly to the end user; (iii) Health care facility or provider that provides diagnostic or therapeutic services to patient(s) or individual(s); (iv) A business party which purchases or receives medical device(s) solely for use by its employees during work activities (e.g. first aid kits and disposable gloves) or for incidental emergency use as long as one is not in the business of offering healthcare service(s) to employees or other individuals; and (iv) A person in the supply chain involves in activities such as storage and transport of medical devices on behalf of the manufacturer, importer, distributor or Local Responsible Person (LRP).

Local Manufacturer/Importer/Distributor

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Establish documented procedure

	Local Manufacturer (QMS)	Importer	Distributor
1. Keeping of transaction records	✓	✓	✓
2. Handling, storage and delivery of medical device	✓	✓	✓
3. Managing product alerts, modifications and recalls	✓	✓	✓
4. Managing reportable adverse incidents in Hong Kong	✓	✓	✓
5. Handling of complaints	✓	✓	✓
6. Tracking of specific medical devices	✓	✓	✓
7. Arranging maintenance and services	✓	✓	✓
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 record)	✓ (e.g. transaction record)
Reporting adverse incidents (Guidance Note GN-03)	✓	✓	✓
Notifying the changes	✓ (Including any major changes in relation to the QMS)	✓	✓
Conforming to the advertising requirements	✓	✓	✓
Others	❑ Submit renewal application **at least 6 months** before the expiry of Listing	❑ Submit renewal application **at least 3 months** before the expiry of Listing	❑ Submit renewal application **at least 6 months** before the expiry of Listing

Local Manufacturer/Importer/Distributor

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Application for Listing of Traders

	Local Manufacturer	Importer	Distributor
Application form	LM (Version 2007)	MD-IP+D (Version 2018)	MD-TREG (Version 2015)
Business registration certificate	✓	✓	✓
Documented procedure	✓	✓	✓
Other information	❑ ISO 13485 certificate or equivalent ❑ List of medical devices manufactured	❑ List of medical devices imported	❑ List of medical devices distributed

Brief Summary

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Documented Procedure	LRP	Local Manufacturer	Importer	Distributor
Validity Period	N.A.	5 years	3 years	3 years
Guidance Note	GN-01	GN-08	GN-07	GN-09
Application Form	MD-C2&3&4 (Version 2011)	LM (Version 2007)	MD-IP+D (Version 2018)	MD-TREG (Version 2015)
Business registration certificate	✓	✓	✓	✓
Documented procedure	✓	✓	✓	✓
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)

Brief Summary

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

End of Session

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Classification of General Medical Devices

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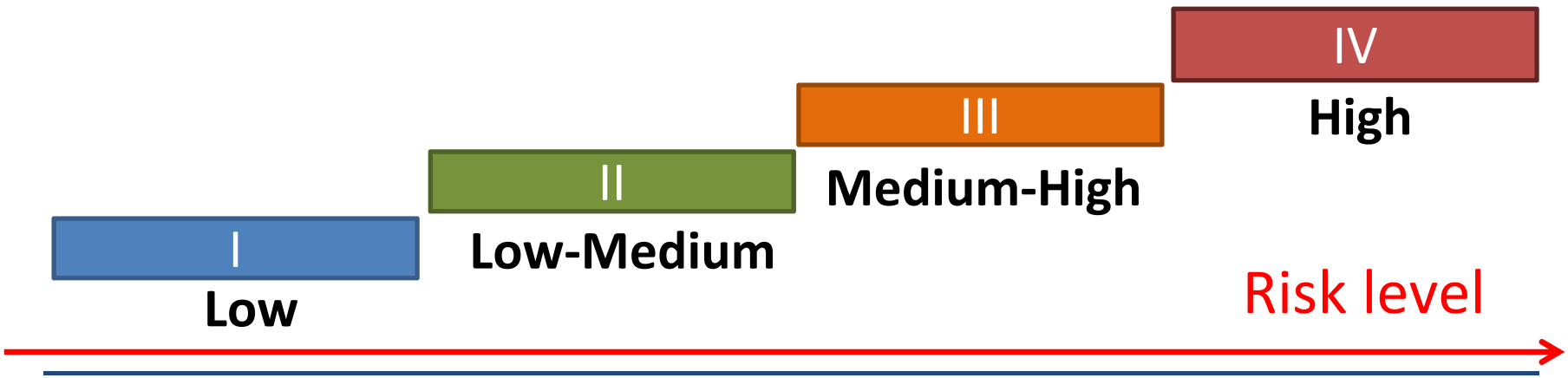
Classification of General Medical Device

