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）**
- **Classification of Medical Devices**
- **How to Prepare Application Documents**
- **Exercise 2 (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- To be eventually superseded by a statutory system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
  - Distributors
- Recognition of Conformity Assessment Bodies (CABs)
- Adverse Incident Reporting System
  - If a reportable incident concerning a listed device happens in HK, it must be reported by the LRP to MDCO. (Guidance Notes GN-03)


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What's New
Another workshop on Application for Listing Class II/III/IV Medical Devices (in English) will be held in August. Please watch out for details.
>>More What's New
Events
Workshops on Application for Listing II/III/IV Medical Devices (14 Jun 2013)
>>More Events
Press Release
Safety alert on GE Healthcare nuclear medicine systems (8 July 2013)
>>More Press Release
Safety Alerts and Communications
Summary of Safety Alerts (Updated on 23 Jul 2013)
Important Safety Alerts (Updated on 19 Jul 2013)
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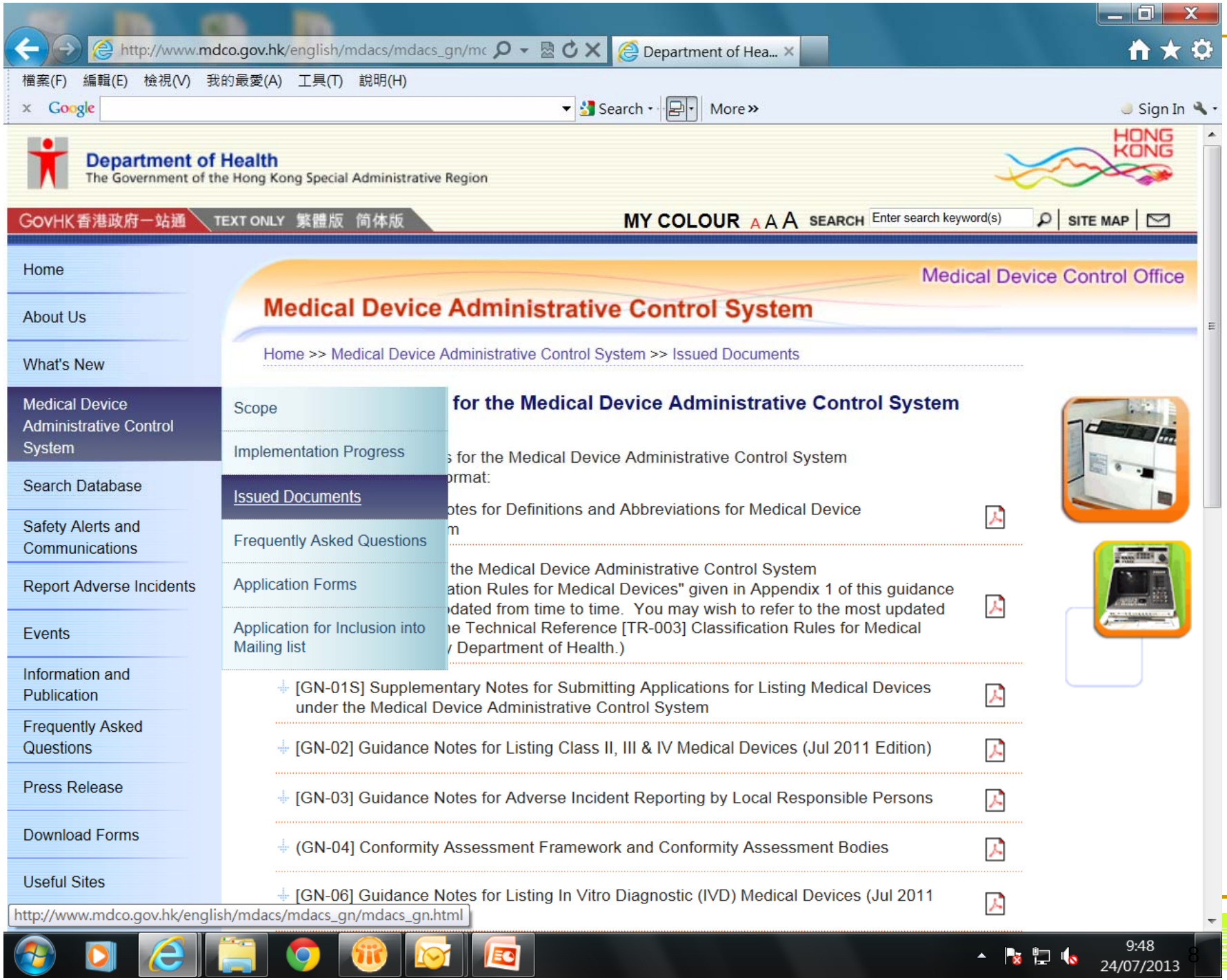
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dated from time to time. You may wish to refer to the most updated
e Technical Reference [TR-003] Classification Rules for Medical
Department of Health.)
[GN-01S] Supplementary Notes for Submitting Applications for Listing Medical Devices under the 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
http://www.mdco.gov.hk/english/mdacs/mdacs_gn/mdacs_gn.html
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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
Guidance Notes for Listing of Distributors	GN-09

Issued Documents

Technical References	Document No.
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 (STED)	TR-002
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 Devices	COP-04

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Medical Device Control Office

Download Forms

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Forms are available in both pdf and word formats:

- Application Form for Listing Class II/III/IV Medical Devices (MD-C2&3&4) (Jul 2011 Edition)
- Essential Principles Conformity Checklist (MD-CCL) (Jul 2011 Edition)
- Application for Recognition (or Change of Scope of Recognition) Under the Conformity Assessment Body Recognition Scheme of the MDACS (CAB-AA)
- Application for the Listing of Local Manufacturers (LM)
- Application for Inclusion on the List of Importers (MD-IP)
- Application for the Listing of In-Vitro Diagnostic Medical Devices (IVDMD) (Jul 2011 Edition)
- Medical Device Adverse Incident Report Form for use by Local Responsible Persons

Adobe Reader is required for viewing and printing the Portable Document Format (PDF) documents. To download Adobe Reader, please click here.

