

## Workshop on Application for Listing Class II/III/IV Medical Devices

#### Medical Device Control Office Department of Health





#### Workshop Agenda

- Exercise 1 (Pre-workshop)
- Medical Device Administrative Control System (MDACS)
- Local Responsible Person (LRP)
- Importer
- Classification of Medical Devices
- Exercise 2/ Break
- How to Prepare Application Documents
- Exercise 3 (Post-workshop)
- Q&A



## Exercise 1 (Pre-workshop)

# Please complete and return Exercise 1 (Please do not read the handout)





## Medical Device Administrative Control System (MDACS)



#### **Medical Device Administrative Control System**

- Voluntary system
- To be eventually superseded by a statutory system
- Aims:
  - To raise the public awareness of the use of safe medical devices
  - To enable traders to familiarize themselves with a system similar to the future mandatory requirements
  - To provide an opportunity to collect more information and feedback from the industry as a reference to fine tune the long-term regulatory system

(Source: Page 20 of the Consultation Document dated July 2003 entitled "Regulation of Medical Devices")



#### Scope of MDACS

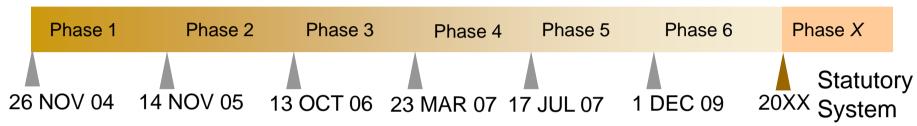
- Listing System
  - Medical Devices (Classes II, III and IV)
  - In vitro diagnostic (IVD) medical devices (Class D)
  - Local Manufacturers
  - > Importers
- Recognition of Conformity Assessment Bodies (CABs)
- Adverse Incident Reporting System
  - If a reportable incident concerning a listed device happens in Hong Kong, it must be reported by the LRP to MDCO. (Guidance Notes GN-03)





#### **Background Information**

#### Implemented by phases



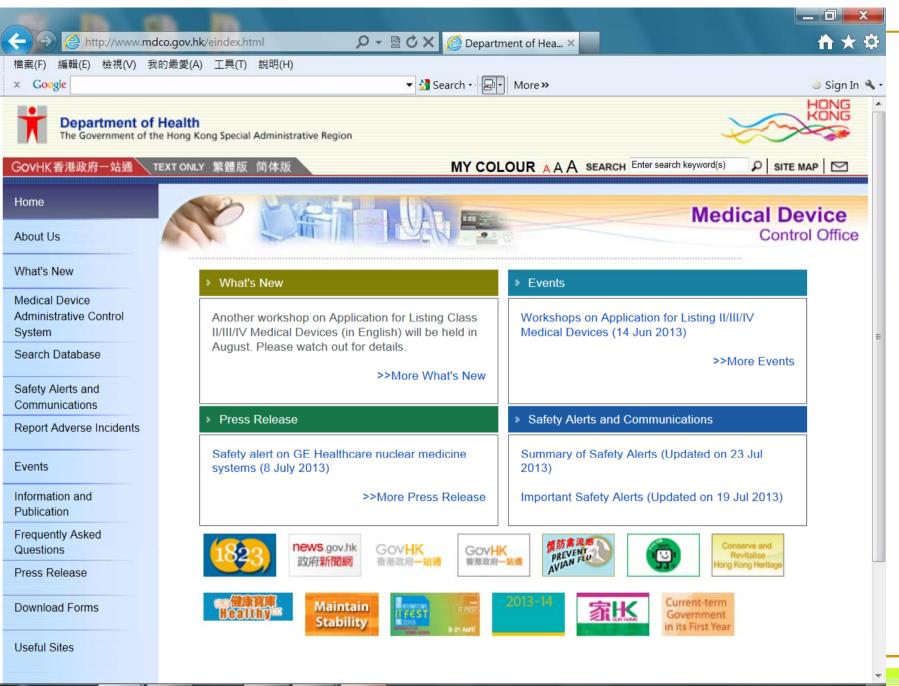
- Phase 1 (Nov 2004): Listing of Class IV devices
- Phase 2 (Nov 2005): Listing of Class II & III devices
- Phase 3 (Oct 2006): Recognition of Conformity Assessment Bodies
- Phase 4 (Mar 2007): Listing of Local Manufacturers
- Phase 5 (Jul 2007): Listing of Importers
- Phase 6 (Dec 2009): Listing of Class D IVD medical devices
- Phase X (20XX): Statutory System

www.mdco.gov.hk

## Information from our website (www.mdco.gov.hk)

- Related Guidance Notes, Code of Practice and Technical References
  - http://www.mdco.gov.hk/english/mdacs/mdacs\_gn/mdacs\_gn.html
- Application Forms
   http://www.mdco.gov.hk/english/download/download.html
- Listed Medical Device
   <a href="http://search.mdco.gov.hk/english/sd/sd\_ld/sd\_ld.php">http://search.mdco.gov.hk/english/sd/sd\_ld/sd\_ld.php</a>
- Asian Medical Device Nomenclature System (AMDNS)
   <a href="http://search.mdco.gov.hk/english/sd/sd\_amdn/sd\_amdn.php">http://search.mdco.gov.hk/english/sd/sd\_amdn/sd\_amdn.php</a>



