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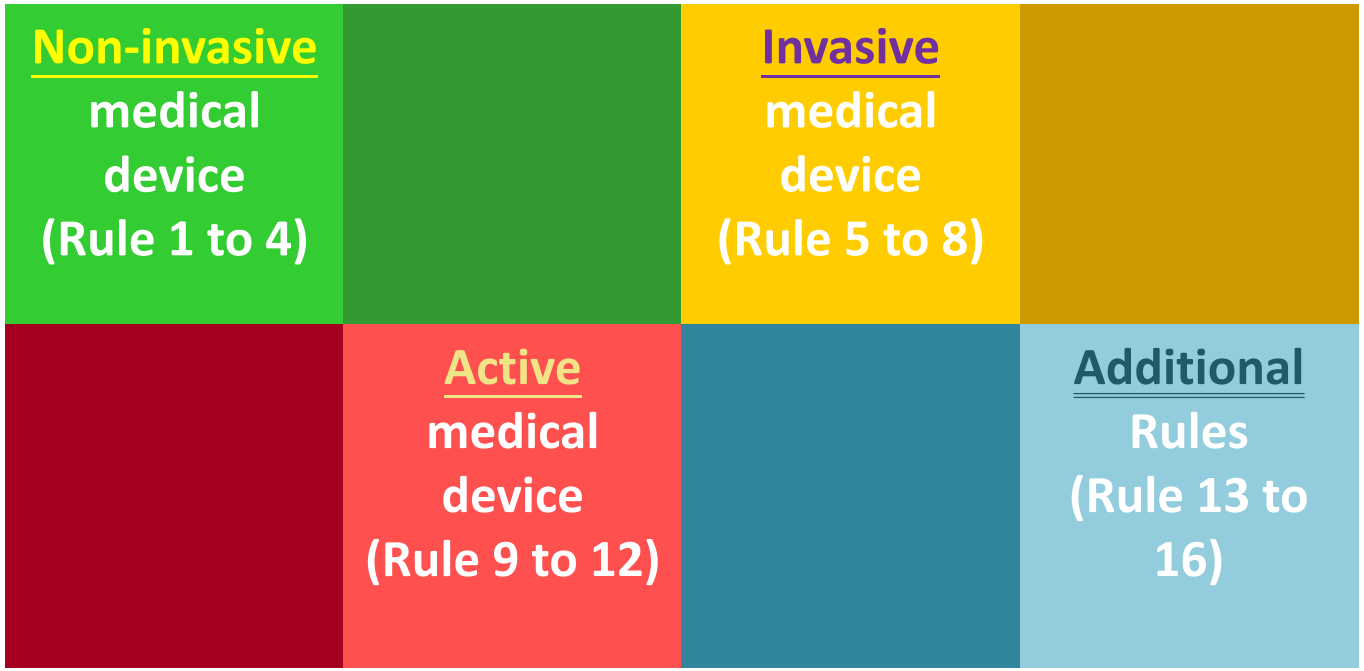
Risk Factor *(including but not limited to)*			
Intended Use of the device	**Duration of Contact between Human Body and the medical device**	**Extent of invasiveness**	**Any drug or energy delivered to the patient**

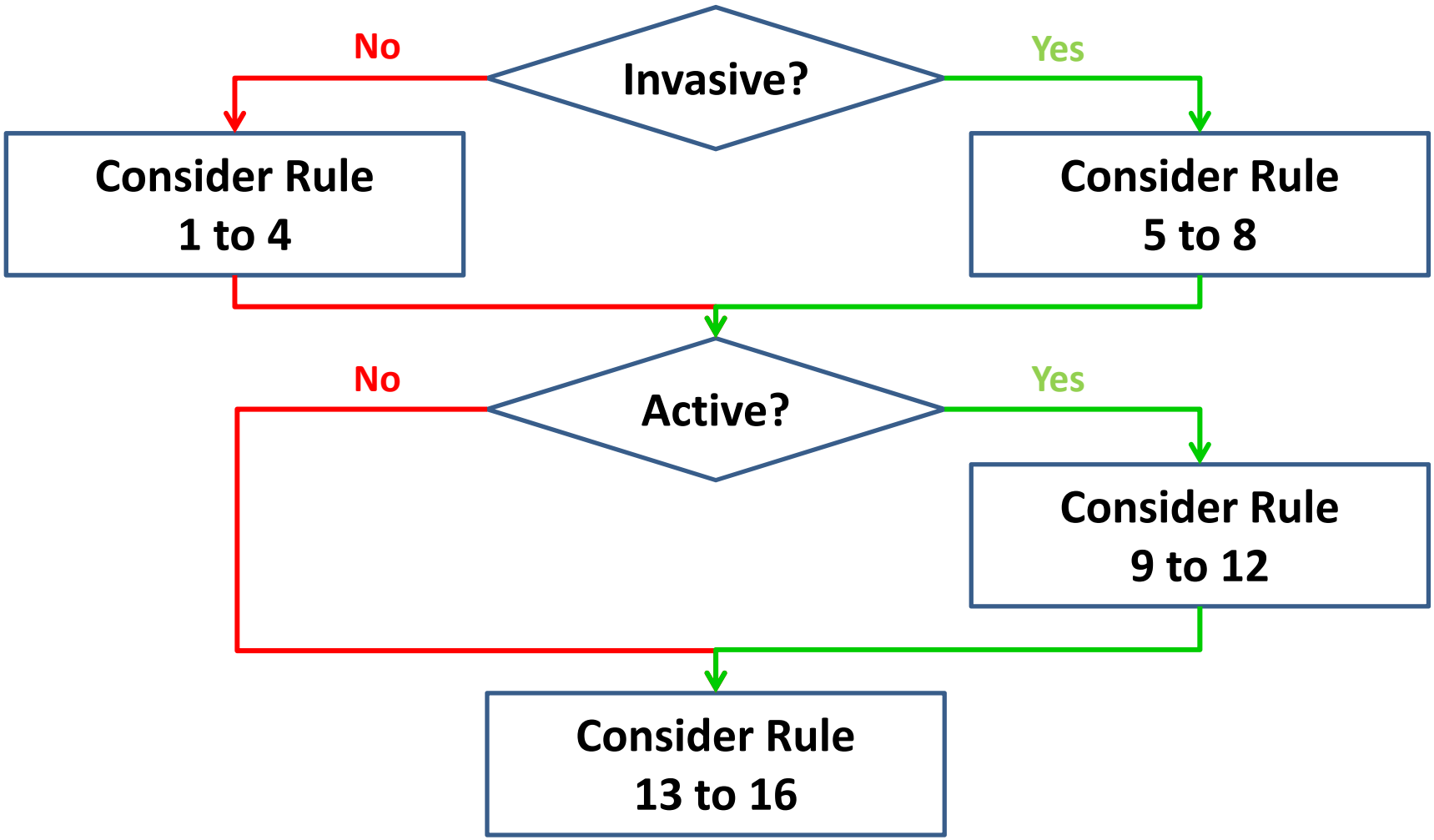
Basic Information of Classification

Classification of General Medical Devices

- The following rules do not apply to *in vitro* diagnostic 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



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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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

Exercise(2)
Classification of
General Medical Devices

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Exercise (2)
Classification of General Medical Devices

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1(a) Infusion System

Infusion Bag (without saline solution)

Classification rules	Which rule applies?
1 to 4	
5 to 8	
9 to 12	
13 to 16	

Exercise (2)
Classification of General Medical Devices

1(b) Infusion System

Intravenous (IV) Set

Classification rules	Which rule applies?
1 to 4	
5 to 8	
9 to 12	
13 to 16	

Exercise (2)
Classification of General Medical Devices

2 Electronic Thermometer (Oral)

Classification rules	Which rule applies?
1 to 4	
5 to 8	
9 to 12	
13 to 16	

3 Pulse Oximeter

Intended Use：
Intended for monitoring, recording and alarming of patient SpO2 in acute care environment in health care facilities.