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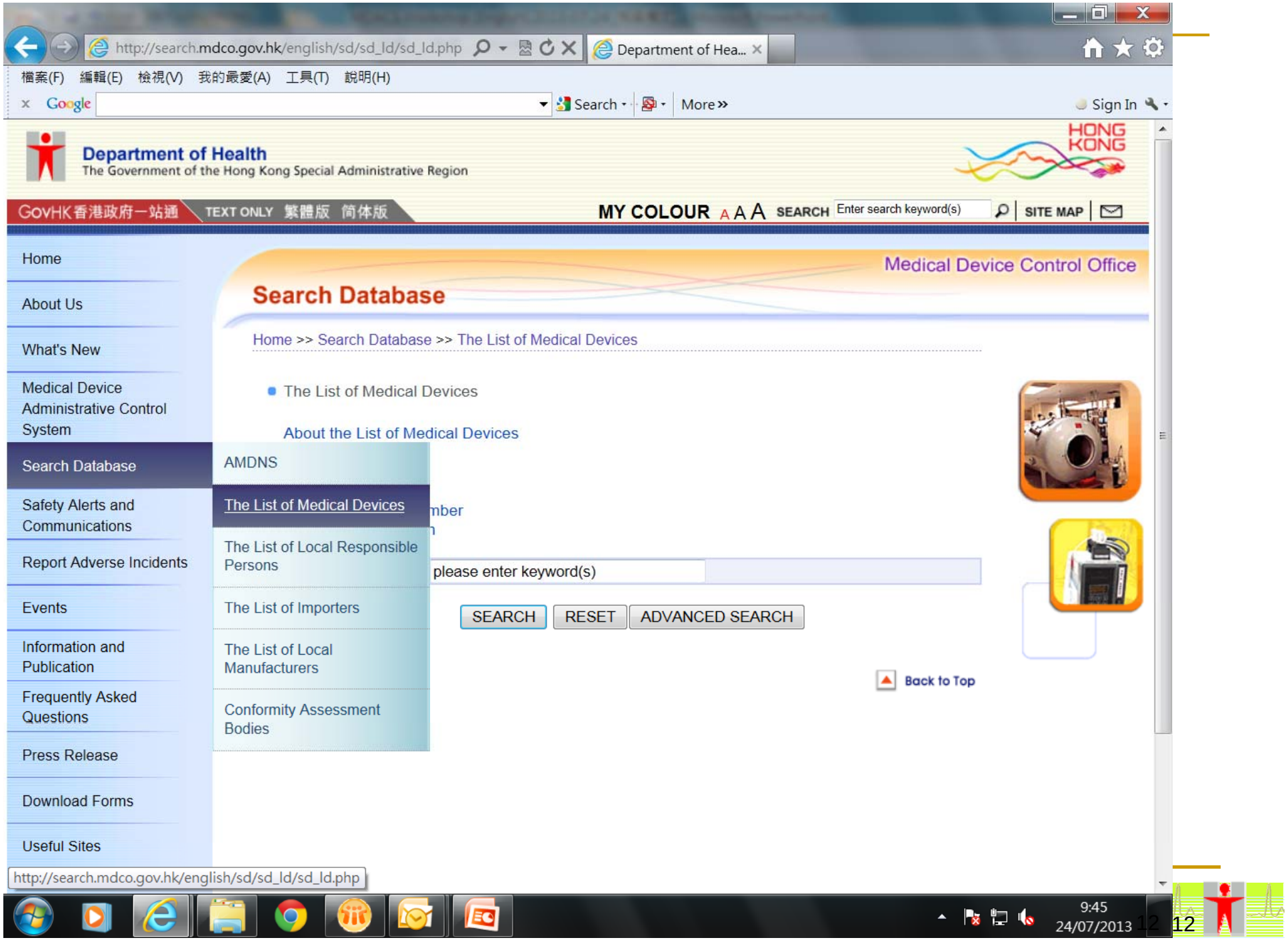
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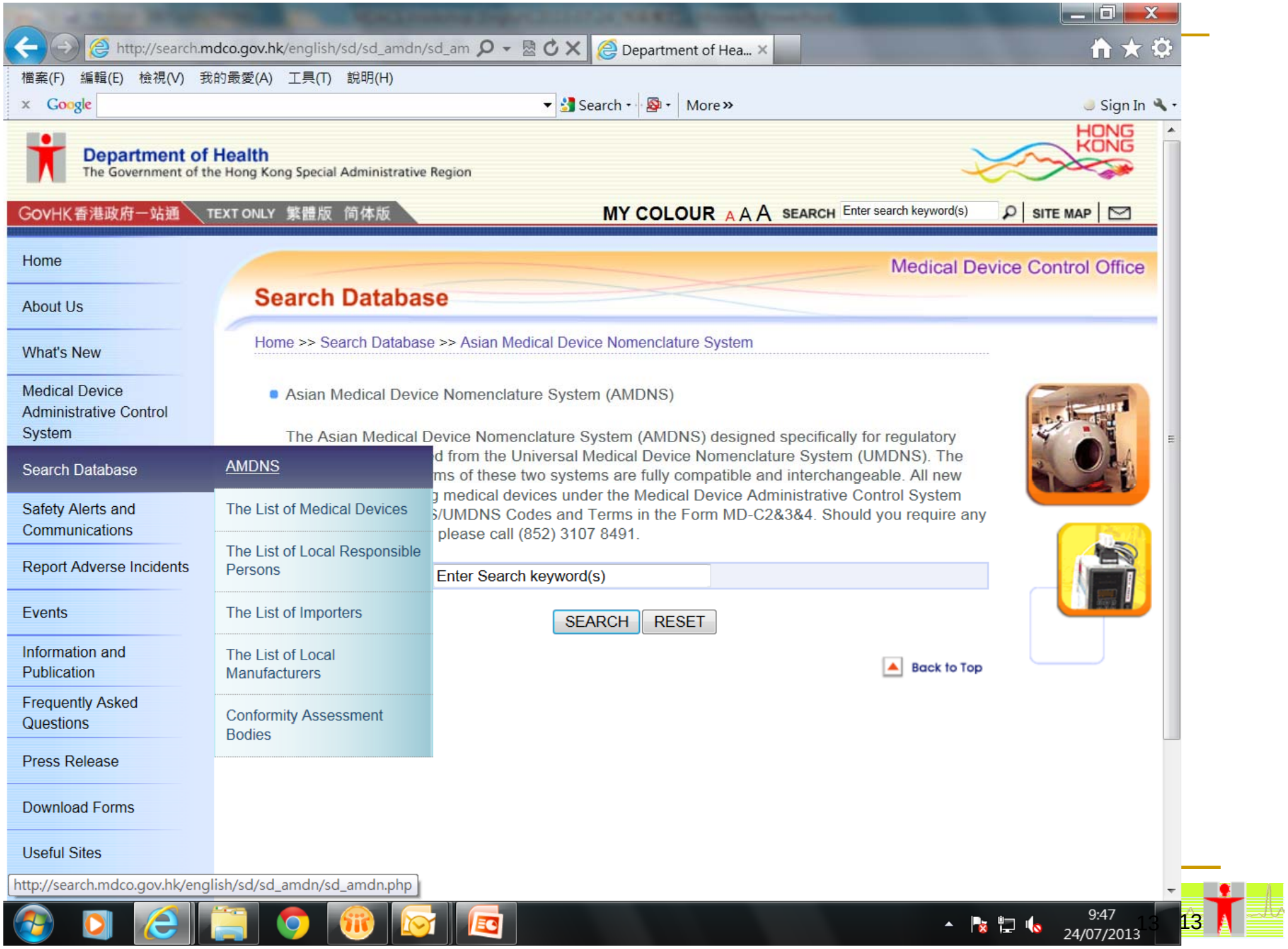
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Asian Medical Device Nomenclature System (AMDNS)
The Asian Medical Device Nomenclature System (AMDNS) designed specifically for regulatory
d from the Universal Medical Device Nomenclature System (UMDNS). The
ms of these two systems are fully compatible and interchangeable. All new
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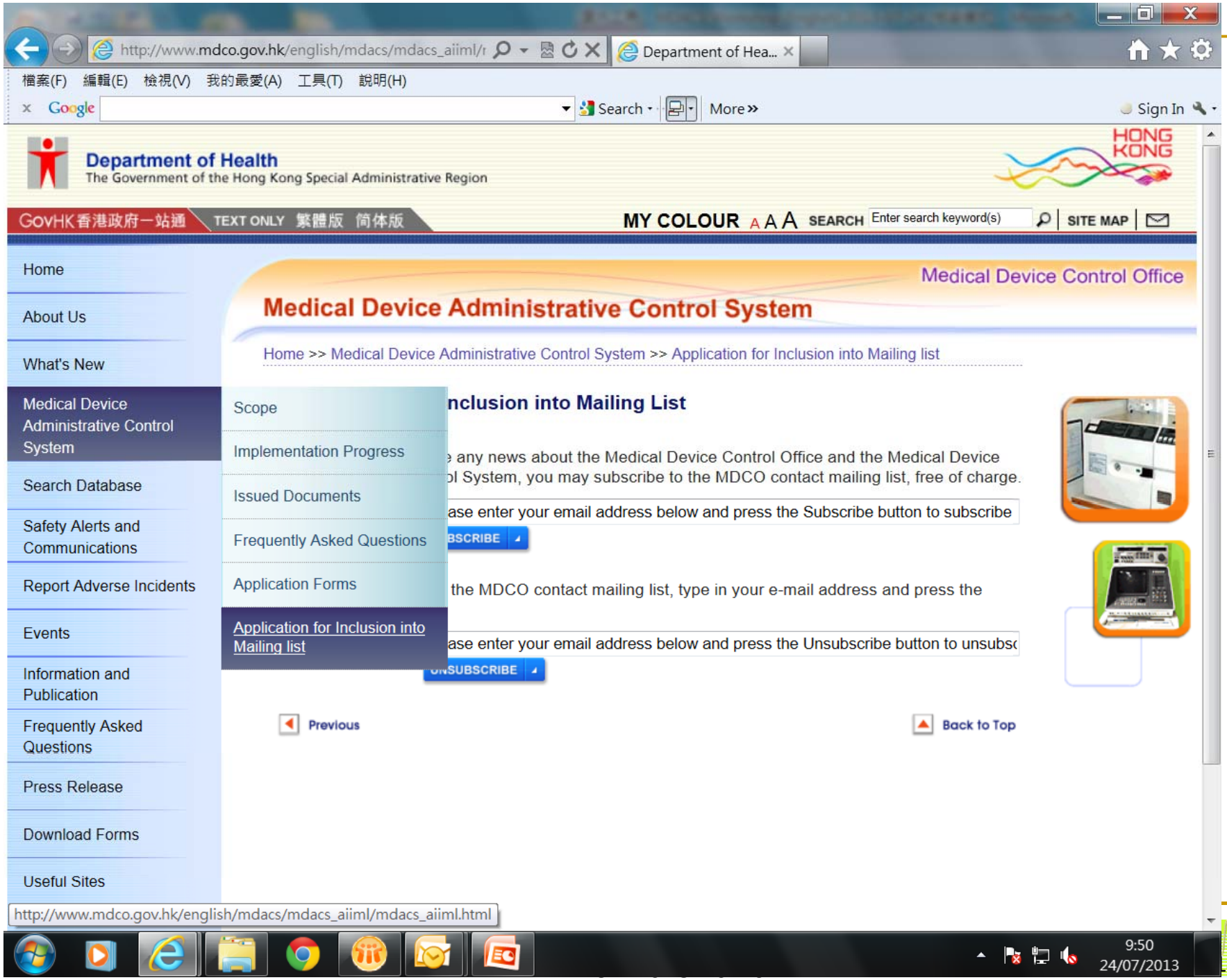
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Local Responsible Person (LRP)