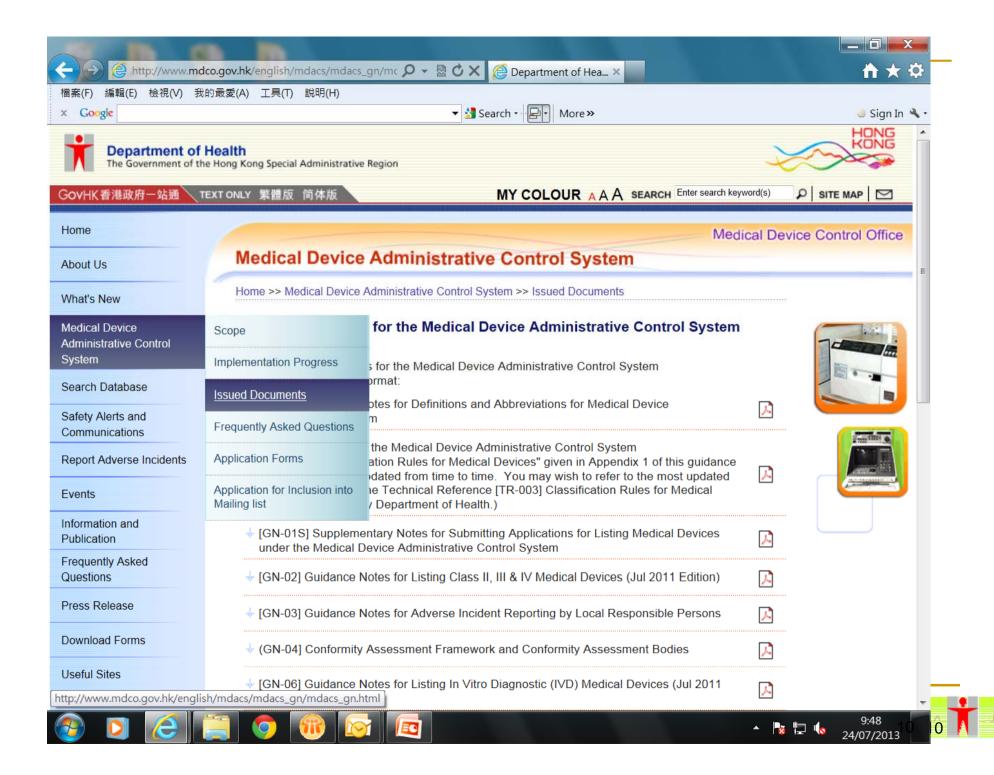












#### **Issued Documents**

Guidance Notes	Document No.
Guidance Notes for Definitions and Abbreviations for MDACS	GN-00
Overview of the MDACS	GN-01
Guidance Notes for Listing Classes 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 of Importers of Medical Devices	GN-07
Guidance Notes for Listing of Local Manufacturers	GN-08



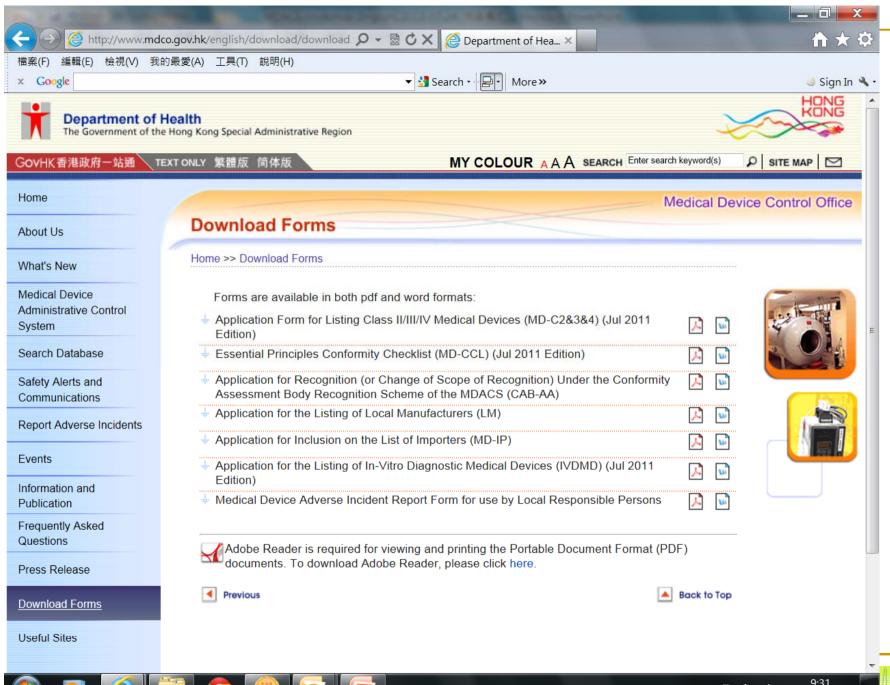


#### **Issued Documents**

Technical References	Document No.	
Principles of Conformity Assessment for Medical Devices	TR-001	
Summary Technical Documentation for Demonstrating TR-002 Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)		
Classification Rules for Medical Devices	TR-003	
Code of Practice	Document No.	
Code of Practice for Local Responsible Persons	COP-01	
Code of Practice for Conformity Assessment Bodies	COP-02	
Code of Practice for Listed Local Manufacturers	COP-03	
Code of Practice for Listed Importers of Medical COP-04 Devices		



