Classification rules	Which rule applies?
1 to 4	
5 to 8	
9 to 12	
13 to 16	

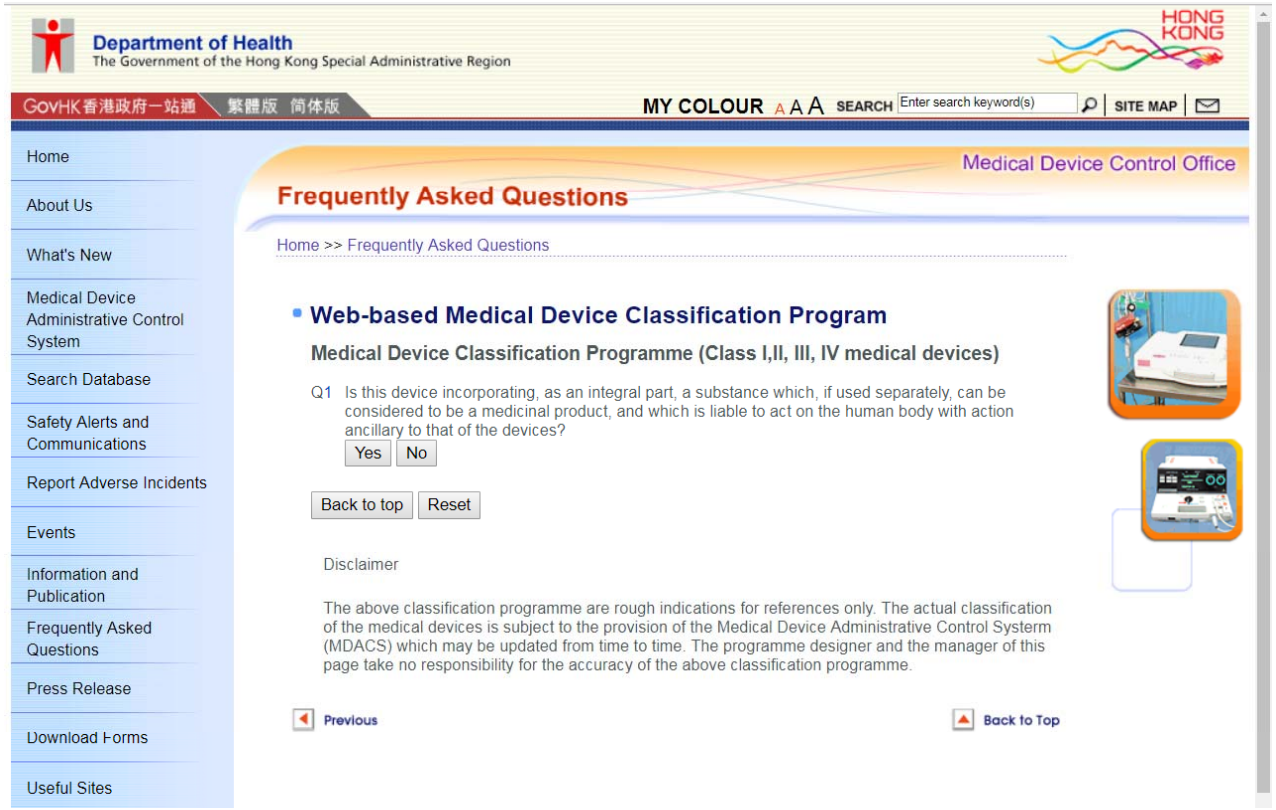
Exercise (2)
Classification of General Medical Devices

4 Surgical laser

Classification rules	Which rule applies?
1 to 4	
5 to 8	
9 to 12	
13 to 16	

Classification of General Medical Devices

- Online classification system
  - https://www.mdco.gov.hk/english/faq/question.html