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:

(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)

Relationship between Manufacturer and LRP

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

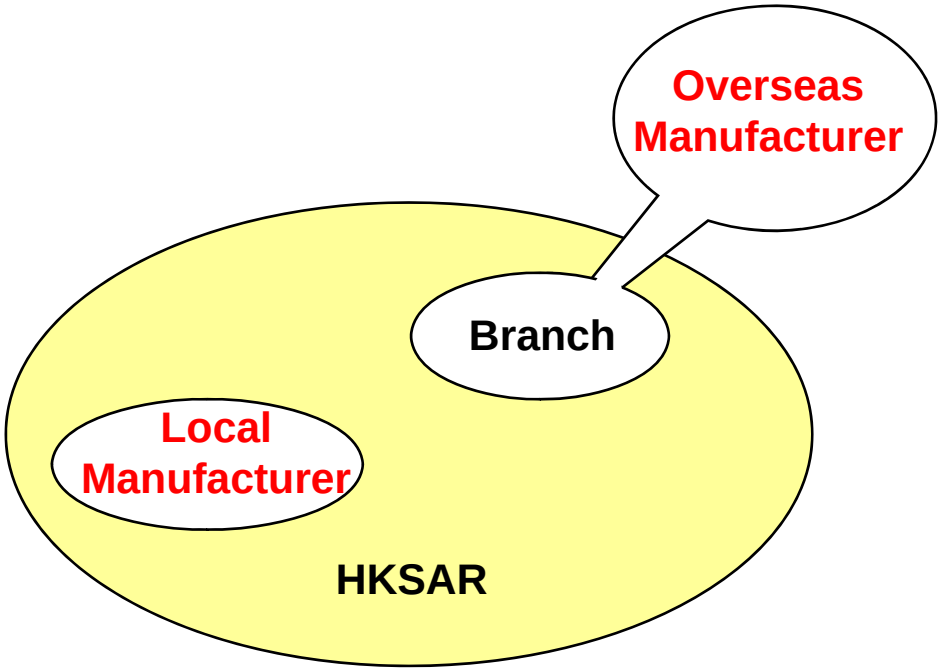


Figure 1

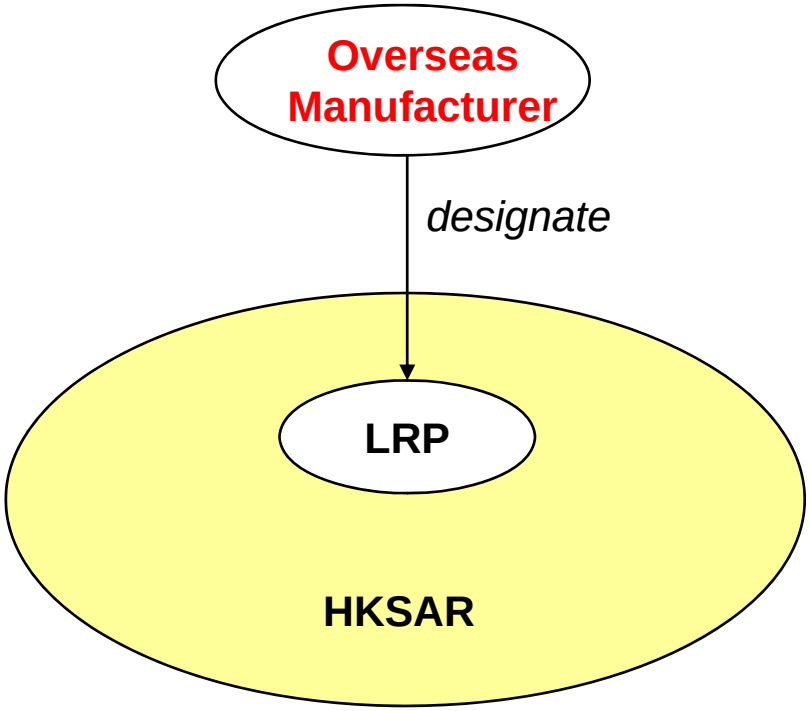
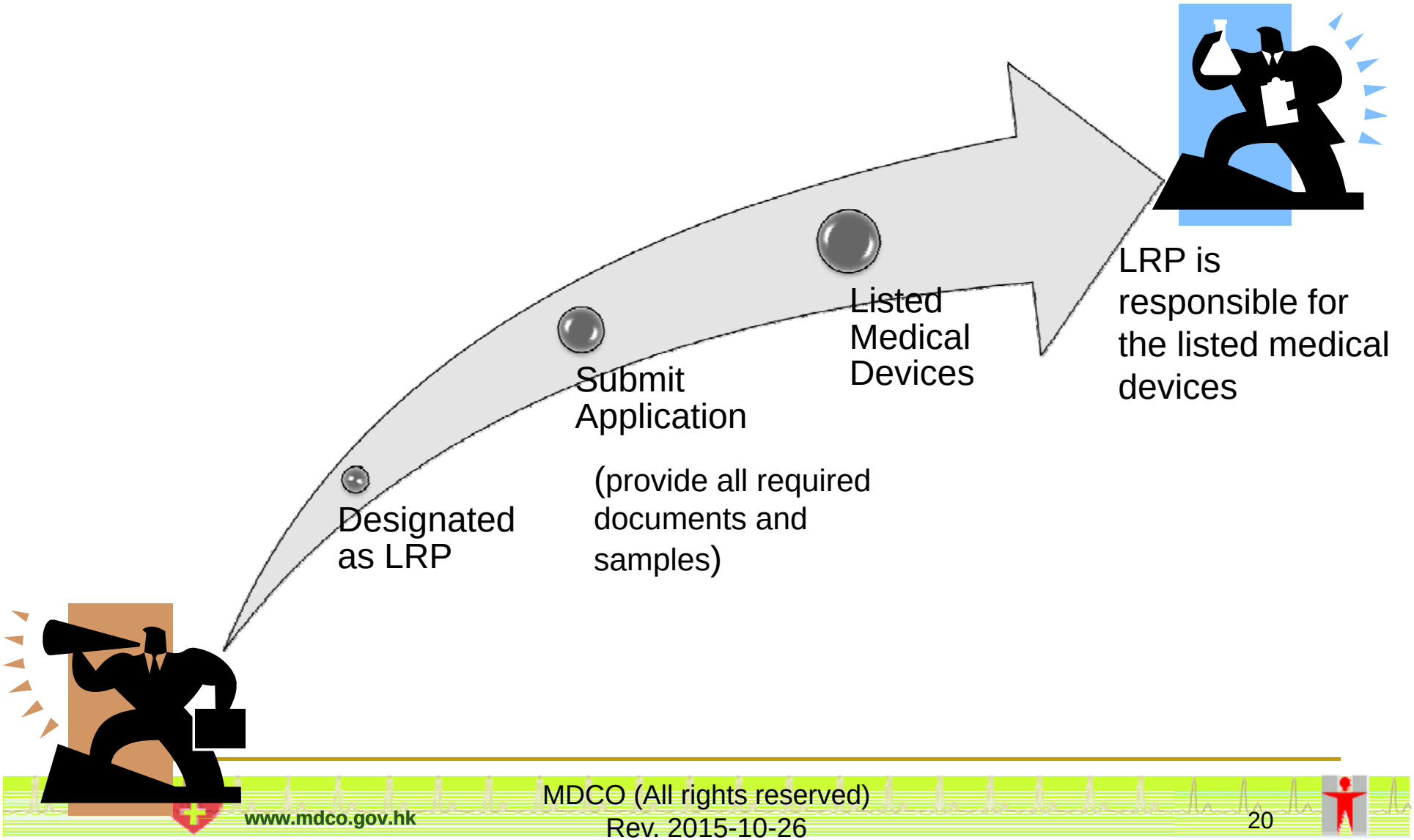