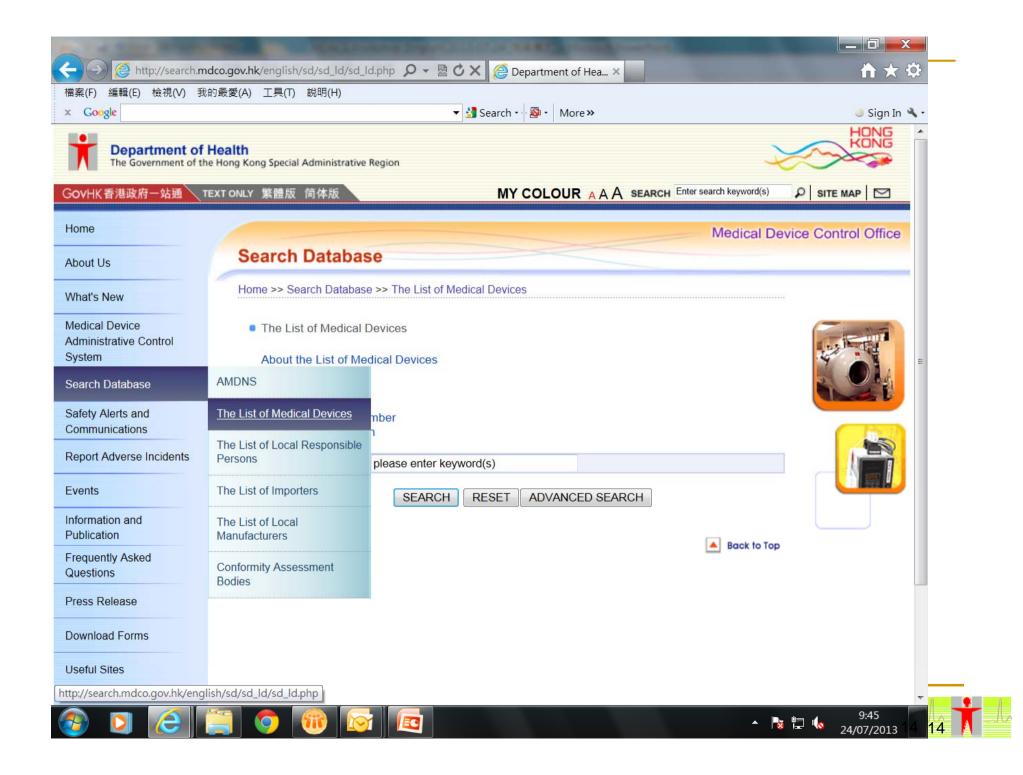


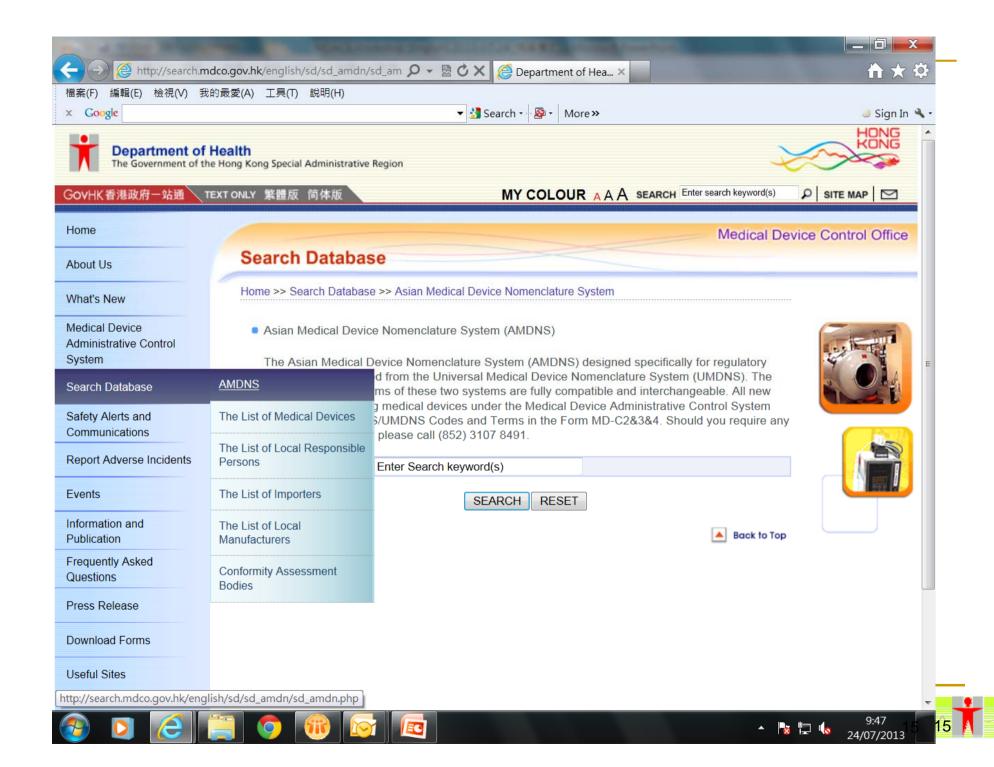


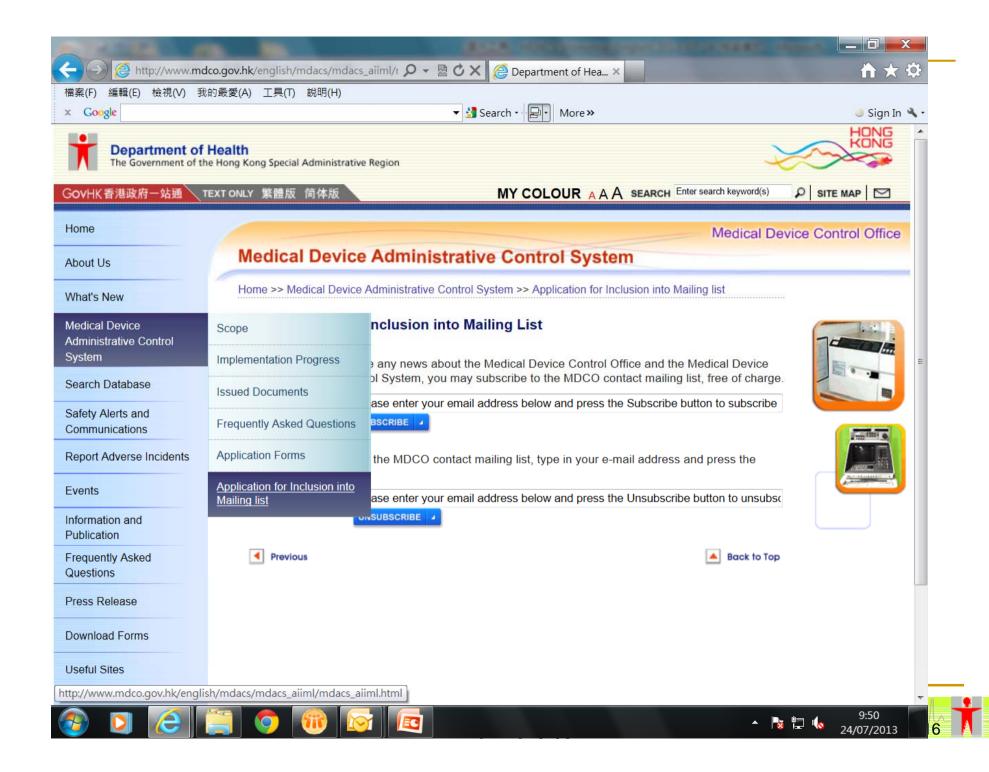












## Local Responsible Person (LRP)



#### Who can be an LRP?

- A legal person incorporated in Hong Kong or
- ★ a legal or natural person with business registration in Hong Kong; and
- who is itself the manufacturer of the device or
- supported by the manufacturer of the device (in the latter case the manufacturer must designate the LRP in writing)