Preparation of Application Documents

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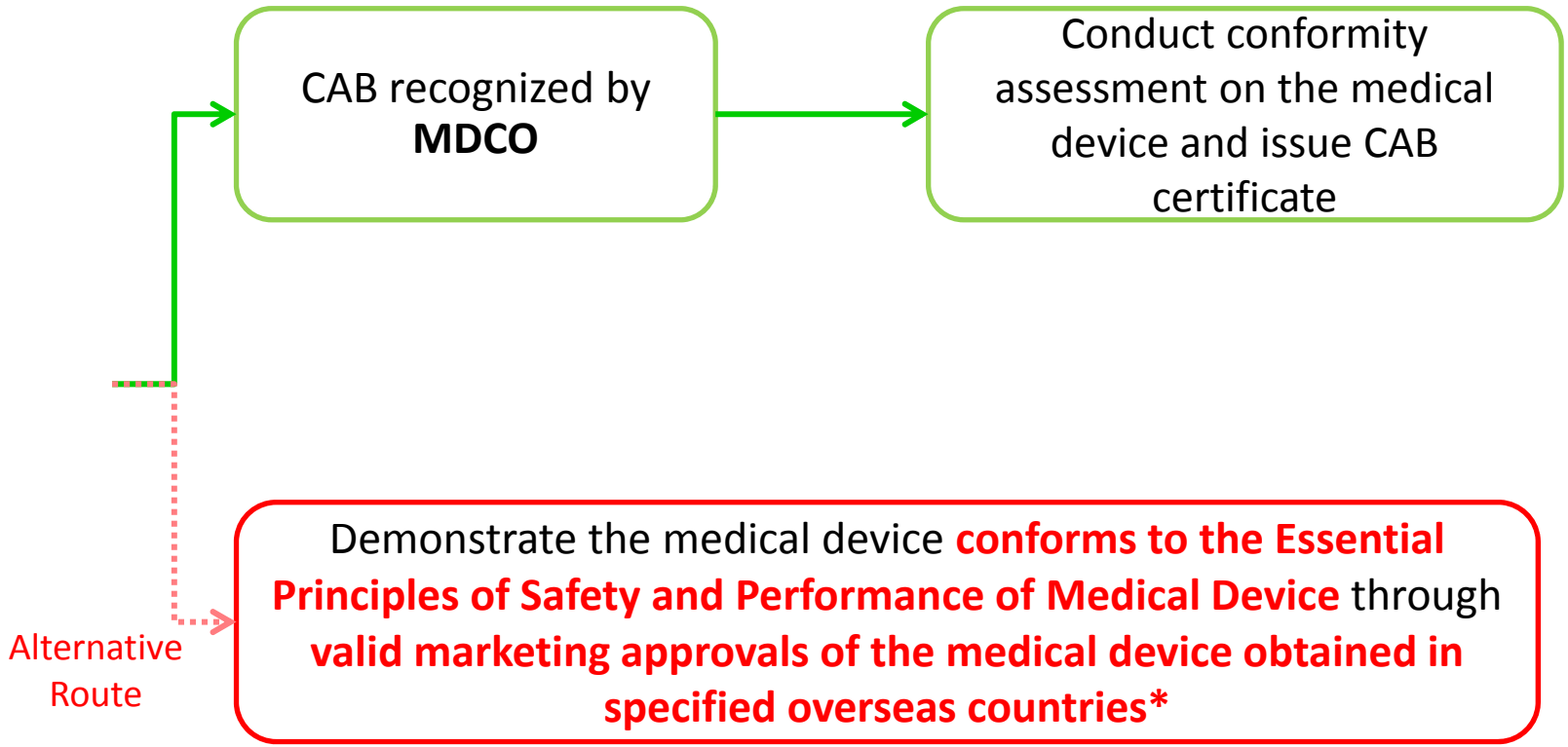
Conformity Assessment Routes



*The founding members of GHTF (Australia, Canada, European Union, Japan and the United States of America)

Preparation of Application Documents

- Application Form (GN-02, Appendix 1)
  - 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
  - Link:
    https://www.mdco.gov.hk/english/mdacs/mdacs_gn/mdacs_gn.html

Part A: Particulars of Manufacturer

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Part A: Particulars of Manufacturer

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

Part A: Particulars of Manufacturer

A002	☐ Registered place of business in Hong Kong: ☐ Copy of business registration certificate (with business registration number _____) is enclosed Contact person: / Telephone: Fax: / E-mail:	(A1) ☐
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 A: Particulars of Manufacturer

- Manufacturer's Quality Management System

  ISO 13485 Certificate

  (Enclosure A2)

Part B: Particulars of Local Responsible Person

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Part B: Particulars of Local Responsible Person

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陳大文		Telephone: 28000000	
	Position: General Manager		E-mail: tchan@cardio.com.hk	
	Contact telephone for public enquiries * : 20000000		Fax : 29000000	
	Mobile telephone for urgent use (24 hours) : 90000000			
	☒ Copy of business registration certificate (with business registration number: BR123467) is enclosed			
B002	Date designated as LRP by the manufacturer: 30/6/2010 ☒ Manufacturer's designation letter is enclosed			(B2) ☐
B003	Established Quality Management System ☐ ISO9001:2000 ☒ ISO9001:2008 or later edition ☐ ISO13485:2003 or later edition ☐ 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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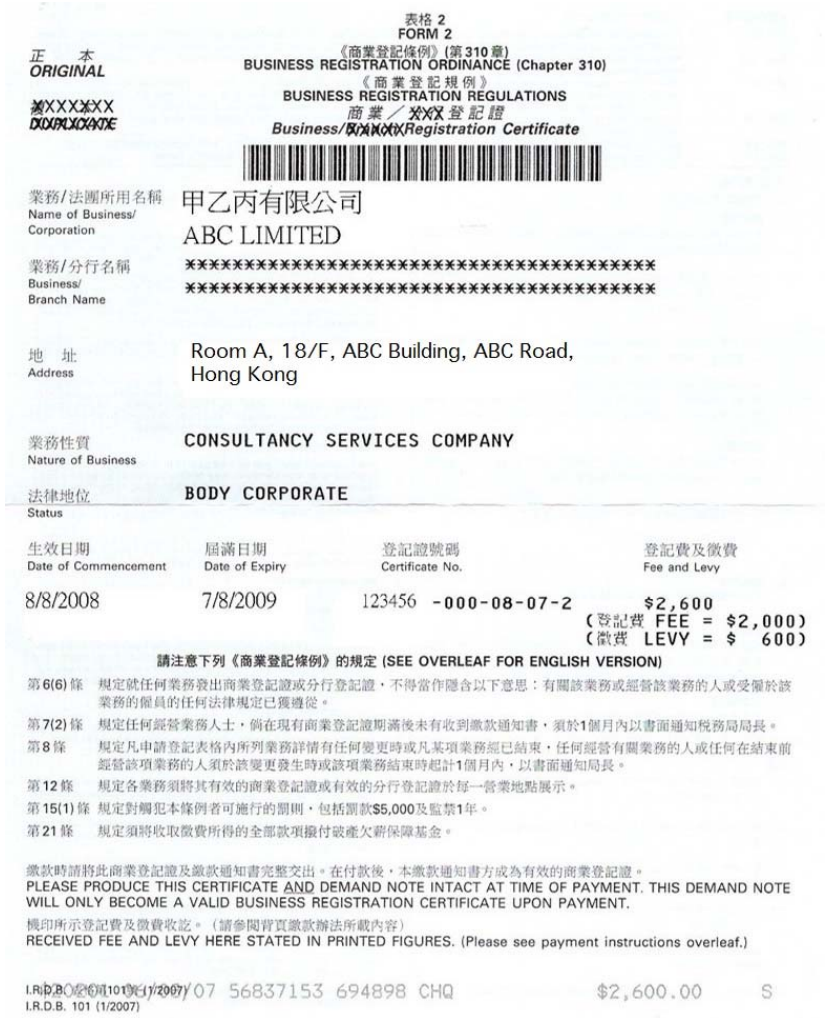
B004	<u>Documented Procedures Established and Maintained</u> ☒ The applicant <u>does not</u> have any medical device listed under the Medical Device Administrative Control System ☒ The procedures indicated in items (i) to (iv) below are enclosed; AND ☒ The procedures indicated in items (v) to (vi) have been established and will be submitted upon request. (i) Keeping of distribution 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 (iv). *(Please go to B005)*; OR ☐ The procedures indicated in items (i) to (iv) have been updated and enclosed.	(B4) ☒
B005	☒ The LRP is also an importer of the device named in Part C Listing No. of Importer: <u>IMP0123456</u> (if applicable)	
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

