

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

2019-01-10

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Workshop



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



Workshop on Application for listing of Class II/III/IV Medical Devices

Please do Exercise 1 now

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

Thank you!



Content

- 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



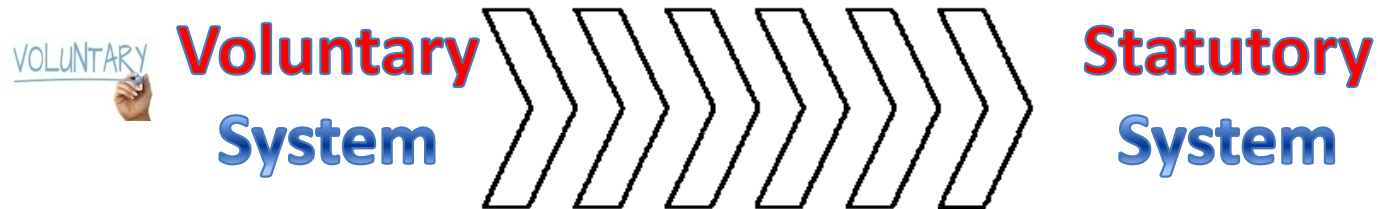
July 2003
<<Regulation of Medical Devices>>
Consultation Document



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



■ 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

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

Medical Device Administrative Control System (MDACS)

Pre-market Control		Post-market Control
<p>Listing System</p> <p>(1) Medical Device</p> <ul style="list-style-type: none"> ➤ General Medical Devices (Class II – IV) <p>(2) Traders</p> <ul style="list-style-type: none"> ➤ Local Responsible Person (LRP) ➤ Local Manufacturer ➤ Importer ➤ Distributor 	<p>Conformity Assessment Body (CAB)</p> <p>Recognition Scheme</p>	<p>Medical Device Safety Alert System & Adverse Incidents Reporting System</p>



MDACS

■ 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



- 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 <ul style="list-style-type: none"> ➢ Local Responsible Person ➢ Local Manufacturer/Importer/Distributor 	■ Licensing of Traders <ul style="list-style-type: none"> ➢ Authorised Representative ➢ Local Manufacturer/Importer/Distributor
	■ CAB Recognition Scheme	■ CAB Recognition Scheme
Post-market Control	■ Medical Device Safety Alert System ■ Adverse Incidents Reporting System	■ Medical Device Safety Alert System ■ Adverse Incidents Reporting System

Listing of Traders

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



Local Responsible Person (LRP)

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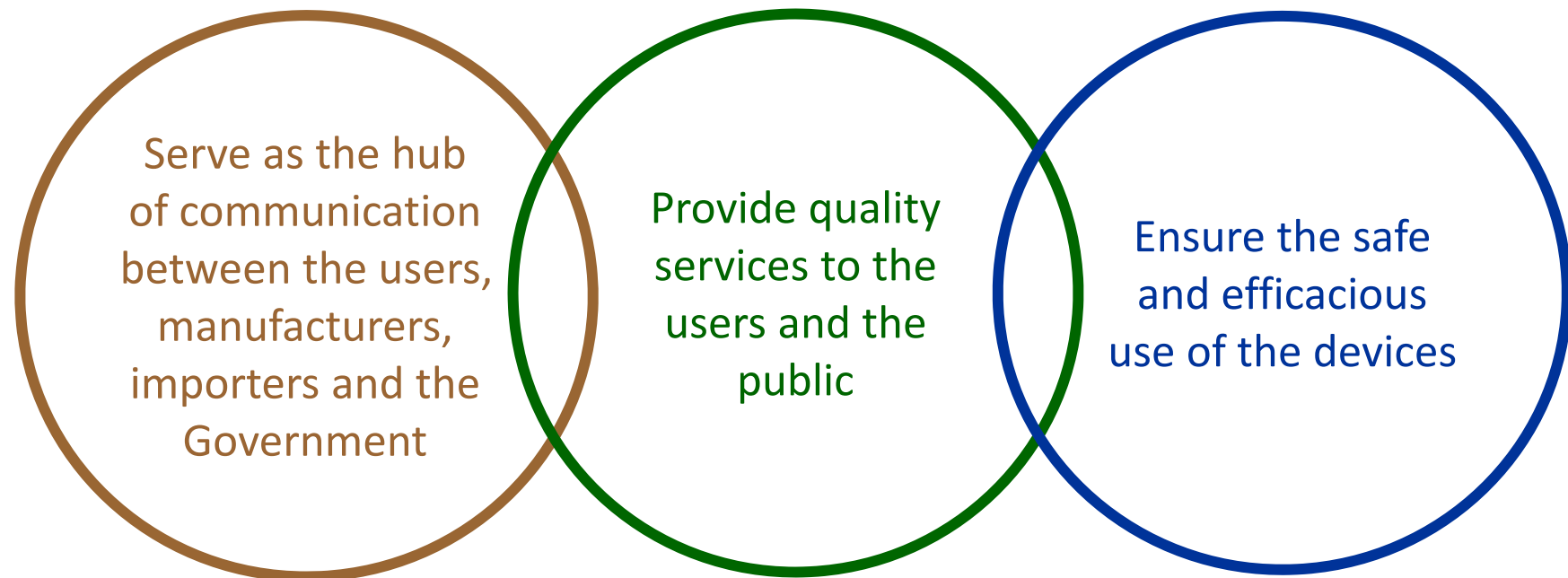
LRP

- What is LRP?
 - 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 device under the MDACS and bears multiple responsibilities in relation to the listed device



LRP

■ The need for LRP





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 Control Office

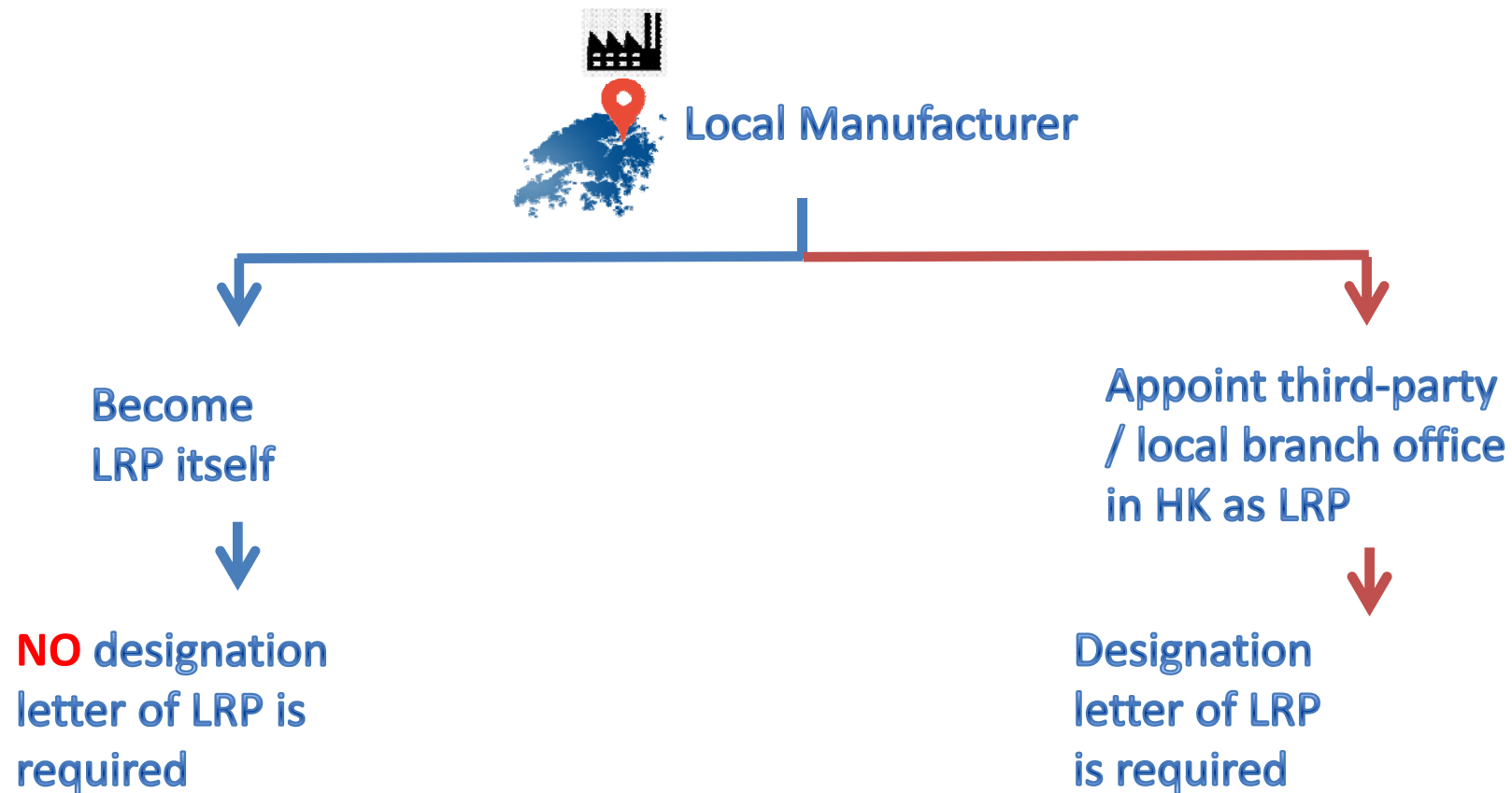
(Applicant should submit completed application form and required information)