Figure 2

Relationship between Manufacturer and LRP

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

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

Communications Hub

- 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

Classification of Medical Devices

Definitions (Ref.: GN-00)

- **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

Definitions (Ref.: GN-00)

- 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.

Definitions (Ref.: GN-00)

- 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.

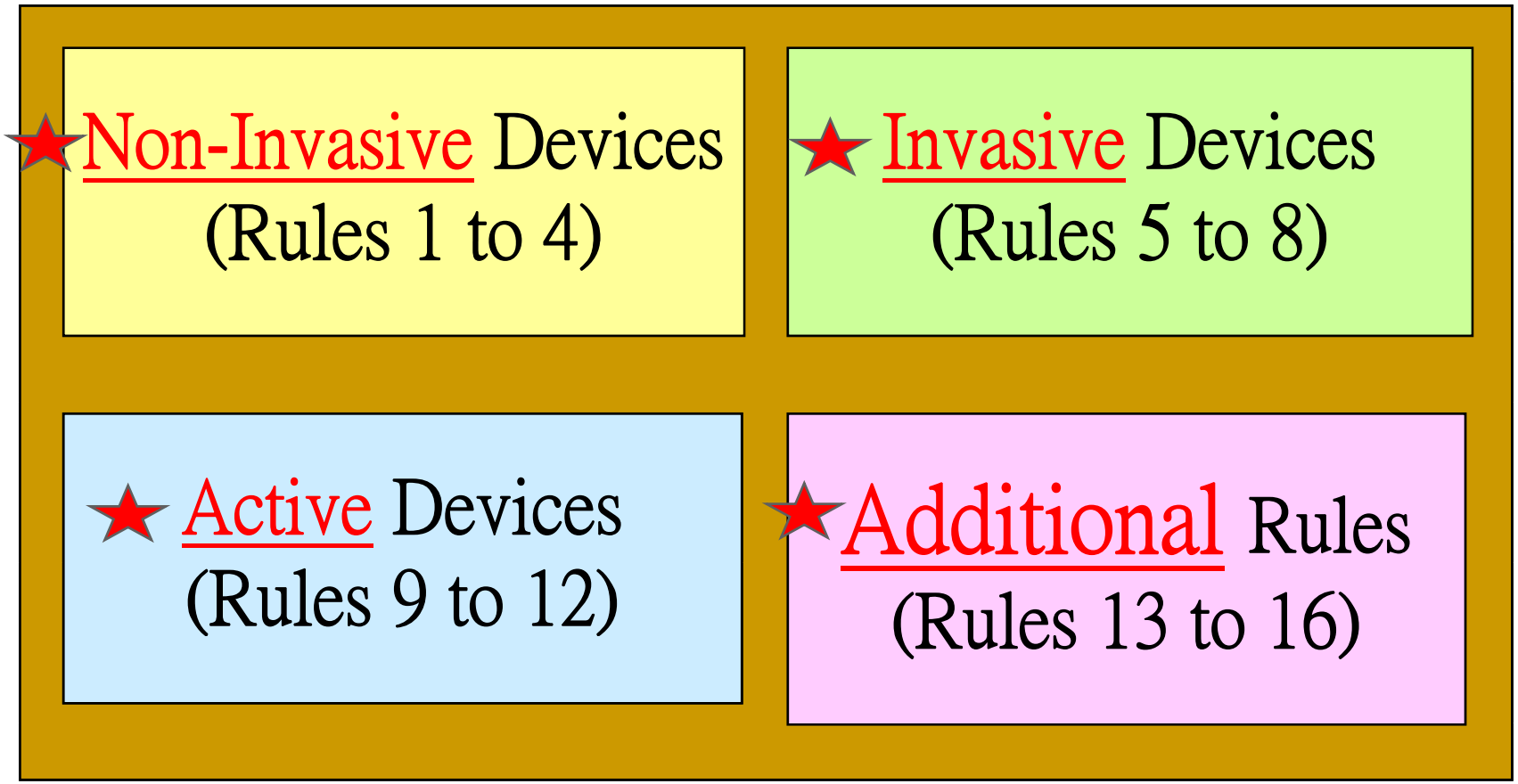
Definitions (Ref.: GN-00)

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



Classification of Medical Devices

Classification program:

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

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W3C HTML 4.01

Medical Device Control Office

Frequently Asked Questions

Home >> Frequently Asked Questions

Web-based Medical Device Classification Program

Medical Device Classification Programme (Class I,II, III, IV medical devices)

Q1 Is this device incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, and which is liable to act on the human body with action ancillary to that of the devices?

Yes | No

Q2 Is this device manufactured from or incorporating animal or human cells / tissues / derivatives?

Yes | No

Q3 Is this device intended specifically to be used for sterilising medical devices, or disinfecting as the end point of processing, but not intended to clean medical devices by means of physical action?

Yes | No

Q4 Is this device used for contraception or the prevention of the transmission of sexually transmitted diseases?

Yes | No

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Disclaimer

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 Systerm (MDACS) which may be updated from time to time. The programme designer and the manager of this page take no responsibility for the