- Valid Business Registration Certificate of LRP

  (Enclosure B1)



表格 2
FORM 2

正 本
ORIGINAL

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

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

業務/分行名稱
Business/ Branch Name
****

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

業務性質
Nature of Business
CONSULTANCY SERVICES COMPANY

法律地位
Status
BODY CORPORATE

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

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

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

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

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

Part B: Particulars of Local Responsible Person

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,

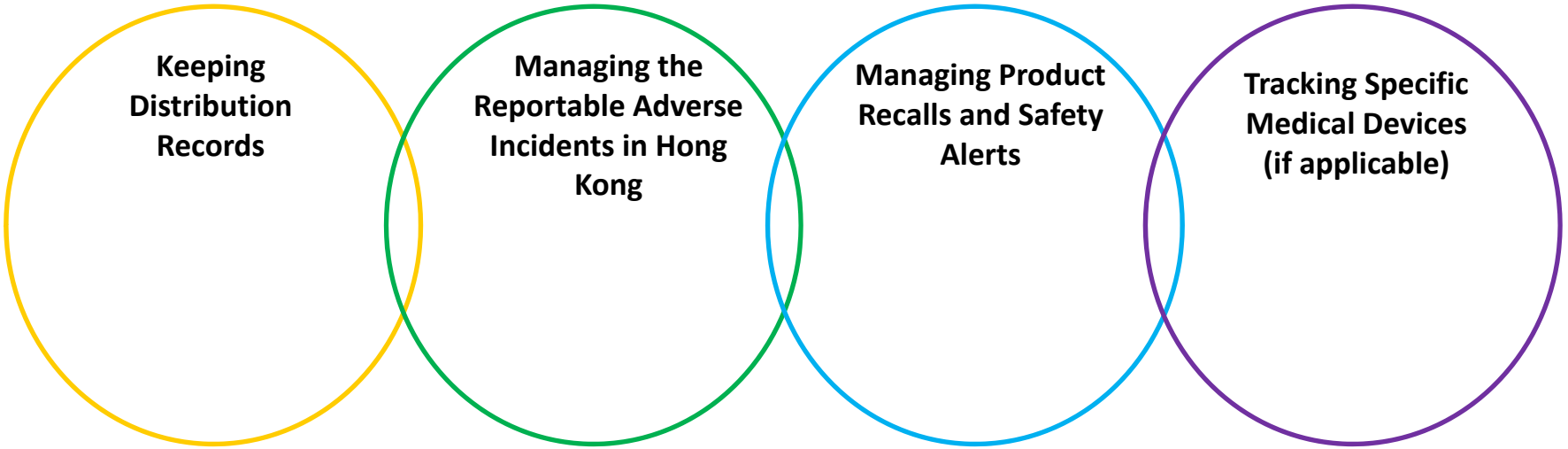
(signature)

(name and title of official signing this letter)

(official chop (if any) of the manufacturer)

Part B: Particulars of Local Responsible Person

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



Part C: Particulars of the Device

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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			

Part C: Particulars of the Device

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 active therapeutic devices in Class III, or intended directly to influence the performance of such devices ☒ intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient ☒ intended for diagnosing in clinical situations where the patient is in immediate danger ☐ intended to administer or exchange energy to or from human body in a potentially hazardous way including ionizing radiation ☐ none of the above	