  - Hong Kong permanent resident



#### Sample Letter for Designating a LRP (GN-01 Appendix 5)

<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:

- 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)

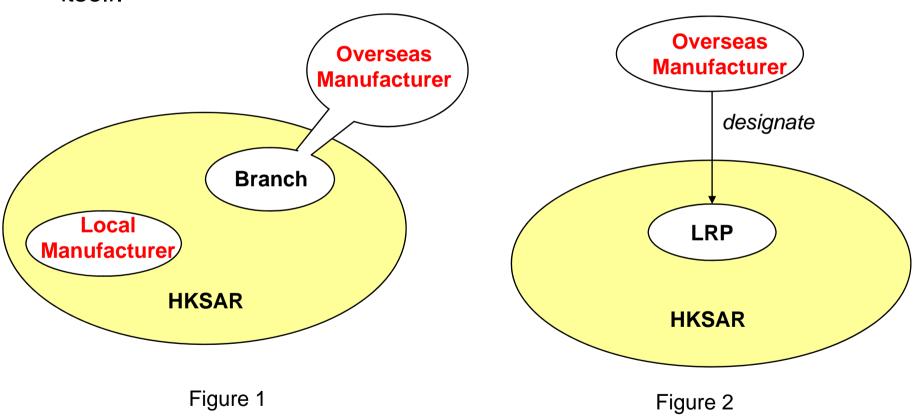
(name and title of official signing this letter)

(official chop (if any) of the manufacturer)



#### Relationship between Manufacturer and LRP

- ➤ Two types of Manufacturer "Local" and "Overseas".
- ➤ Local Manufacturer can "designate" LRPs or becomes LRP by itself.