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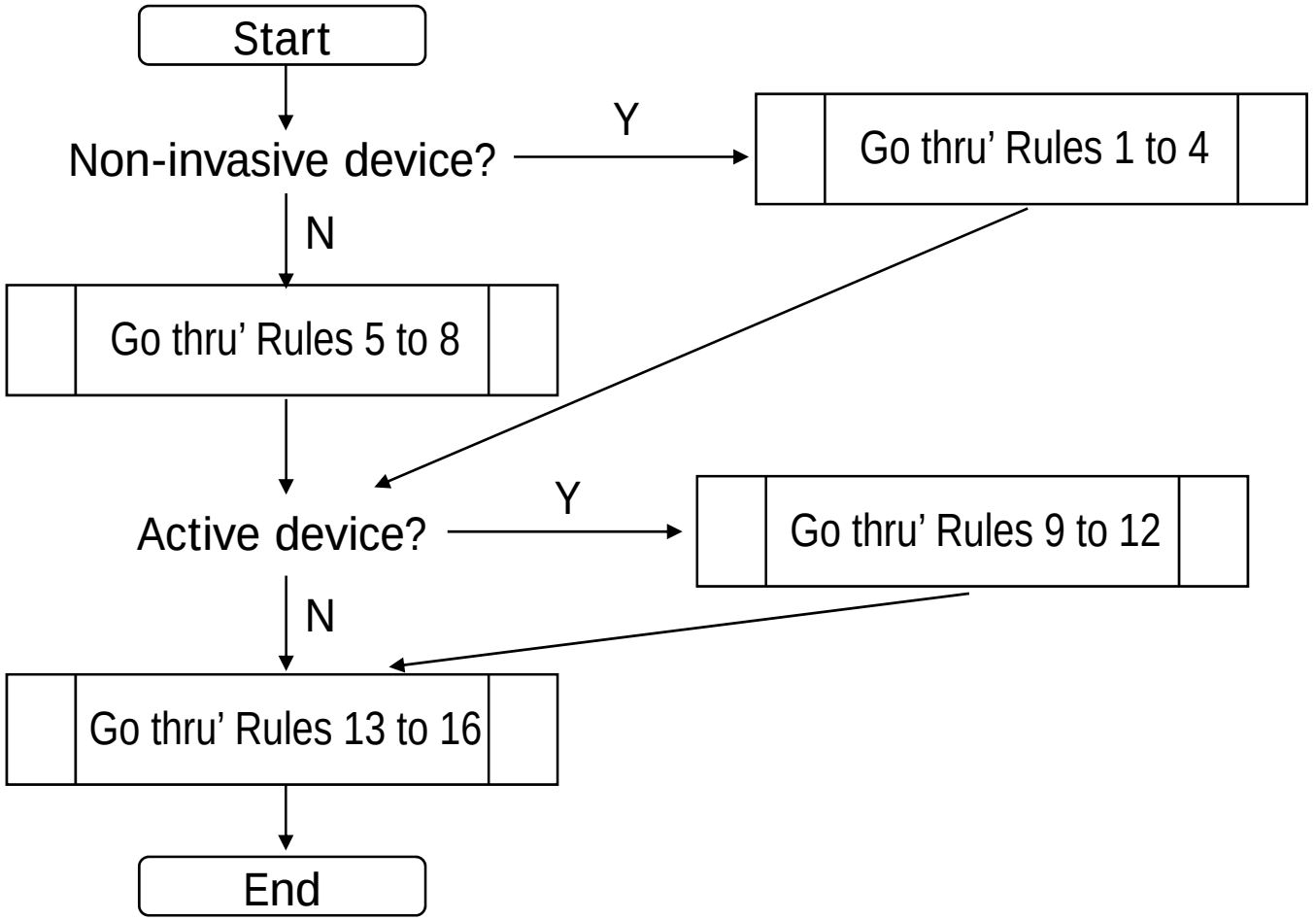
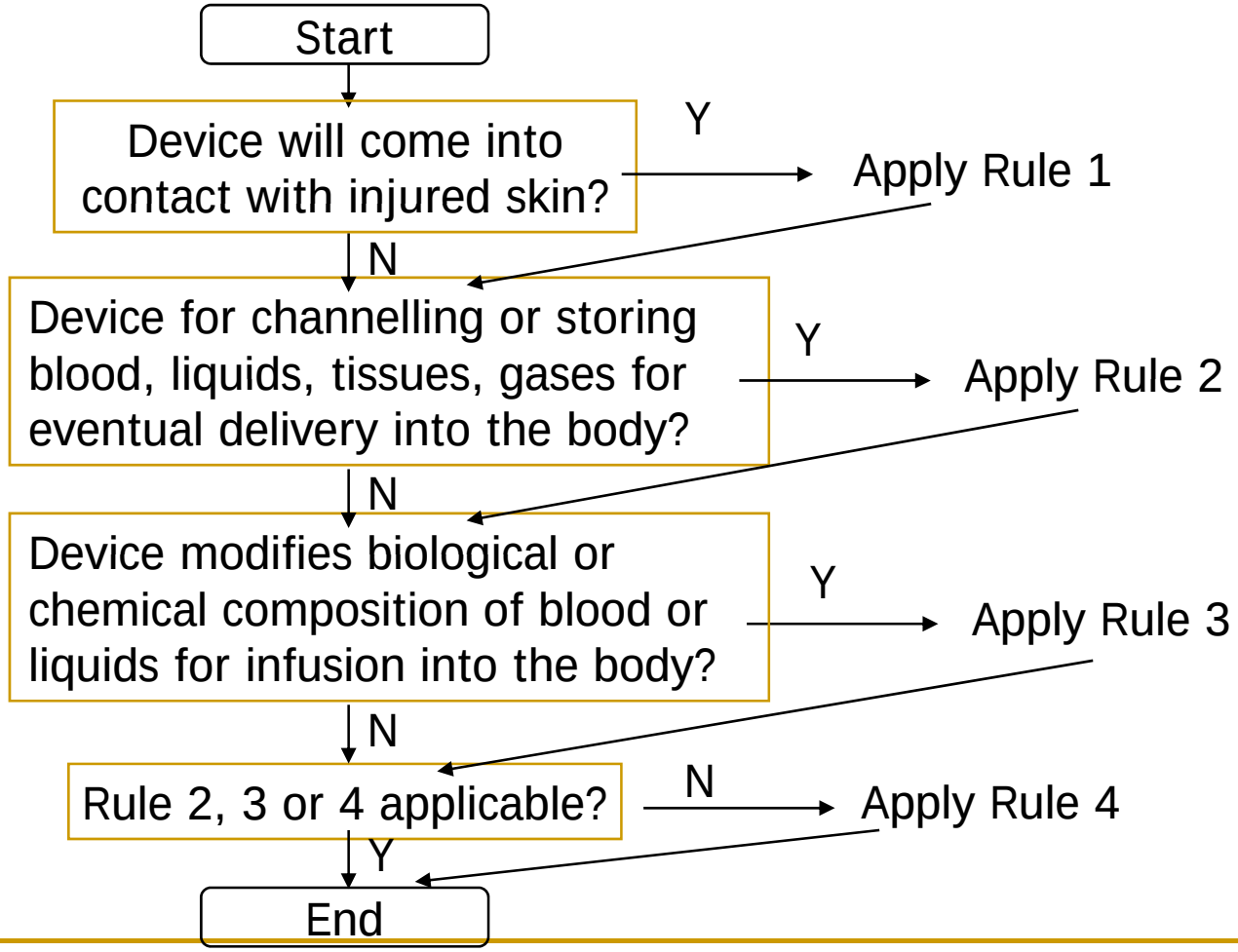
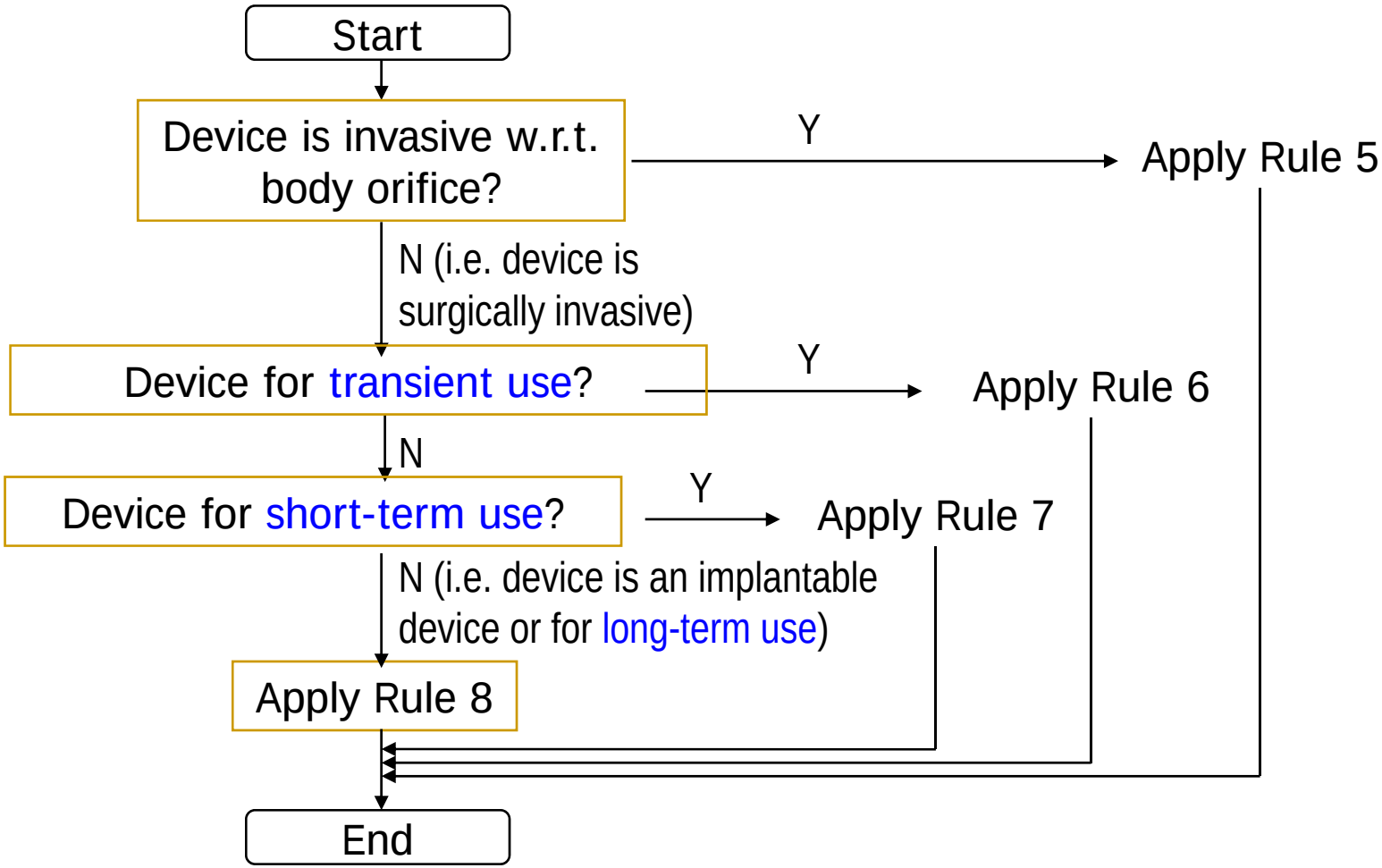
Classification of Medical Devices