Part C: Particulars of the Device

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

	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) ☒

Part C: Particulars of the Device

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	

Part C: Particulars of the Device

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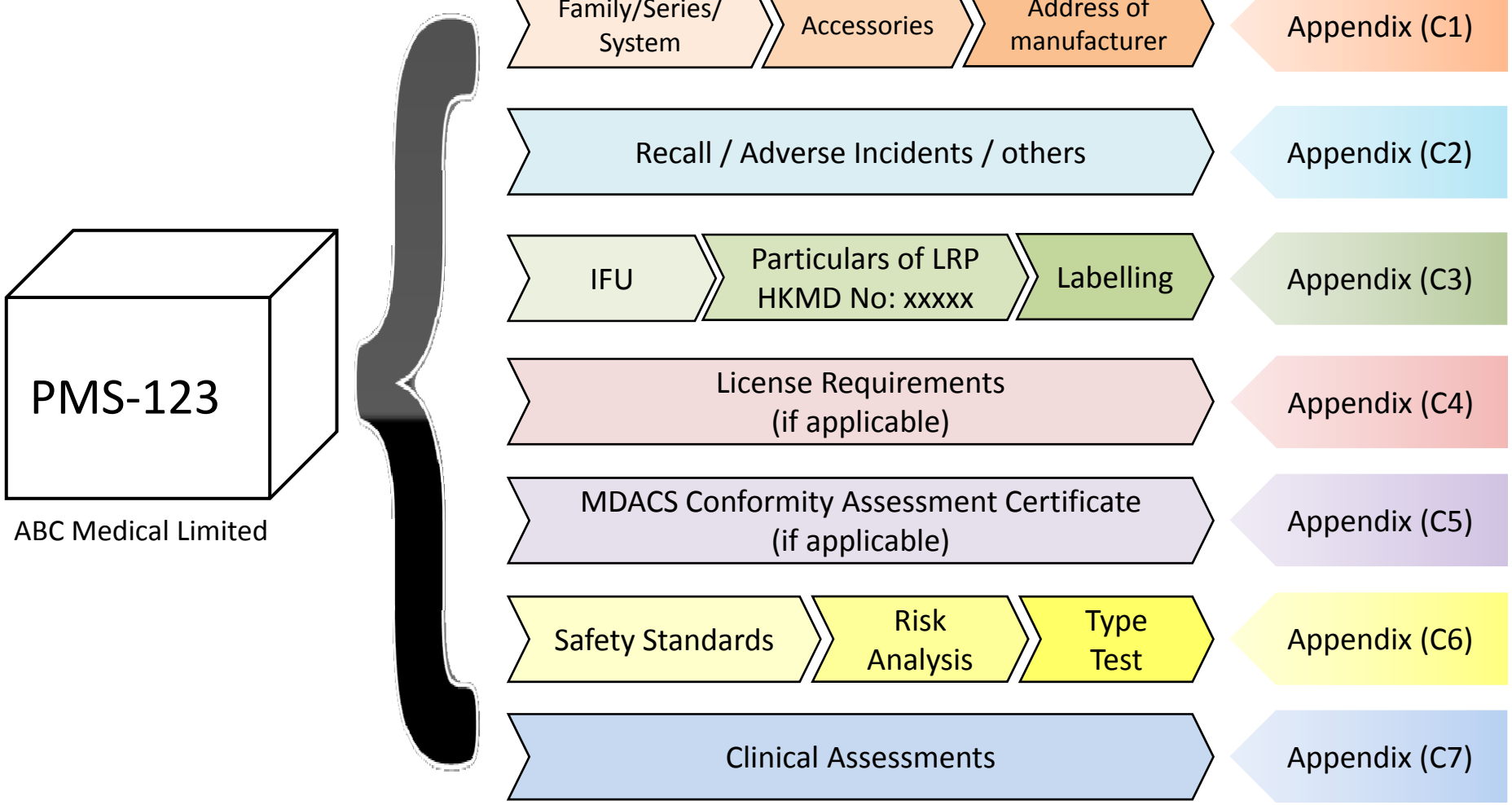
C013	Labelling Requirements Instructions for use are available (Note: Devices intended for self-use by consumers must be accompanied by instructions for use written in both English and Chinese): ☒ in English ☐ in Chinese ☒ A set of device labelling copies is enclosed ☒ Sample of Special Listing Information 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

C015	Conformity Assessment ☐ MDACS Conformity Assessment Certificate issued by one of the Conformity Assessment Bodies recognized by MDCO MDACS Conformity Assessment Body number: _____	(C5) ☐
C016	Safety and Risk Analysis International or national safety standards with which the device complies: *(1) IEC 60601-1:1988+ A1:1991+A2:1995; (2) IEC 60601-1-2:2004; (3) IEC 60601-1-8:2003; (4) IEC 60601-2-49:2001* ☒ 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	(C7) ☒

Part C: Particulars of the Device

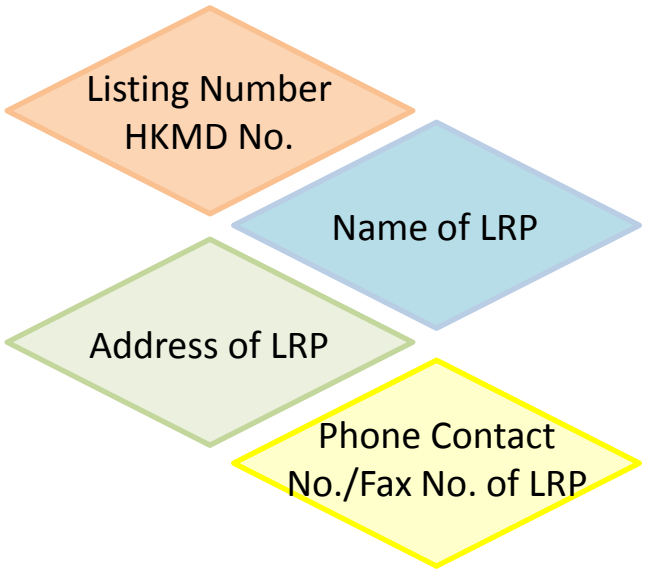


Part C: Particulars of the Device

- Instruction for Use (IFU), Labelling and Special Listing Information (Appendix C3)

  - Bilingual IFU is required for device intended for self-use or self-testing

  - Special Listing Information Includes:



Part C: Particulars of the Device

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- Conformity Assessment Certificate (Appendix C5)
  - **Conformity Assessment Body (CAB)** means a body recognized by the MDCO to engage in the performance of procedures for determining whether the device fulfills the relevant MDACS requirements
  - Recognized CABs: SGS, TUV SUD and BSI

Part D: Marketing Approval & Essential Principles

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Department of Health

Part D: Marketing Approvals & Essential Principles

Note	Part D: Marketing Approvals and Essential Principles	Encl.
D001	Marketing Approvals in Foreign Countries ☒ Approval obtained for the medical device to be placed on the market of the following countries: ☐ Australia (The Therapeutic Goods Administration) ☐ Canada (Health Canada) ☒ Member countries of European Union that have implemented the European Council Directives 90/385/EEC and 93/42/EEC and a copy of the EC Declaration of Conformity is enclosed ☐ Japan (Ministry of Health, Labour and Welfare) ☒ United States of America (U.S. Food and Drug Administration) ☐ 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 in accordance with the EU Medical Device Directives and Essential Principles Declaration of Conformity are enclosed	(D1) ☒

Part D: Marketing Approvals & Essential Principles

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Marketing Approvals(Appendix D1)

- Other than conformity assessment certificates issued by CABs recognised by MDCO, applicants can also choose to provide evidence of specific marketing approvals to prove that the device conforms to the Essential Principles of Safety and Performance

- Marketing Approvals currently accepted by MDCO:
  - Certificates issued by founding members of GHTF:
    1. Australia
    2. Canada
    3. The European Union(Countries that implements MDD)
    4. Japan
    5. USA
  - China (Trial period: from 1st June, 2018 to 30th September, 2018)