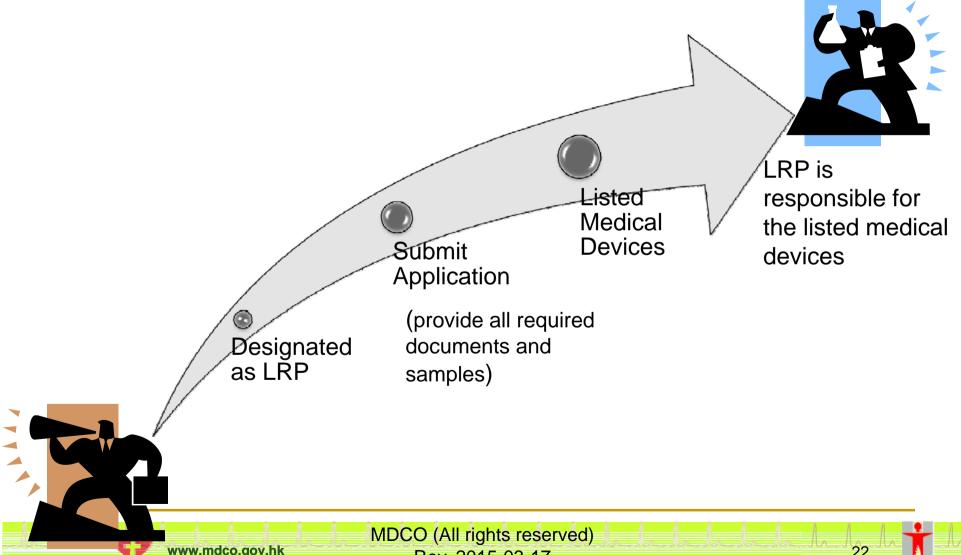


#### Relationship between Manufacturer and LRP

Type of Manufacturer	Itself	Designate
Local Manufacturer	✓	<b>√</b>
Overseas Manufacturer (branch in Hong Kong)	✓ (H.K. Branch)	✓
Overseas Manufacturer (without branch in Hong Kong)	X	<b>√</b>



#### **Responsible Person for Listed Medical Devices**



#### The LRP:

- is the applicant for Listing of medical devices
- applies, on his own initiative, for
- ★renewal of Listing at least 3 months before expiry of Listing

#### LRP's Responsibility



- Application for listing of medical devices
- Efficient communication channels
- Reporting changes
- Making records available for inspection
- Maintain distribution records

Safe and Efficacy

- Managing reportable adverse incidents in HK
- Product alerts, modifications and recalls
- Tracking of specific medical devices

Quality of Services

- Maintenance and services arrangements
- Compliant handling





### Listing Importers of Medical Devices



#### **Importer of Medical Devices**

#### Who is an Importer?

 A legal or natural person who brings or entrust others to bring medical devices that fall within the scope of MDACS into Hong Kong.

(But does not include any person who is employed or engaged by such person to carry such products into Hong Kong such as courier)



#### **Importer of Medical Devices**

Listed devices Non-listed devices



**Importer** 

Listing of Importer (under voluntary system)

a) A body corporate or partnership:

Proof of body corporate/partnership (e.g., Business Registration Certificate)

b) Individual:

Identification document



#### **Obligations of Listed Importers**

#### **Establishment of Procedures**

(Keeping of distribution records; handling complaints, advisory notices and reportable adverse incident)

Making Distribution Records available for inspection

**Obligations of Listed Importers** 

Requirements in Respect of Advertisement, Promotional Materials etc.

Other obligations (notify the MDCO of any changes to the information submitted)



#### **End of Session**





### Classification of Medical Devices



#### **Medical Device:**

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 :-

- diagnosis, prevention, monitoring, treatment or alleviation of disease; or
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury; or



- investigation, replacement, modification, or support of the anatomy or of a physiological process; or
- supporting or sustaining life; or



- control of conception; or



- disinfection of medical devices; or
  - 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.





#### Invasive device:

Device, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.

#### Active medical device:

Device whose operation depends on a source of electrical energy or any source of power.



	Transient use	normally intended for continuous use for less than 60 minutes
	Short-term use	normally intended for continuous use for between 60 minutes and 30 days
*	Long-term use	normally intended for continuous use for more than 30 days





#### **Classification of Medical Devices**

- Class I (lowest risk) Class IV (highest risk)
- Classification depends on:
  - Intended Use
  - Characteristics of the device, etc.
- All classification rules in TR-003 must be taken into consideration
- If more than one rule applies, the rule putting the device into the highest class prevails



#### **Classification of Medical Devices**

Non-Invasive Devices (Rules 1 to 4)

★ Invasive Devices (Rules 5 to 8)

Active Devices (Rules 9 to 12)

Additional Rules (Rules 13 to 16)