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



LRP

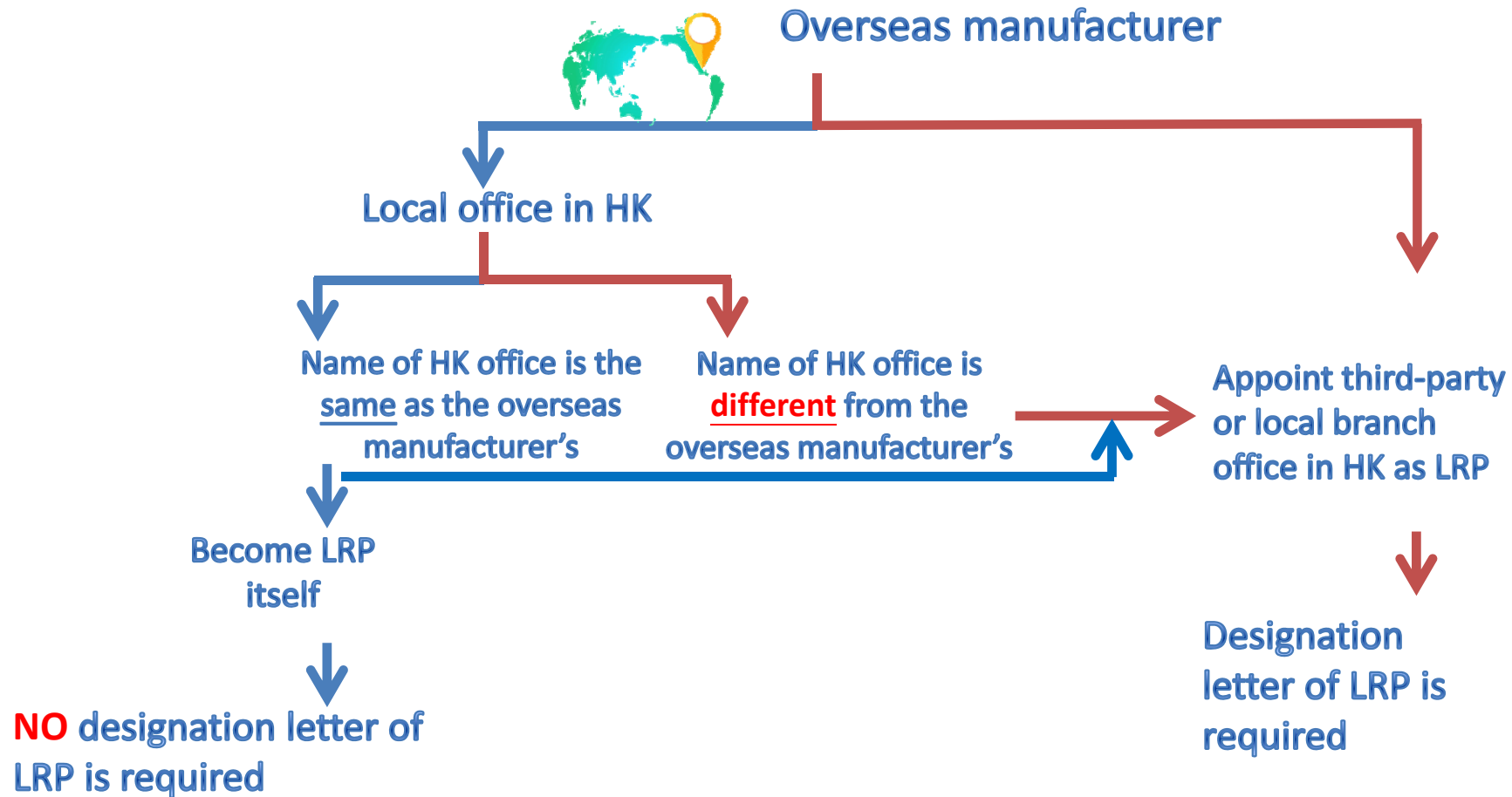
■ Relationship between LRP and **Local Manufacturer**





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,

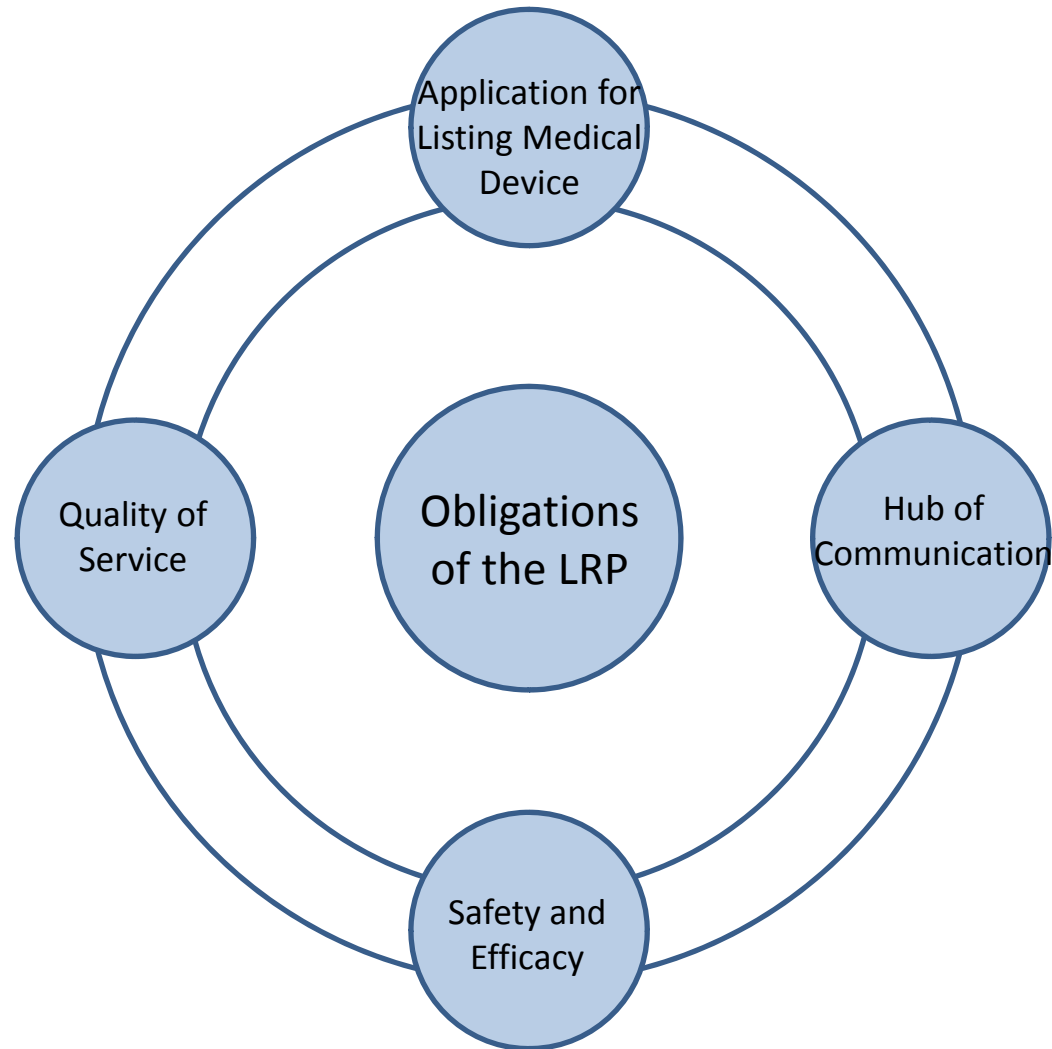
(signature)