Part D: Marketing Approvals & Essential Principles

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- Marketing Approvals (Appendix D1)- Conformity to the Essential Principles
  - If the device had obtained marketing approvals from the GHTF founding members on or after 1st January, 2005, then the applicant has to provide:
    - Essential Principles Conformity Checklist (MD-CCL); or
    - Essential Requirements Checklist prepared according to the European Medical Device Directives and a Essential Principles Declaration of Conformity (GN-02 Annex 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*	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

EU Essential Requirements Checklist

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Annex I: Essential Requirements Council Directive 93/42/EEC	Proof document (documented evidence / Reference

Essential Requirements according to Council Directive 93/42/EEC Annex I	Appli-cable (Y/N/A)	Applied Standard / Proof Document *Note: Delete standard from column, if not applicable*		Remark	ER Com-pliant (Y/N/A)
I General Requirements					
1. The devices must be designed and manufactured in such a way that, when used on the conditions and for the purposes intended, 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 intended 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. This shall include: reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users)	Y	EN ISO 13485 EN ISO 14971 EN 62366 MEDDEV 2.7.1 EN 980 EN 1041 EN ISO 10993-1 EN ISO 14602 EN ISO 14630 EN ISO 21534 EN ISO 11607-1 EN ISO 11607-2 EN 556-1 EN ISO 11137-1 EN ISO 11137-2 EN ISO 11737-1 EN ISO 11737-2 EN ISO 17665-1 EN ISO 17664	QM Certificate Risk Management Report SEV EN 62366 Clinical Evaluation Report SEV EN 980 SEV EN 1041 SEV EN ISO 10993-1 SEV EN ISO 14602 SEV EN ISO 14630 SEV EN ISO 21534 SEV EN ISO 11607-1 SEV EN ISO 11607-2 SEV EN 556-1 SEV EN ISO 11137-1 SEV EN ISO 11137-2 SEV EN ISO 11737-1 SEV EN ISO 11737-2 SEV EN ISO 17665-1 SEV EN ISO 17664	N/A	Y
2. The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:	Y	EN ISO 13485 EN ISO 14971 EN ISO 14630 EN ISO 21534 EN ISO 11607-1 EN ISO 11607-2	QM Certificate Risk Management Report SEV EN ISO 14630 SEV EN ISO 21534 SEV EN ISO 11607-1 SEV EN ISO 11607-2	N/A	Y
2. (1) eliminate or reduce risks as far as possible (inherently safe design and construction),	Y	EN ISO 14971	Risk Management Report	N/A	Y
2. (2) where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,	Y	EN ISO 14971 EN 62366	Risk Management Report SEV EN 62366	N/A	Y

Essential Principles Declaration of Conformity (GN-02 Annex 3)

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Department of Health

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 Samples

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Overseas Marketing Approvals

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General Medical Device

Countries	Marketing Approvals
Australia	Australia Therapeutic Goods Administration (TGA) Device Registration Licence
Canada	Health Canada (HC) Medical Device Licence
Japan	Japan Ministry of Health, Labour and Welfare (MHLW) • Pre-market Certification (Ninsho) from a Japanese Registered Certification Body • Pre-market Approval (Shonin) from MHLW
USA	• Premarket Notification (PMN/510K clearance) • Premarket Approval (PMA)
EU	• Directive 93/42/EEC (MDD) • Directive 90/385/EEC (AIMD)

EU
EC Marketing Approval (by EU NB)

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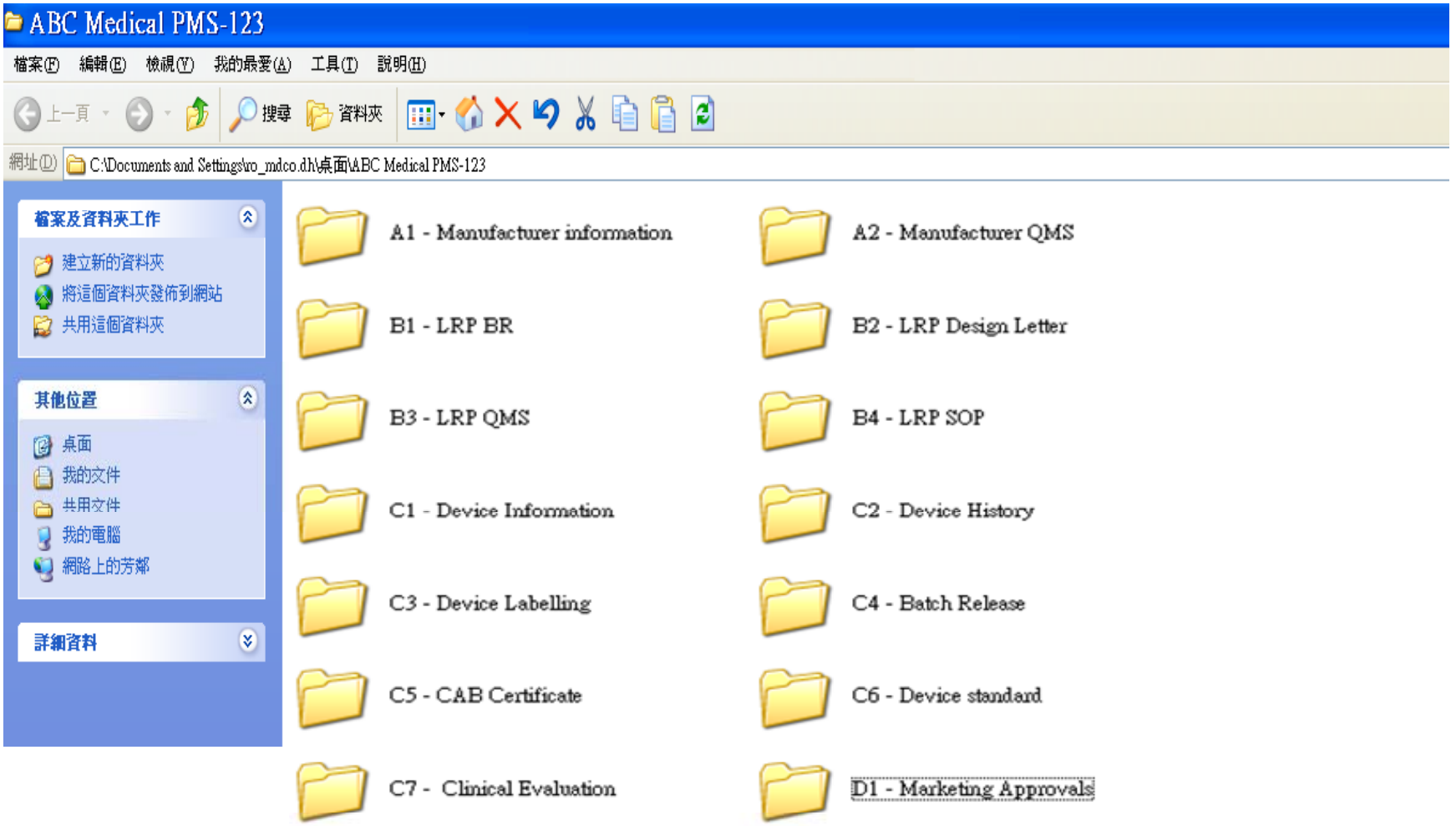
Department of Health