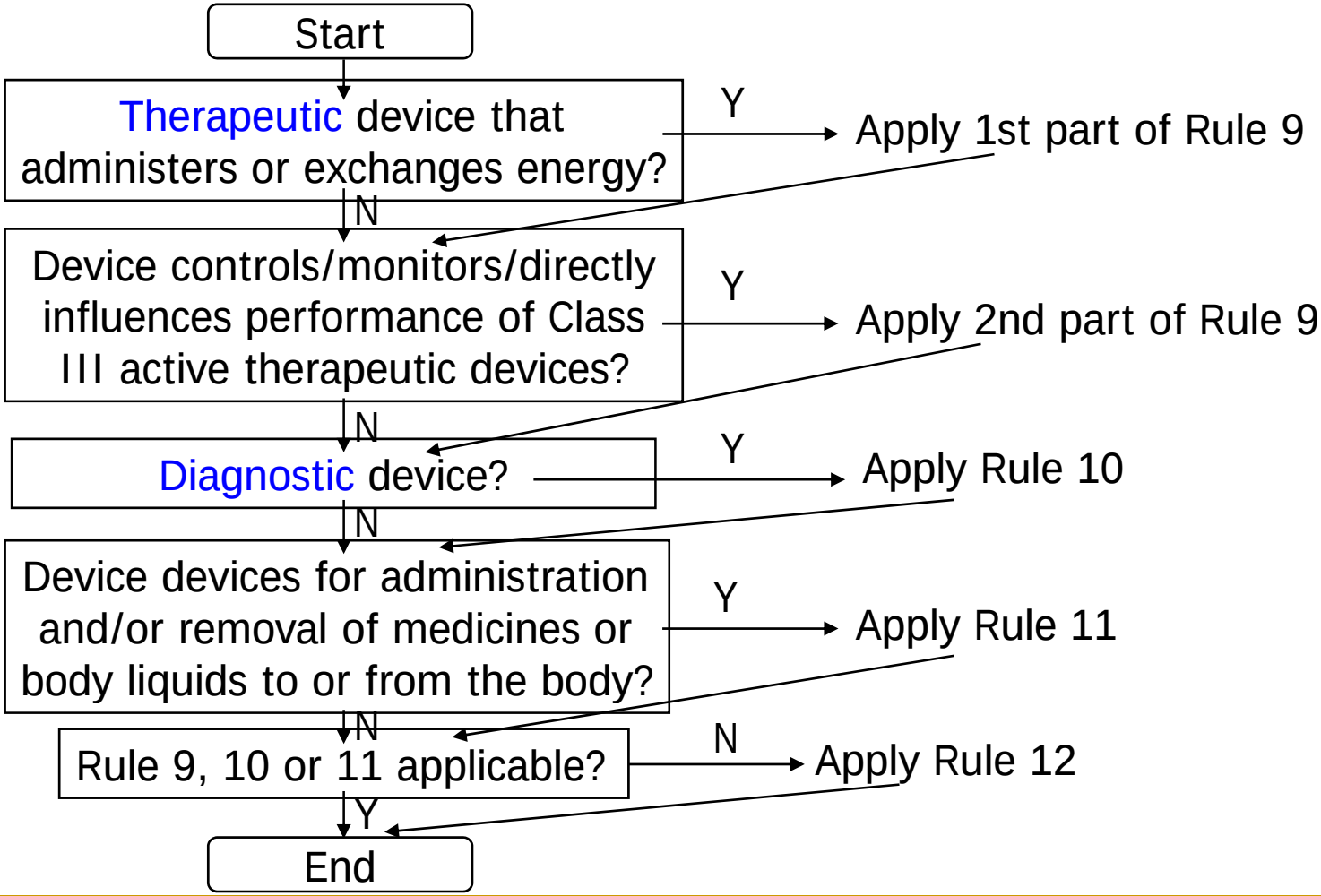
Go thru' Rules 1 to 4 (if the device is non-invasive)