(name and title of official signing this letter)

(official chop (if any) of the manufacturer)



LRP





LRP



■ Application for listing medical devices

- 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

■ 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

■ 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

■ 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 in which the “Special Listing Information” is printed, such as a receipt

Local Manufacturer/Importer/Distributor



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Local Manufacturer/Importer/Distributor

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**

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



■ Establish documented procedures

	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
<u>Making records available for inspection</u>	✓ (Records and documents regarding to QMS or products)	✓ (e.g. transaction record)	✓ (e.g. transaction record)
<u>Reporting adverse incidents</u> (Guidance Note GN-03)	✓	✓	✓
<u>Notifying the changes</u>	✓ (Including any major changes in relation to the QMS)	✓	✓
<u>Conforming to the advertising requirements</u>	✓	✓	✓
Others	<input type="checkbox"/> Submit renewal application at least 6 months before the expiry of Listing	<input type="checkbox"/> Submit renewal application at least 3 months before the expiry of Listing	<input type="checkbox"/> Submit renewal application at least 6 months before the expiry of Listing

Local Manufacturer/Importer/Distributor

■ 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 procedures	✓	✓	✓
Other information	<ul style="list-style-type: none"> <input type="checkbox"/> ISO 13485 certificate or equivalent <input type="checkbox"/> List of medical devices manufactured 	<ul style="list-style-type: none"> <input type="checkbox"/> List of medical devices imported 	<ul style="list-style-type: none"> <input type="checkbox"/> List of medical devices distributed



Brief Summary

	LRP	Local Manufacturer	Importer	Distributor
Validity of listing	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 procedures	✓	✓	✓	✓
Other Information	<ul style="list-style-type: none"> ❑ Designation Letter ❑ QMS certificate (if applicable) 	<ul style="list-style-type: none"> ❑ ISO 13485 certificate or equivalent ❑ List of medical device manufactured 	<ul style="list-style-type: none"> ❑ List of medical devices imported ❑ QMS certificate (if applicable) 	<ul style="list-style-type: none"> ❑ List of medical devices distributed ❑ QMS certificate (if applicable)



Brief Summary

Requirments	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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Short Break

Classification of General Medical Devices

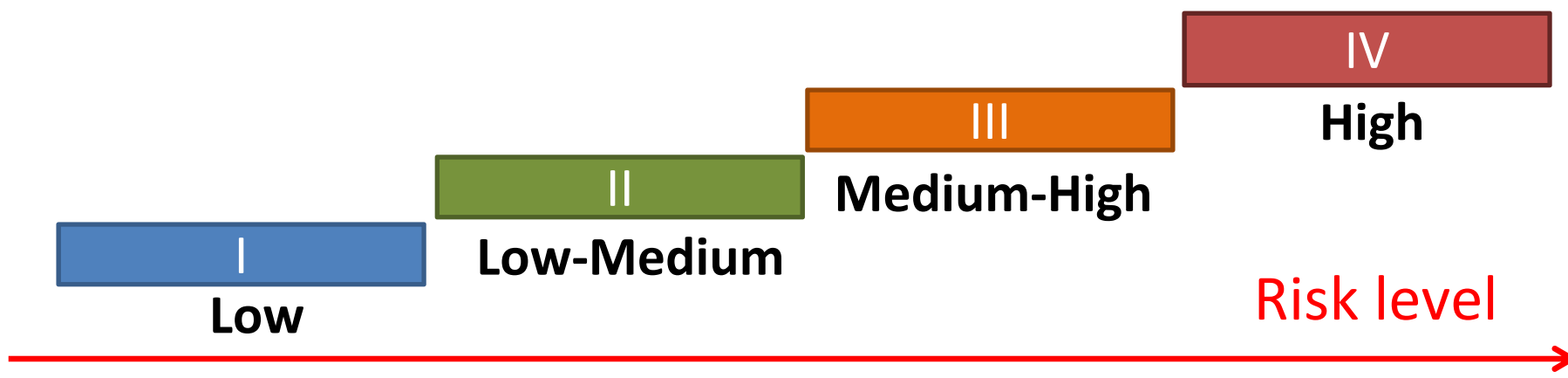
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Classification of General Medical Device

- 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

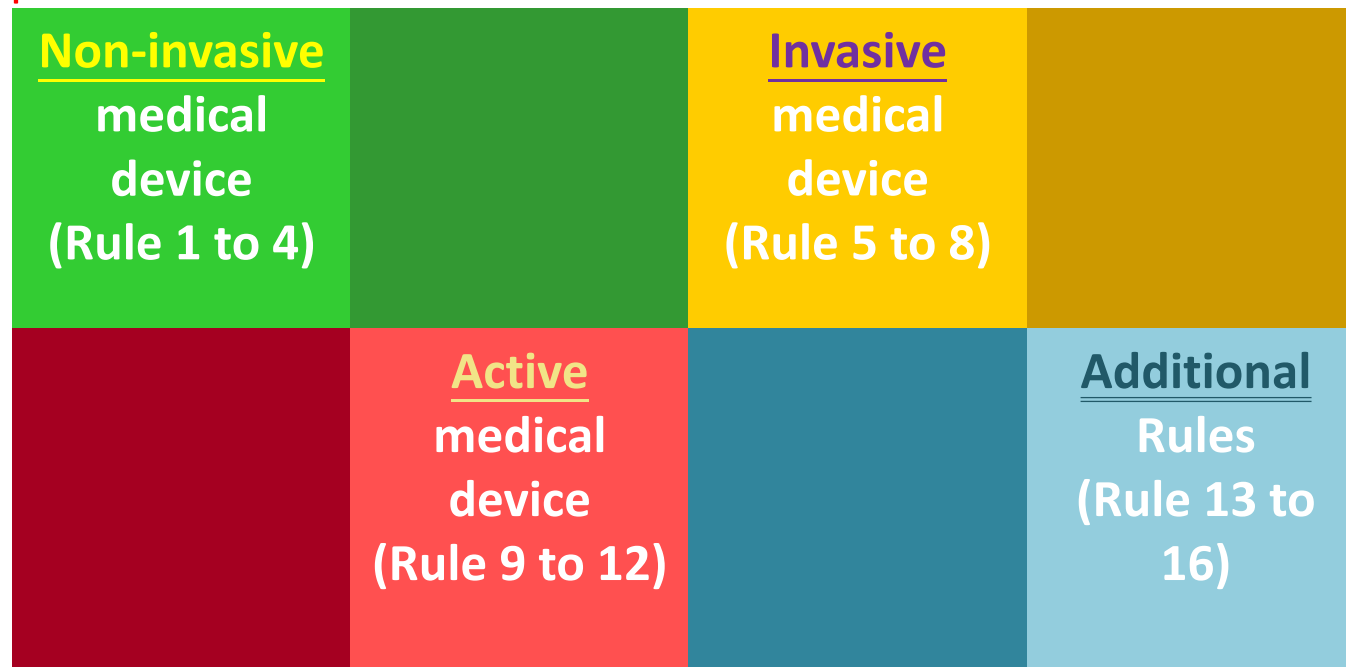
Risk Factor <i>(including but not limited to)</i>			
Intended Use of the device	<u>Duration of Contact</u> between Human Body and the medical device	Extent of <u>invasiveness</u>	Any <u>drug</u> or <u>energy</u> delivered to the patient