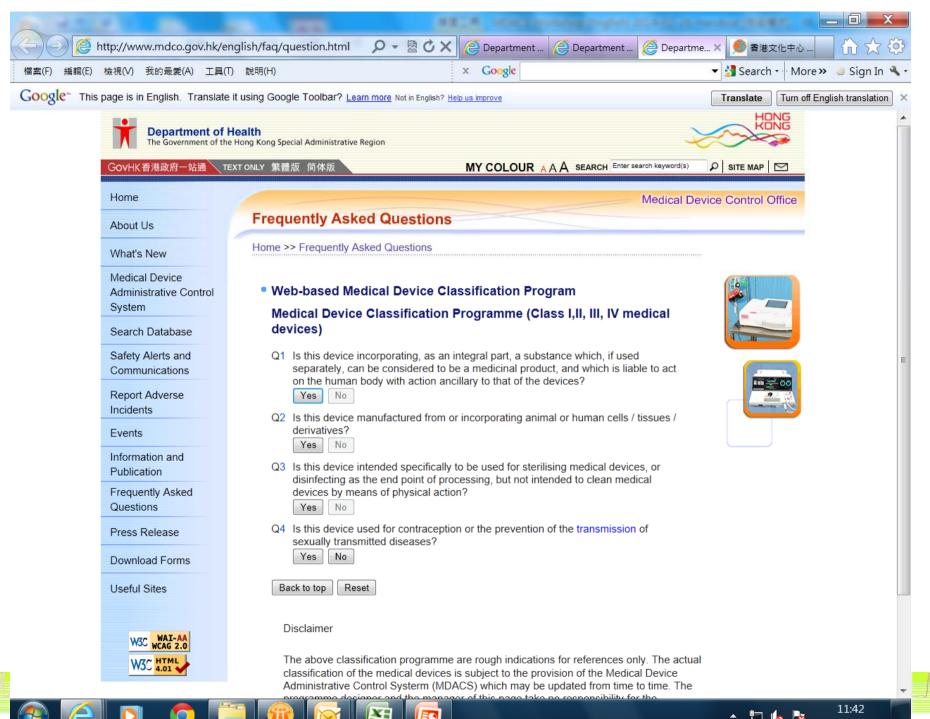


### **Classification of Medical Devices**

#### Classification program:

http://www.mdco.gov.hk/english/faq/question.html

















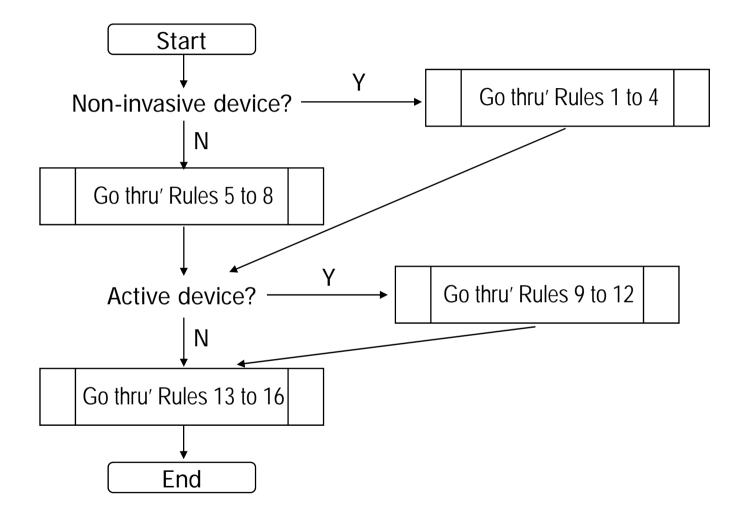






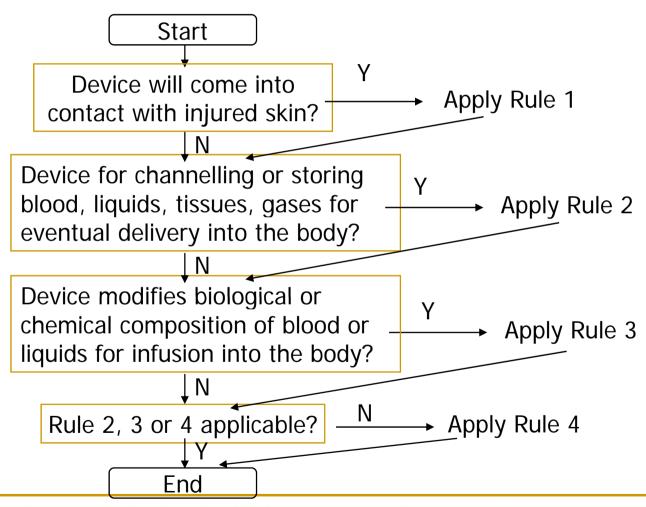


### **Classification of Medical Devices**





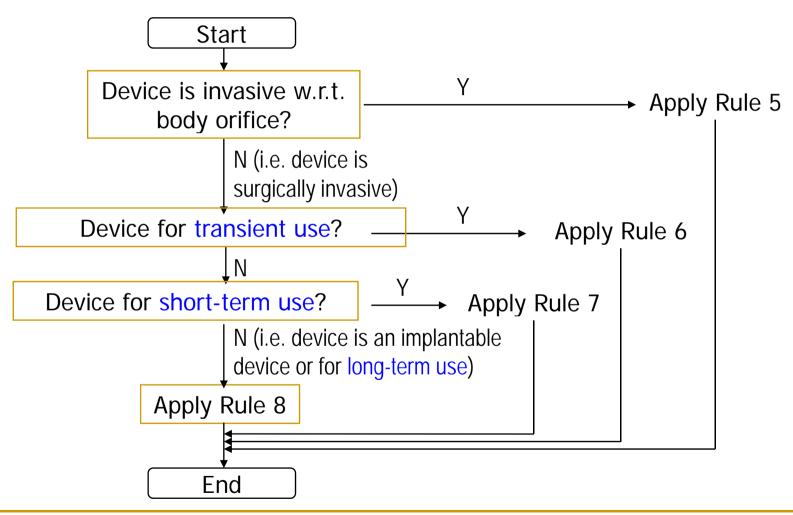
## Go thru' Rules 1 to 4 (if the device is non-invasive)