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



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



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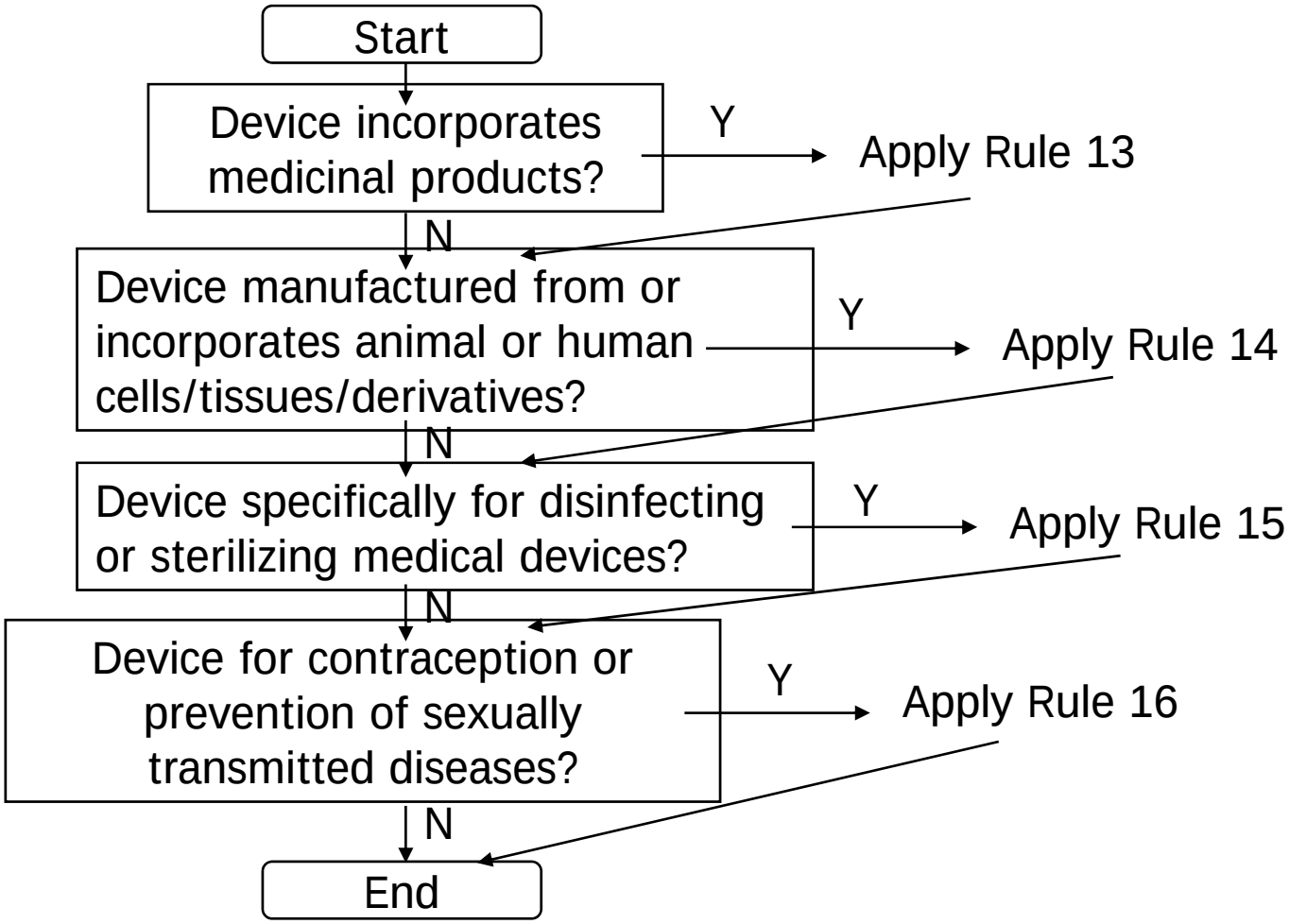
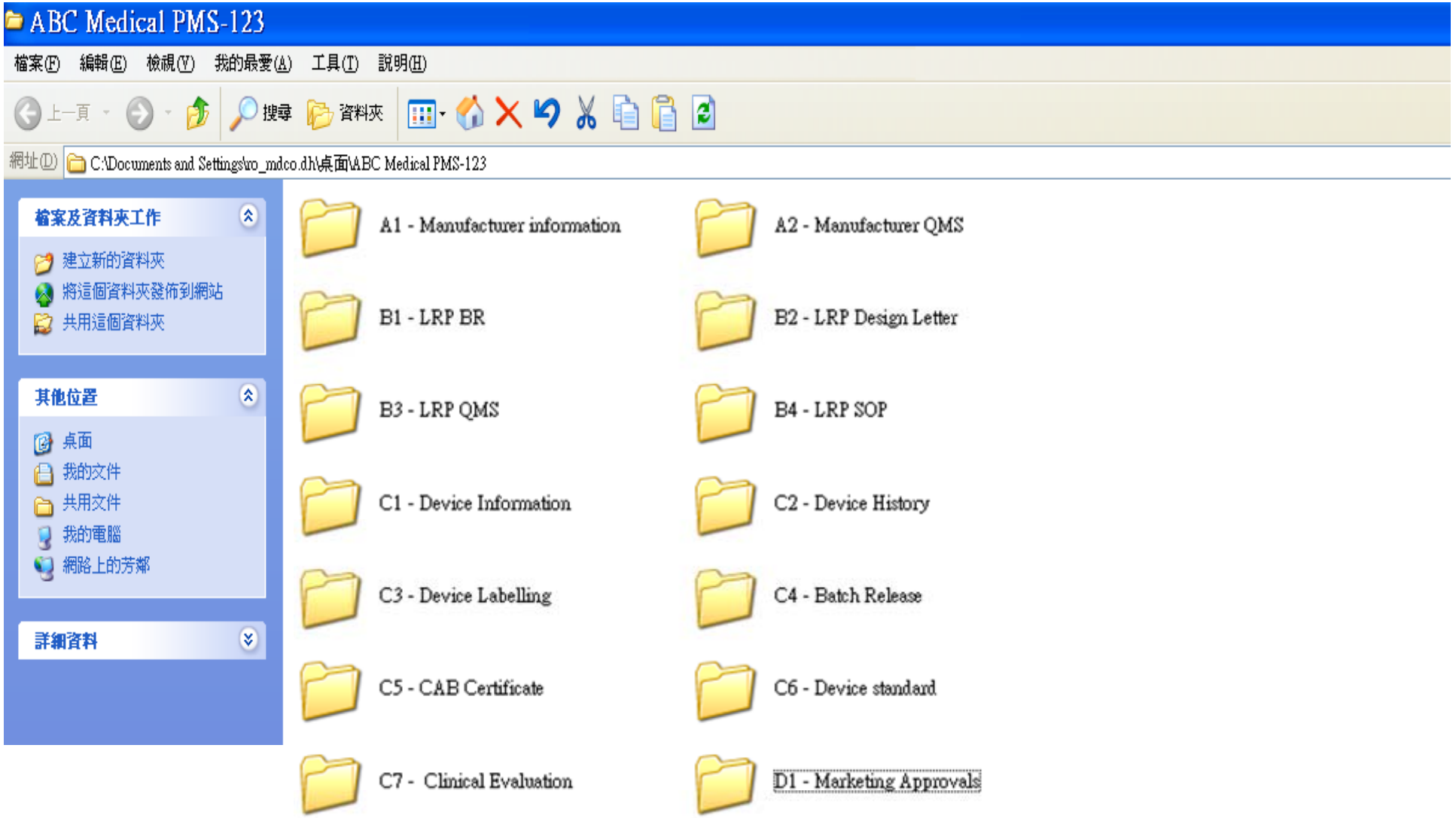
Go thru' Rules 13 to 16