[Basic Information of Classification](#)

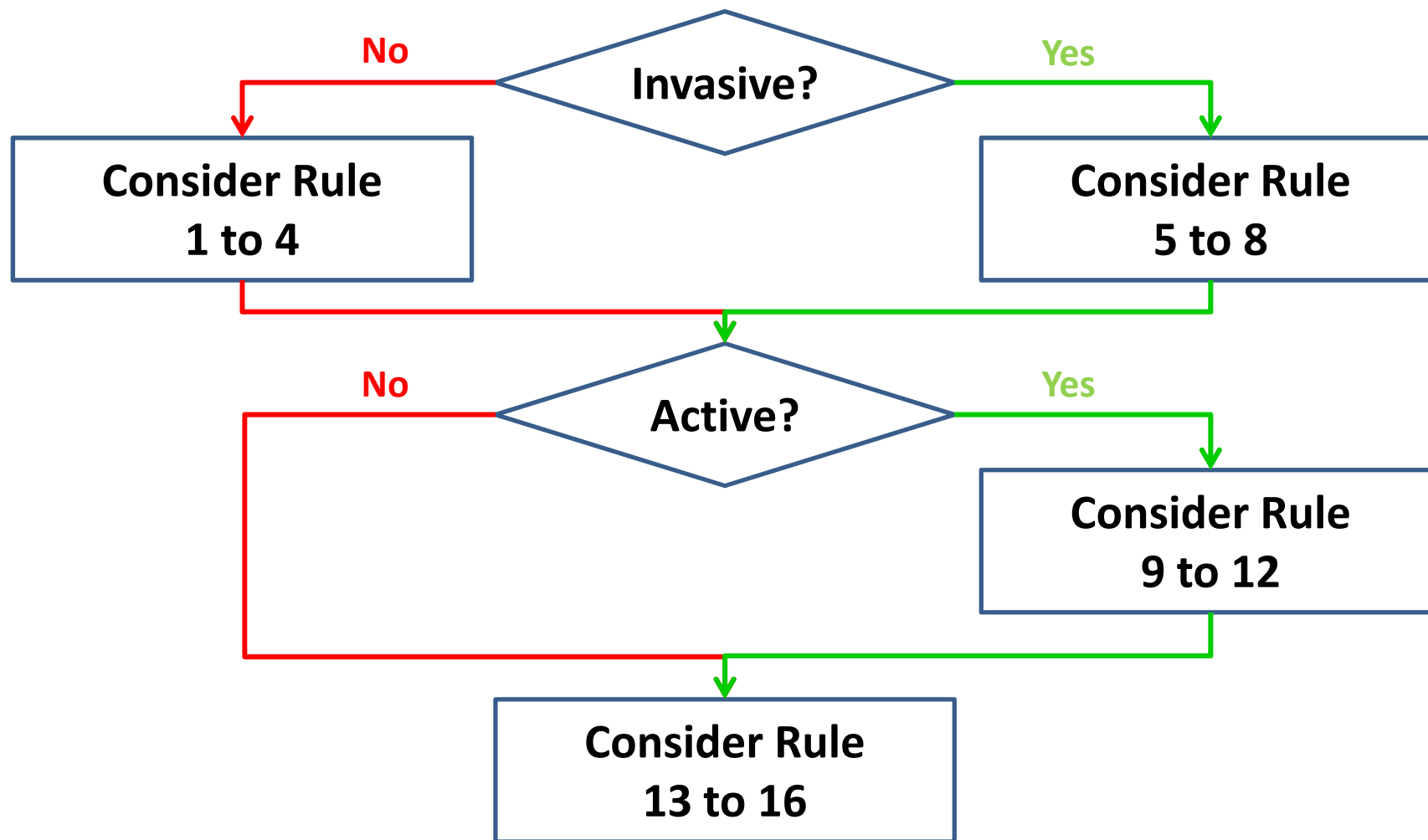


Classification of General Medical Devices

- 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)

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**?