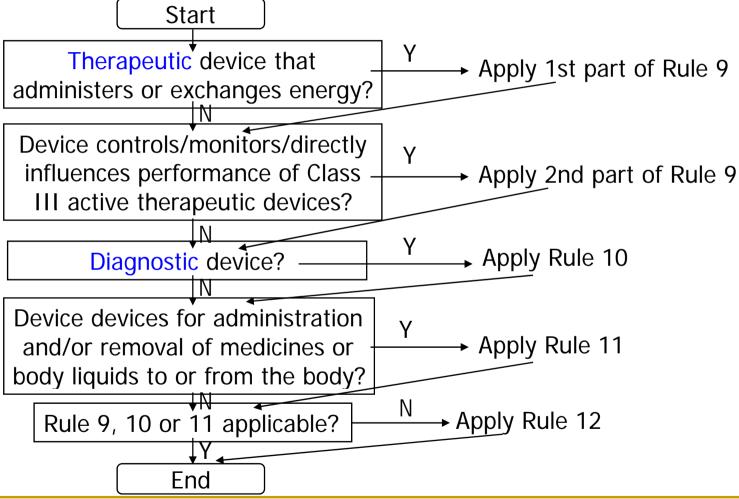


## Go thru' Rules 5 to 8 (if the device is invasive)





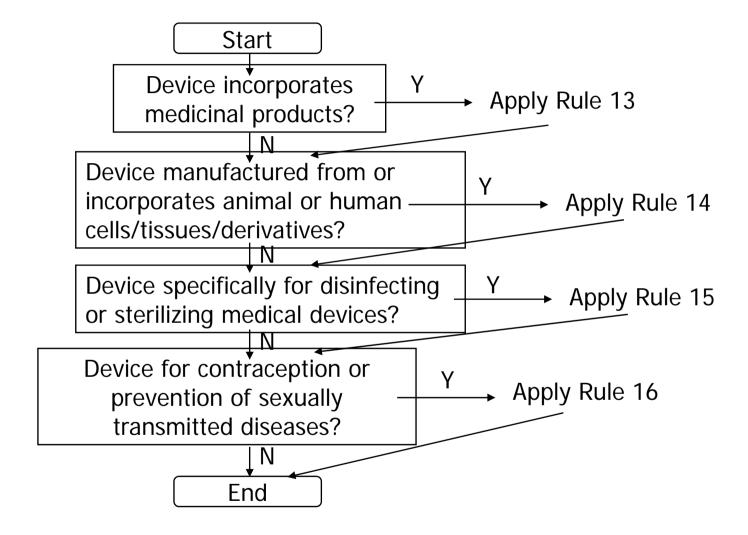
## Go thru' Rules 9 to 12 (if the device is active)







#### Go thru' Rules 13 to 16







# Exercise 2 (Classification of medical devices)

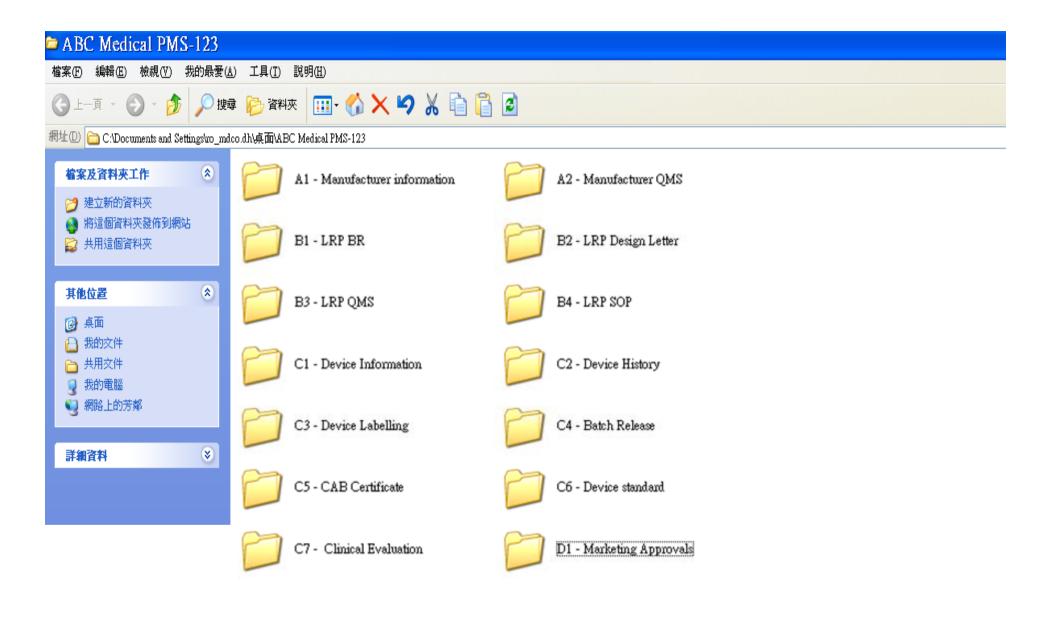
Please return the completed exercise at the end of the workshop.

**Many Thanks!** 



## How to prepare an application







#### **LRP**



#### **Business Registration Certificate (B1)**

FORM 2 《商業登記條例》(第310章) BUSINESS REGISTRATION ORDINANCE (Chapter 310) ORIGINAL **BUSINESS REGISTRATION REGULATIONS 海XXXXXX**X 商業/XXX登記證 DXIXIPLXXXXXIXE Business/RXXXXXRegistration Certificate

業務/法團所用名稱 Name of Business/ Corporation

甲乙丙有限公司

業務/分行名稱 Business/ Branch Name

LRP MEDICAL SUPPLIES LIMITED

地址 Address

UNIT Alo 6/F WONG'S BUILDING 33 HUNG TO ROAD KWUN TONG

業務性質 Nature of Business

法律地位

8/8/2008

DUDI CUNIUNHIL

生效日期 Date of Commencement 屈滿日期 Date of Expiry

7/8/2009

Certificate No.