MDD/AIMD Conformity Assessment Procedures

	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	-
Declaration of Conformity (DoC)	Annex VII	Annex 7

Preparation of Application Documents



Further Information

- Online Resources(www.mdco.gov.hk)
  - Related Guidance notes, Technical References and Codes of Practice https://www.mdco.gov.hk/english/mdacs/mdacs_gn/mdacs_gn.html
  - Application Form https://www.mdco.gov.hk/english/download/download.html
  - List of Medical Device https://www.mdco.gov.hk/english/sd/sd_ld/sd_ld.php

Further Information

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 Incident 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

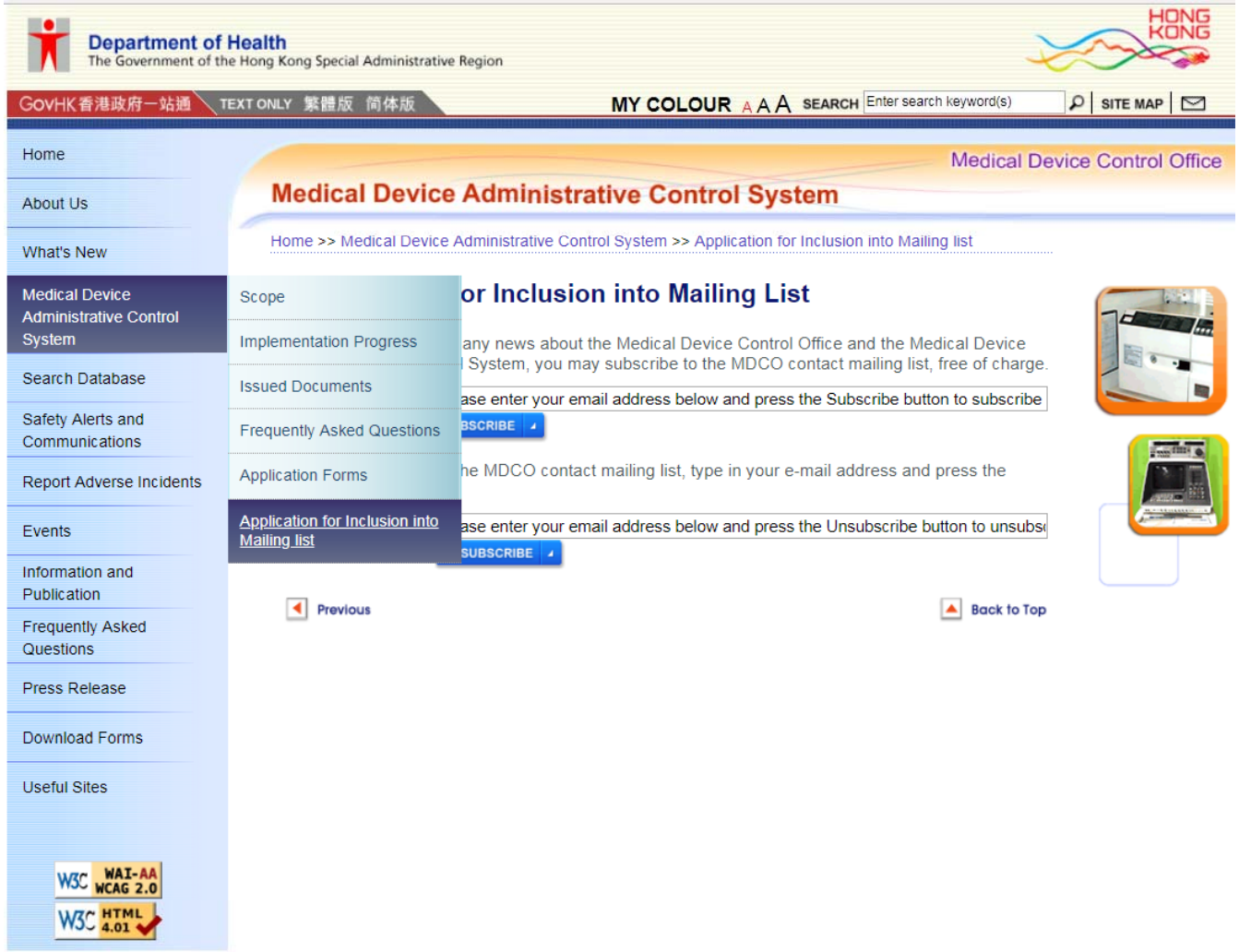
Issued Documents
Technical Reference

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

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

Other Information



Contact Us

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Department of Health

Department of Health
Medical Device Control Office (MDCO)

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

Phone: 3107 8484

Fax: 3157 1286

Email:
mdco@dh.gov.hk

Website:
www.mdco.gov.hk