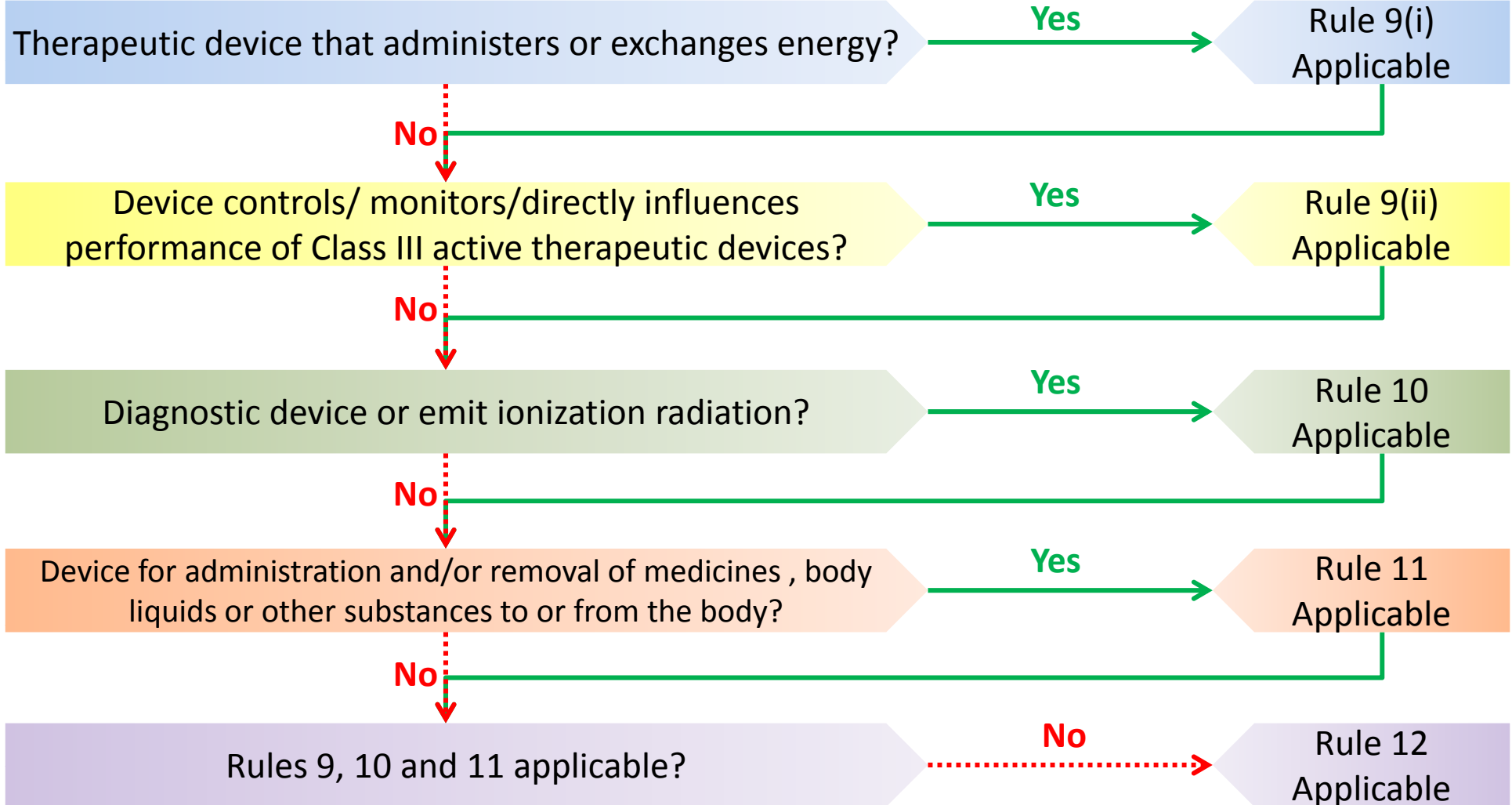
Yes

Rule 7
Applicable

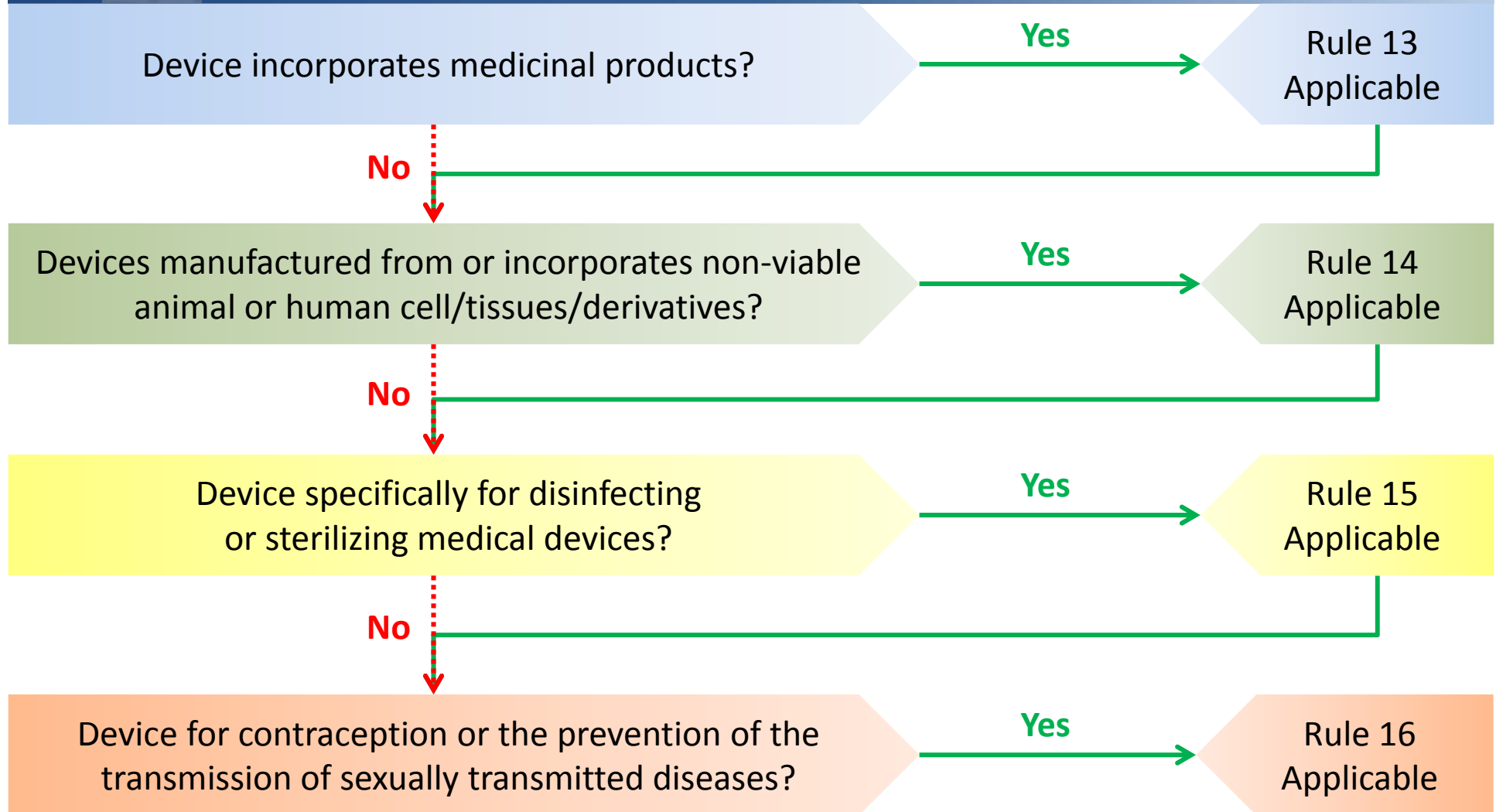
No (i.e. device is an implantable device
or for long-term use)


Rule 8
Applicable

Classification Rules 9 to 12 (Active Medical Device)



Classification Rules 13 to 16 (Additional Rules)



The background of the slide is a faded image of medical equipment, including a patient bed with a monitor displaying vital signs and waveforms, and another monitor showing data. The text is overlaid on a dark blue rectangular box.

Exercise(2) Classification of General Medical Devices





Exercise (2)

Classification of General Medical Devices

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	



Exercise (2)

Classification of General Medical Devices

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



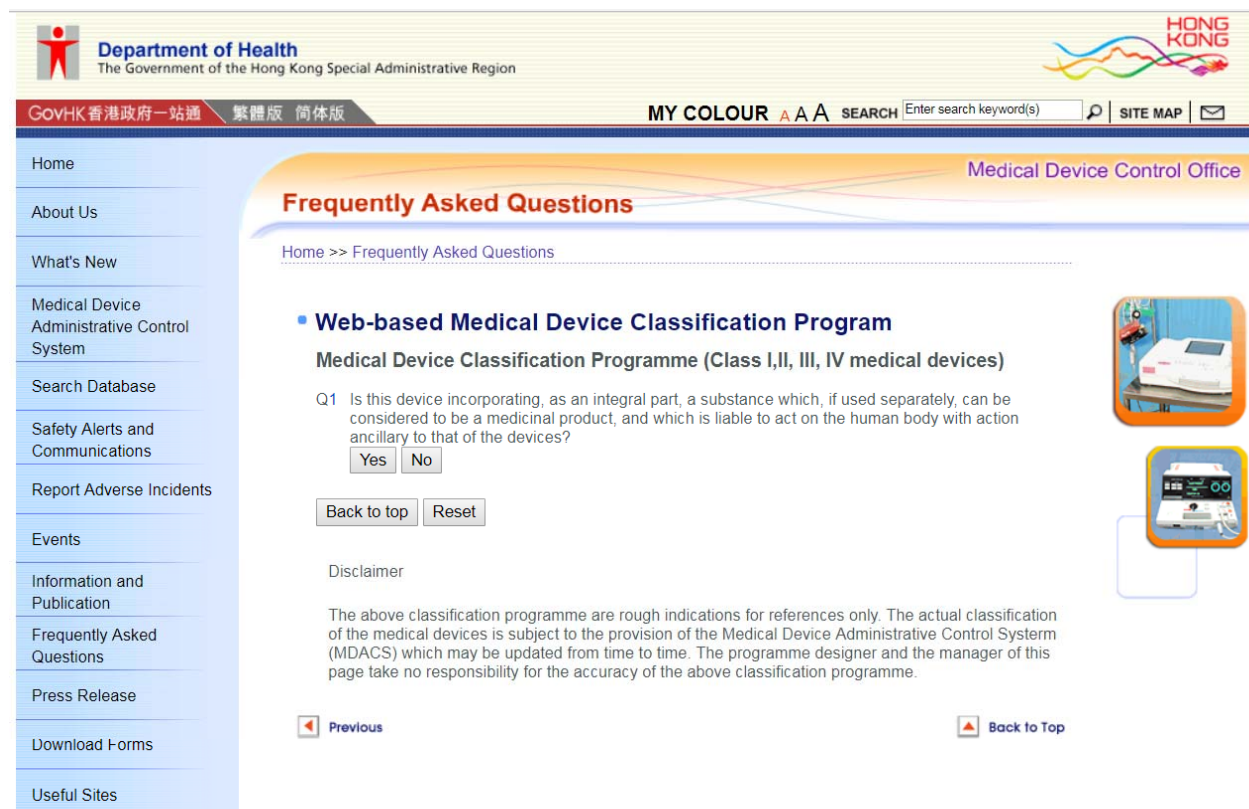
4 Surgical laser

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>



The screenshot shows the Department of Health website's 'Frequently Asked Questions' page for the Medical Device Classification Program. The page features a navigation menu on the left with links such as 'Home', 'About Us', 'What's New', 'Medical Device Administrative Control System', 'Search Database', 'Safety Alerts and Communications', 'Report Adverse Incidents', 'Events', 'Information and Publication', 'Frequently Asked Questions', 'Press Release', 'Download Forms', and 'Useful Sites'. The main content area is titled 'Frequently Asked Questions' and includes a breadcrumb trail 'Home >> Frequently Asked Questions'. A prominent heading reads 'Web-based Medical Device Classification Program' followed by 'Medical Device Classification Programme (Class I,II, III, IV medical devices)'. A question (Q1) asks: '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 'Yes' and 'No' buttons. There are also 'Back to top' and 'Reset' buttons. A disclaimer states: 'The above classification programme 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 programme.' At the bottom of the content area, there are 'Previous' and 'Back to Top' navigation links. The page also features a search bar, a 'SITE MAP' link, and a 'GOVHK 香港政府一站通' banner.