123456 -000-08-07-2

登記費及徵費 Fee and Levy

\$2,600 (登記費 FEE = \$2,000) (徽費 LEVY = \$ 600)

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

業務的僱員的任何法律規定已獲遵從。

第7(2)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.)

LRP20多6 1010 1/1/2007 07 56837153 694898 CHQ I.R.D.B. 101 (1/2007)

\$2,600.00



### Local Responsible Person (LRP)

Manufacturer's designation letter (B2)

(See GN-01, Appendix 5)

#### Appendix 5

#### Sample Letter for Designating a Local Responsible Person

<Name of manufacturer>
<Address of manufacturer>

Date:

<Name of LRP>
<Address of LRP>

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- (iii) any subsequent changes and modifications;
- (iv) details of any recalls, alerts, and related preventive and corrective actions; and
- (v) investigations and reports related to adverse incidents and post market surveillance.

Yours faithfully,

(signature)

(name and title of official signing this letter)

(official chop (if any) of the manufacturer)

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### LRP designation letter (B2):

- Issued by the manufacturer



- ★ Contains:
  - ✓ Manufacturer's name
  - ✓ Manufacturer's address
  - ✓ LRP's name
  - ✓ LRP's address





## LRP's documented procedures (B4)

- Procedures to be submitted in the 1<sup>st</sup> application for Listing of medical devices:
  - √ Keeping of distribution records
  - ✓ Management of product recalls and field safety notices
  - ✓ Handling of reportable adverse incidents in HK







#### **Medical Device**

Family/Series/ Accessories Manufacturing site(s) (C1)

Recalls/Adverse Incidents / Banning

(C2)

### Model: PMS-123

ABC Medical Co., Ltd.

#### **Labelling samples:**

LRP information (Name/address/Tel.), Listing No. (HKMD No.), IFUs, product/package labels

(C3)

If applicable: Wholesale Poisons Licence, Antibiotics Permit, Irradiating Apparatus Licence, etc.

(C4)

If applicable: HK MDACS Conformity
Assessment Certificate

(C5)

Type Test Certificate/Report

Risk Analysis Report (C6)

Clinical evaluation report

(C7)

#### (C3)

- ★ If a medical device is intended for self-use by consumers, the instructions for use should be written in both English and Chinese
  - Special Listing Information contains:
- ★ ✓ Listing no. (HKMD No.)
  - ✓ LRP's name
  - ✓ LRP's address
  - ✓ LRP's tel./fax
    LRP's email address





#### Medical Device (D1) EU Approval

CE Certificates				
EC Design-Examination Certificate	Annex II section 4 MDD			
	Annex 2 section 4 AIMD			
EC Type Examination Certificate	Annex III MDD			
	Annex 3 AIMD			
Full Quality Assurance System Approval	Annex II Section 3 MDD			
Certificate	Annex 2 section 3 AIMD			
EC Verification Certificate	Annex IV MDD			
	Annex 4 AIMD			
Production Quality Assurance System	Annex V MDD			
Approval Certificate	Annex 5 AIMD			
Product Quality Assurance System Approval Certificate	Annex VI MDD			







#### Medical Device Control Office Department of Health

#### 儀器 (D1)

Medical Device Administrative Control System
Essential Principles Conformity Checklist

D./I	2	50	
IAT	cu.	$\sim$	10

Brand Name and Model:

Clause	Essential Principle	Applicable	Method of Conformity	Identity of Specific Documents
Seneral	Requirements	2 2		ži:
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.	Y	ISO13485: 2003Medical devices Quality management systems Requirements for regulatory purposes ISO14971:2007Medical	Document No. DMF1234
2.	The solutions adopted by the manufacturer for the design and manufacture of the devices should conform to safety principles, taking account of the generally incknowledged state of the art. When risk reduction is required, the manufacturer should control the risks so that the residual risks associated with each hazard is judged acceptable. The manufacturer should apply the following principles in the priority order listed:  • identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse,  • eliminate risks as far as reasonably practicable through inherently	Y	devices Application of risk management to medical devices	
	<ul> <li>safe design and manufacture,</li> <li>reduce as far as is reasonably practicable the remaining risks by taking adequate protection measures, including alarms,</li> <li>inform users of any residual risks.</li> </ul>			
3.	Devices should achieve the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions within the scope of the definition of a medical device.	Υ		
4.	The characteristics and performances referred to in Clauses 1, 2 and 3 should			\$3

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#### 儀器 (D1)

★ Essential Principles Conformity Checklist (form MD-CCL) is not required if the earliest recognised foreign marketing approval is obtained in or before 2004



#### Appendix 3

#### 儀器 (D1)

Sample of
Essential Principles
Declaration of
Conformity
(see GN-02, Appendix 3)

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> and <Model(s)>

<Date>

#### < 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

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

<Signature>

<Name and Title>

<Company Name>

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### Contact us

**Medical Device Control Office** 

**Department of Health** 

Address: Room 3101, 31/F, Hopewell Centre,

183 Queen's Road East, Wan Chai

**Telephone: 3107 8484** 

Fax: 3157 1286

Email: mdco@dh.gov.hk

Website: www.mdco.gov.hk



## Exercise 3 (Post-workshop)

## Please complete and return Exercise 3 and evaluation form

Many thanks!



## Thank you!

(The content of this presentation serves as reference only. Please refer to the Department of Health for detailed operations of MDACS)



## Q&A