Preparation of Application Documents

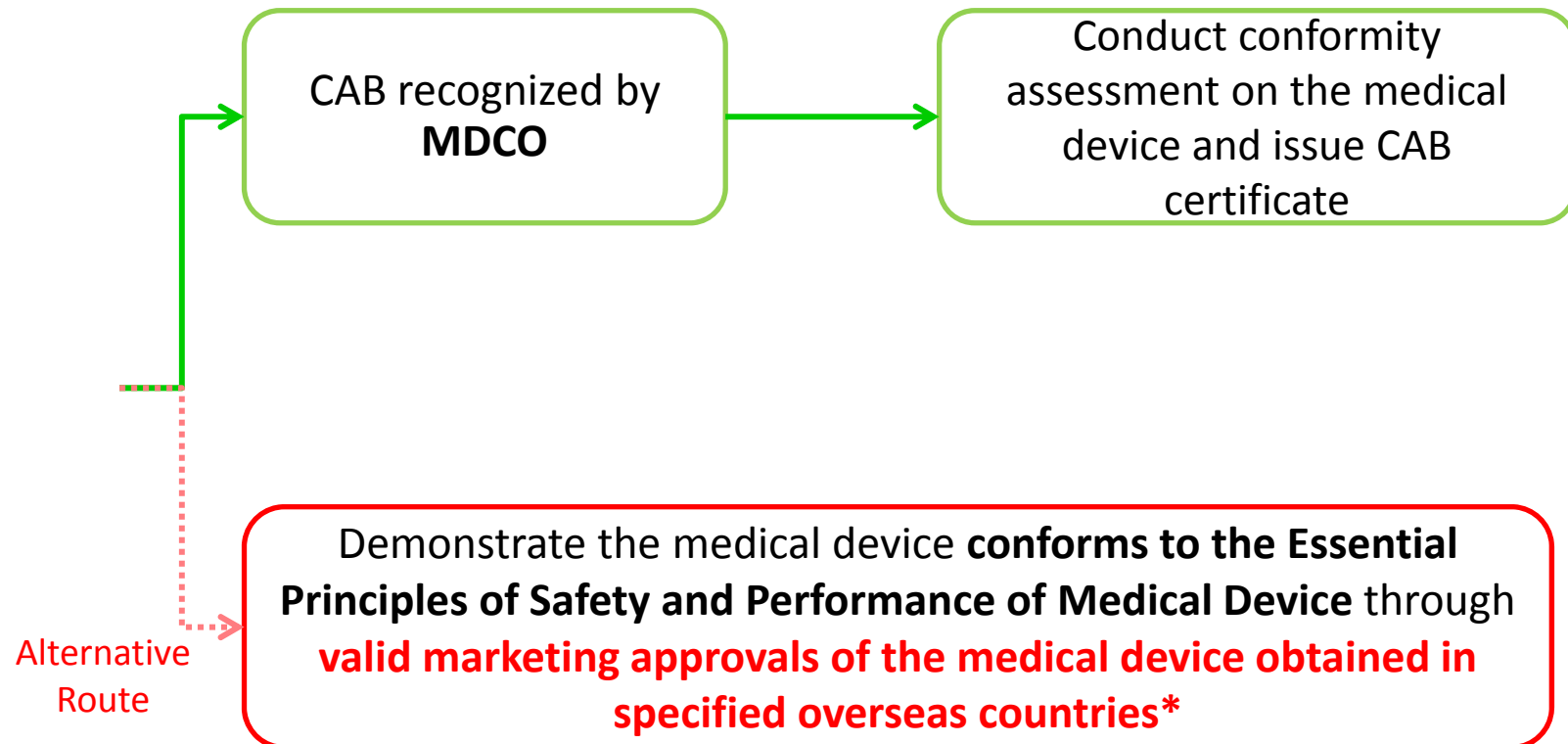
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Conformity Assessment Routes



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



Preparation of Application Documents



- Application Form
 - Part A: Particulars of Manufacturer
 - Part B: Particulars of Local Responsible Person
 - Part C: Particulars of the Device
 - Part D: Marketing Approvals and Essential Principles

Part A: Particulars of Manufacturer

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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 A: Particulars of Manufacturer



■ Manufacturer's Quality Management System

ISO 13485 Certificate *(Enclosure A2)*

CAB SYSTEM LTD

CERTIFICATE

for a

Quality Management System

according to

DIN EN ISO 9001:2000 , JIS Q 9001:2000
EN ISO 13485:2003
ISO 13485:2003

CAB System Ltd, hereby certifies that

Manufacturer: ABC MEDICAL LTD
1324N. Derby Road,
Arlington VA, USA

has established and maintains a quality management system. Conformance with the requirements of the standards has been audited.
The organization is subject to a yearly surveillance audit.

Registration No.: 12345678910

Report No.: 1234567

Date of expiry: 23.10.2009

Scope: refer to Attachment

Certification Body

Yokohama, 24.10.2006



Part B: Particulars of Local Responsible Person



Part B: Particulars of Local Responsible Person

Note	Part B: Particulars of Local Responsible Person (LRP)		Encl.	
B001	LRP's name*	<i>in English</i>	CARDIO SUPPLIES LTD	(B1) <input 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: <u>BR123467</u>) is enclosed				
B002	Date designated as LRP by the manufacturer: 30/6/2010		(B2) <input type="checkbox"/>	
	☒ Manufacturer's designation letter is enclosed			
B003	<u>Established Quality Management System</u>		(B3) <input type="checkbox"/>	
	<input type="checkbox"/> ISO9001:2000	<input checked="" type="checkbox"/> ISO9001:2008 or later edition		
	<input type="checkbox"/> ISO13485:2003 or later edition	<input type="checkbox"/> None		
☒ 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 (iv) below are enclosed; AND</p> <p><input checked="" type="checkbox"/> The procedures indicated in items (v) to (vi) have been established and will be submitted upon request.</p> <p>(i) Keeping of distribution records</p> <p>(ii) Management of product recalls and field safety notices</p> <p>(iii) Handling of reportable adverse incidents in Hong Kong</p> <p>(iv) Tracking of specific medical devices (if applicable)</p> <p>(v) Complaints handling</p> <p>(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 (iv). (<i>Please go to B005</i>); OR</p> <p><input type="checkbox"/> The procedures indicated in items (i) to (iv) have been updated and enclosed.</p>	(B4) <input checked="" type="checkbox"/>
B005	<p><input checked="" type="checkbox"/> The LRP is also an importer of the device named in Part C</p> <p>Listing No. of Importer: <u>IMP0123456</u> (if applicable)</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 / 登記證
Business / Registration Certificate

XXXXXX
XXXXXXXXXXXX

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
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

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. © 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 and address
- ✓ Descriptions of the device(s)
- ✓ Manufacturer's signature and official stamp (if applicable)
- ✓ Date

<Name of LRP>
<Address of LRP>

Dear Sirs,

<Name of manufacturer>
<Address of manufacturer>

Date:

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)

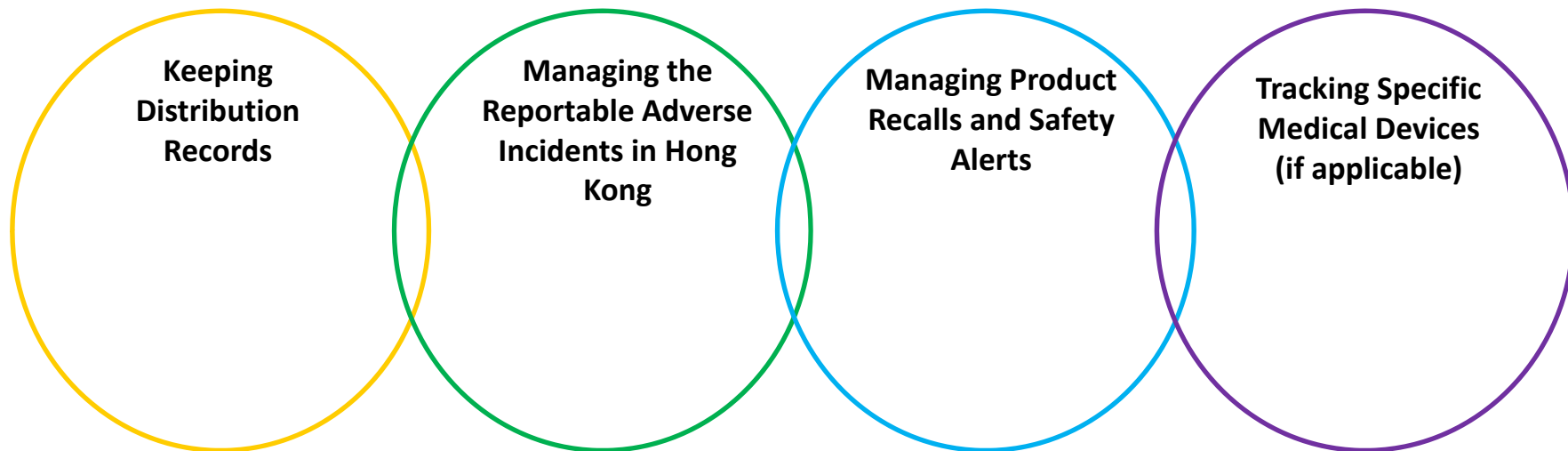
(name and title of official signing this letter)

(official chop (if any) of the manufacturer)



Part B: Particulars of Local Responsible Person

- Documented Procedure of LRP (Appendix B4)
 - The documented procedures 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





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 MDS-01 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			



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 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)</u> (Use separate sheet if required): (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><u>Labelling Requirements</u></p> <p>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):</p> <p><input checked="" type="checkbox"/> in English <input type="checkbox"/> in Chinese</p> <p><input checked="" type="checkbox"/> A set of device labelling copies is enclosed</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><u>Licencing Requirements</u></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"/>

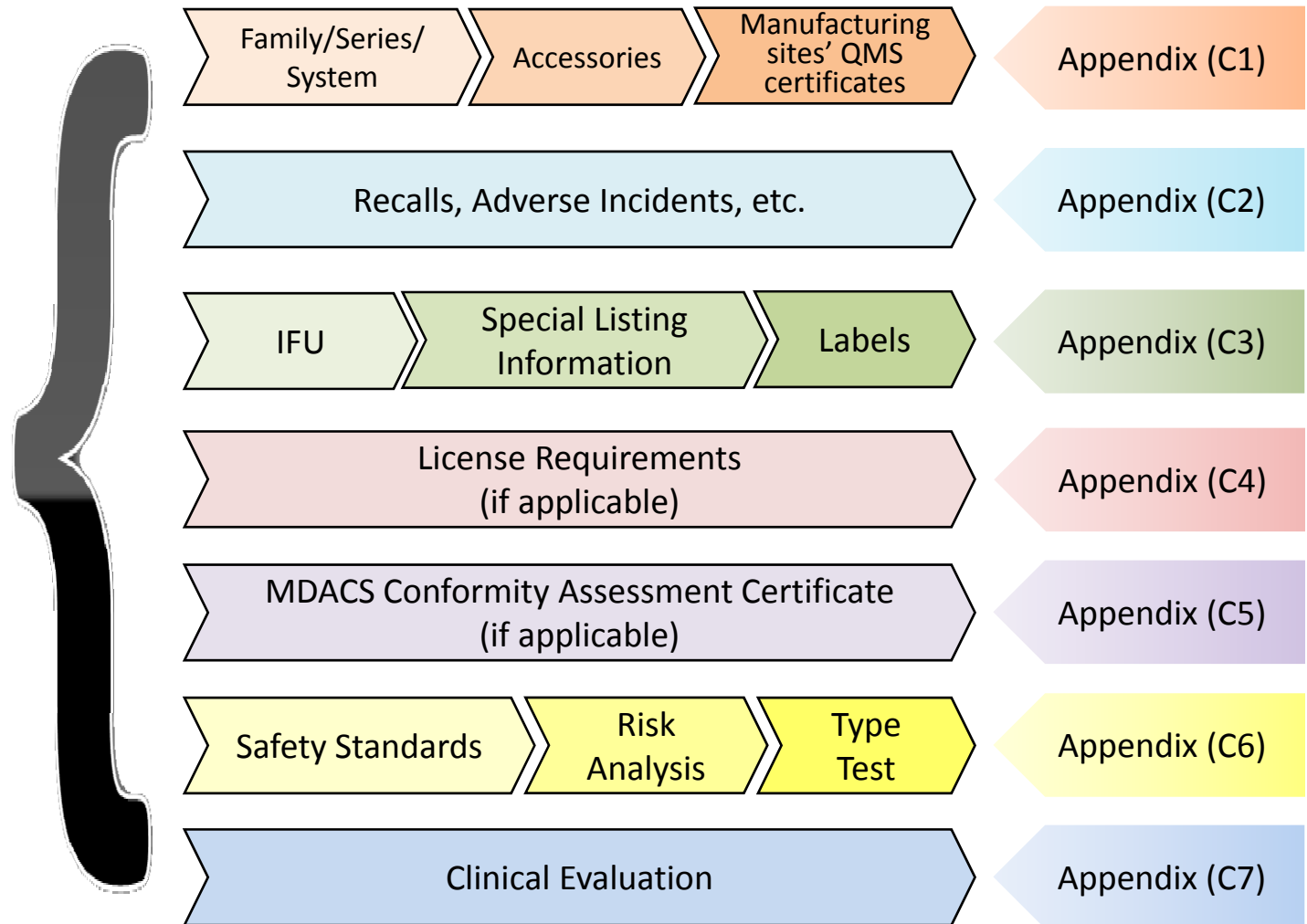
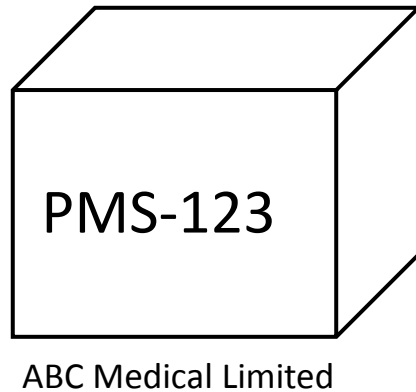


Part C: Particulars of the Device

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 MDCO</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 60601-1:1988+ A1:1991+A2:1995; (2) IEC 60601-1-2:2004; (3) IEC 60601-1-8:2003; (4) IEC 60601-2-49:2001</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

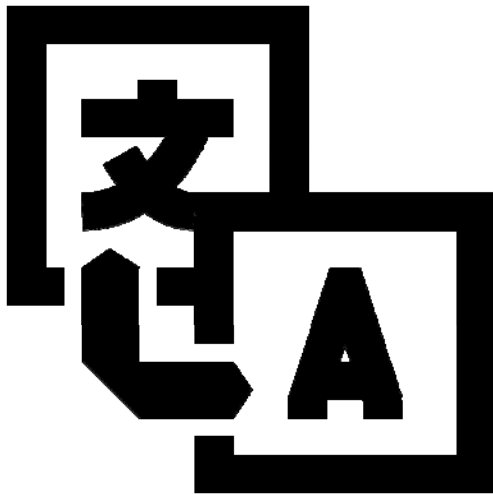




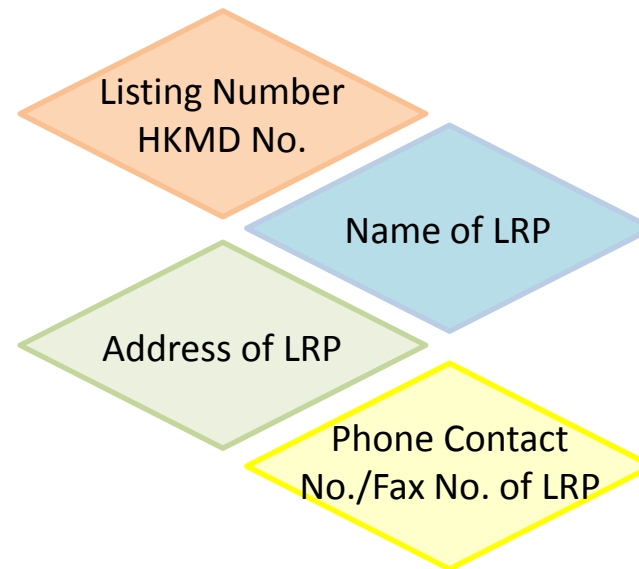
Part C: Particulars of the Device

■ Instruction for Use (IFU), Labels 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

- 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:

Part D: Marketing Approval & Essential Principles



Part D: Marketing Approvals & Essential Principles

Note	Part D: Marketing Approvals and Essential Principles	Encl.
D001	<p><u>Marketing Approvals in Foreign Countries</u></p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Approval obtained for the medical device to be placed on the market of the following countries: <ul style="list-style-type: none"> <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 the European Council Directives 90/385/EEC and 93/42/EEC and a copy of the EC Declaration of Conformity is enclosed <input type="checkbox"/> Japan (Ministry of Health, Labour and Welfare) <input checked="" type="checkbox"/> United States of America (U.S. Food and Drug Administration) <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 in accordance with the EU Medical Device Directives and Essential Principles Declaration of Conformity are enclosed 	(D1) <input checked="" type="checkbox"/>

Part D: Marketing Approvals & Essential Principles

■ 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



Part D: Marketing Approvals & Essential Principles



■ 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)



衛生署
Department of Health

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)



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 Annex 3)

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





Overseas Marketing Approvals

■ General Medical Device

Countries	Marketing Approvals
Australia	Australia Therapeutic Goods Administration (TGA) ARTG Certificate
Canada	Health Canada (HC) Medical Device Licence
Japan	Japan Ministry of Health, Labour and Welfare (MHLW) <ul style="list-style-type: none">• Pre-market Certification (Ninsho)• Pre-market Approval (Shonin) from MHLW
USA	<ul style="list-style-type: none">• Premarket Notification (510(k) clearance)• Premarket Approval (PMA)
EU	<ul style="list-style-type: none">• Directive 93/42/EEC (MDD) EC certificates• Directive 90/385/EEC (AIMD) EC certificates



EU

EC Marketing Approval (by EU NB)

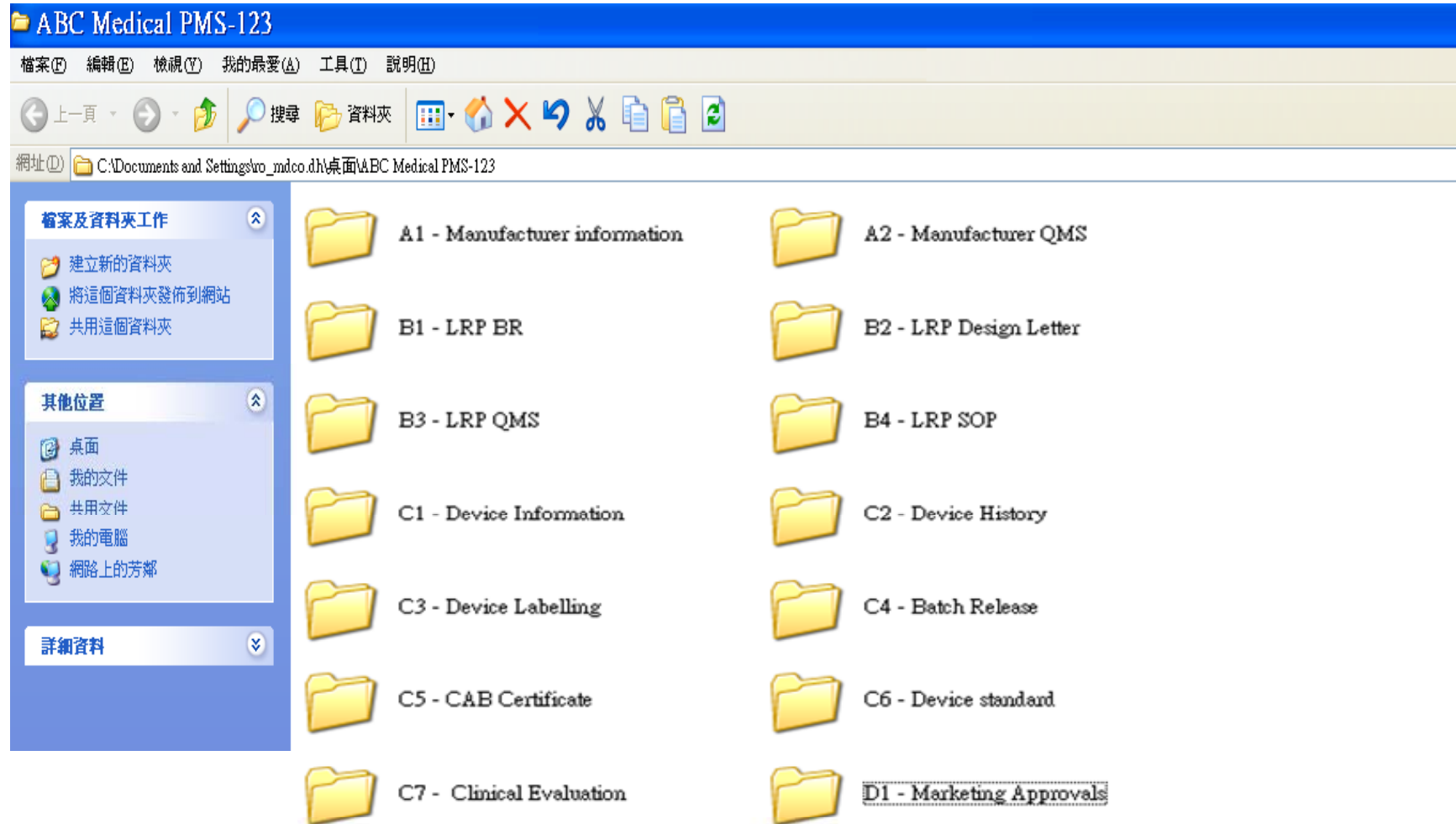


MDD/AIMD Conformity Assessment Procedures

	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	-



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_Id/sd_Id.php



Further Information



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

GOVHK 香港政府一站通 TEXT ONLY 繁體版 简体版 MY COLOUR A A A SEARCH [Enter search keyword(s)] SITE MAP

Home Medical Device Control Office

Medical Device Administrative Control System

Home >> Medical Device Administrative Control System >> Issued Documents

Guidance Notes for the Medical Device Administrative Control System

Issued Documents

- [GN-01S] Supplementary Notes for Submitting Applications for Listing Medical Devices under the Medical Device Administrative Control System
- [GN-02] Guidance Notes for Listing Class II, III & IV Medical Devices (Jul 2011 Edition)
- [GN-03] Guidance Notes for Adverse Incident Reporting by Local Responsible Persons
- [GN-04] Conformity Assessment Framework and Conformity Assessment Bodies
- [GN-06] Guidance Notes for Listing In Vitro Diagnostic (IVD) Medical Devices (Jul 2011 Edition)
- [GN-07] Guidance Notes for Listing of Importers of Medical Devices (Apr 2018 Edition)
- [GN-08] Guidance Notes for Listing of Local Manufacturers
- [GN-09] Guidance Notes for Listing of Distributors

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Issued Documents Guidance Note

Guidance Notes for Definitions and Abbreviations for Medical Device
Administrative control System

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Overview of the Medical Device Administrative Control System

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Guidance Notes for Listing Class II, III & IV Medical Devices

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Guidance Notes for Adverse Incident Reporting by Local Responsible Persons

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Guidance Notes for Listing of Importers of Medical Devices

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Guidance Notes for Listing of Local Manufacturers

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Guidance Notes for Listing of Distributors

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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




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