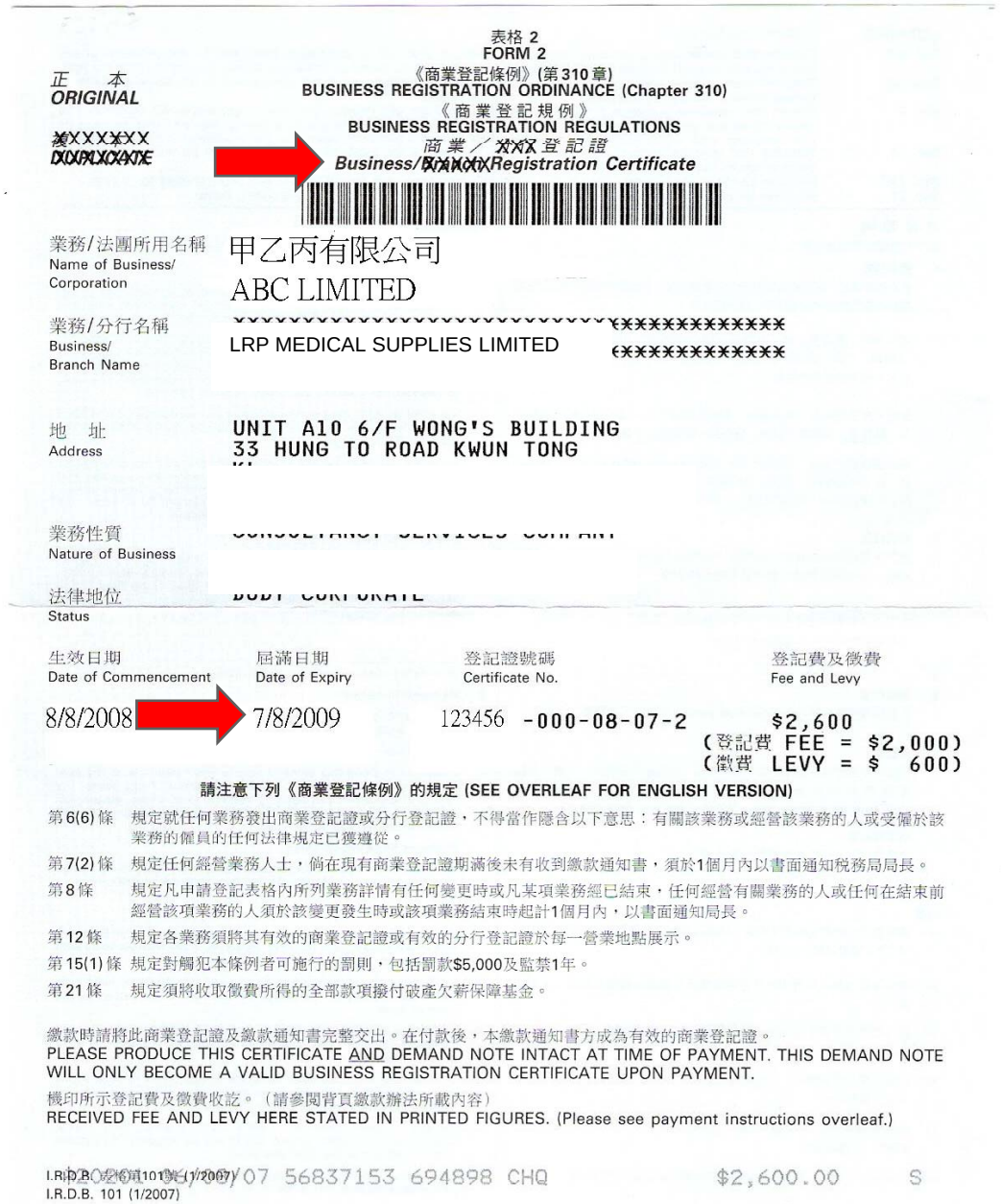


How to prepare an application



LRP

Business Registration Certificate (B1)



表格 2
FORM 2
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BUSINESS REGISTRATION ORDINANCE (Chapter 310)
《商業登記規例》
BUSINESS REGISTRATION REGULATIONS
商業登記證
Business 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
LRP MEDICAL SUPPLIES LIMITED

地 址
Address
UNIT A10 6/F WONG'S BUILDING
33 HUNG TO ROAD KWUN TONG

業務性質
Nature of Business

法律地位
Status

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.)

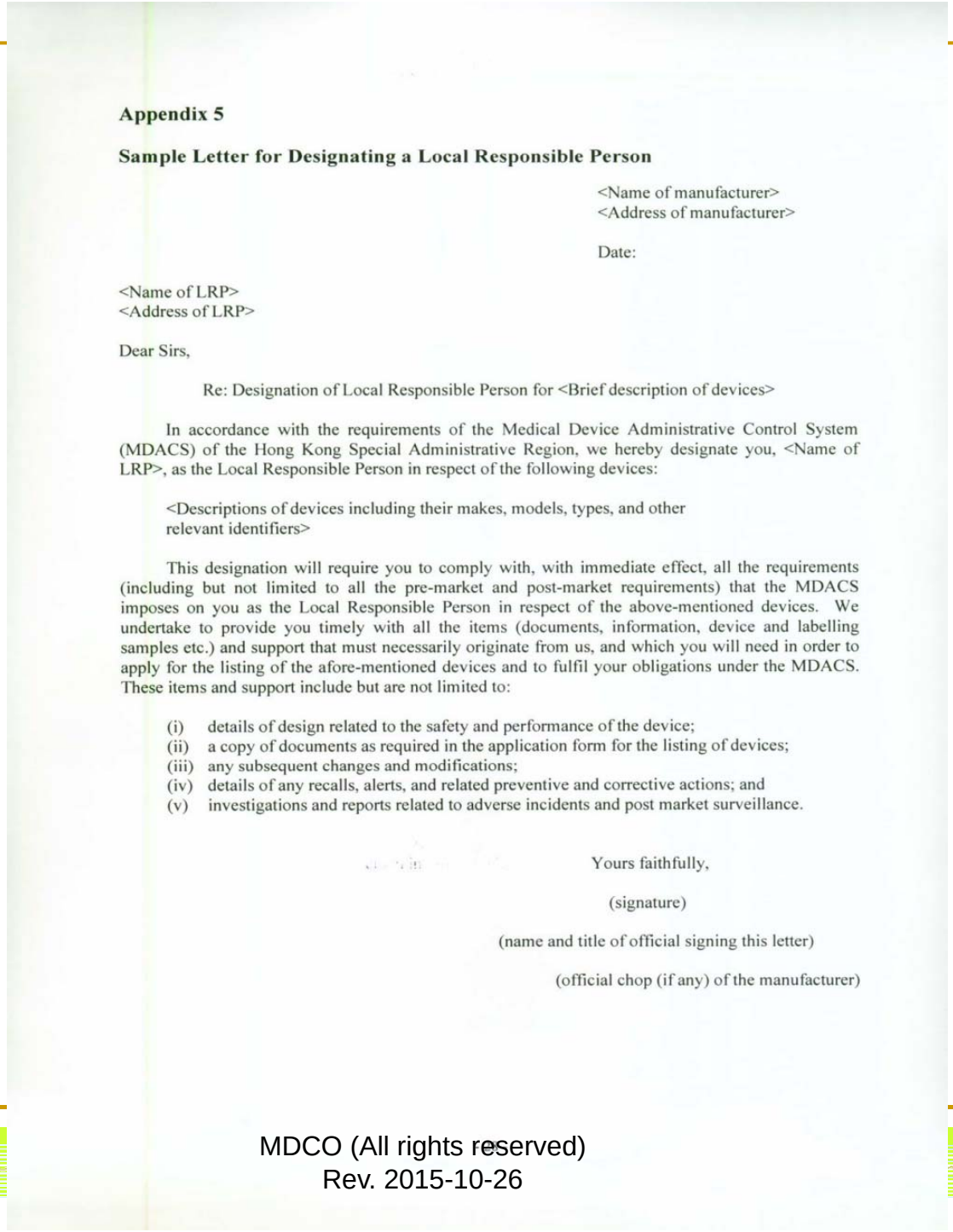
07 56837153 694898 CHQ $2,600.00 S

I.R.D.B. 101 (1/2007)

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>

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 designation letter (B2):

- Issued by the manufacturer

★ - **Contains:**

✓Manufacturer’s name

✓Manufacturer’s address

✓LRP’s name

✓LRP’s address

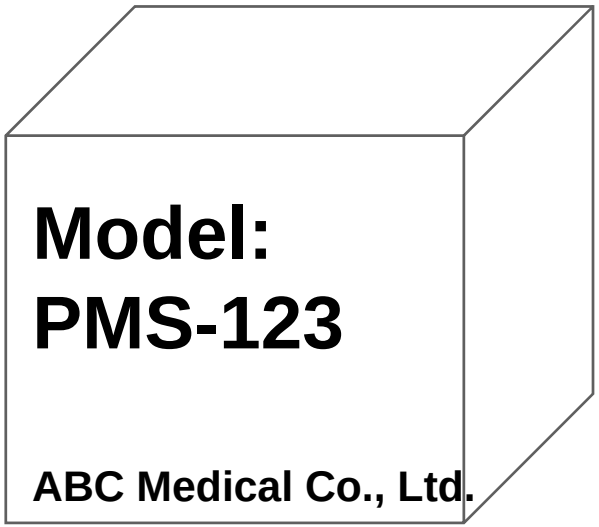
✖ ~~LRP’s tel./fax~~

LRP's documented procedures (B4)

- Procedures to be submitted in the 1st 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

- ~~Customer survey~~

Medical Device



Family/Series/ System

Accessories

Manufacturing site(s)

(C1)

Recalls/Adverse Incidents / Banning

(C2)

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 Certificate	Annex II Section 3 MDD Annex 2 section 3 AIMD
EC Verification Certificate	Annex IV MDD Annex 4 AIMD
Production Quality Assurance System Approval Certificate	Annex V MDD Annex 5 AIMD
Product Quality Assurance System Approval Certificate	Annex VI MDD

儀器 (D1)

Medical Device Control Office
Department of Health

Medical Device Administrative Control System
Essential Principles Conformity Checklist

Make: _____

Brand Name and Model: _____

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.	Y	ISO13485: 2003--Medical devices -- Quality management systems -- Requirements for regulatory purposes ISO14971:2007--Medical devices -- Application of risk management to medical devices	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 acknowledged 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 safe design and manufacture, • reduce as far as is reasonably practicable the remaining risks by taking adequate protection measures, including alarms, • inform users of any residual risks.	Y		
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.	Y		
4.	The characteristics and performances referred to in Clauses 1, 2 and 3 should			

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**

儀器 (D1)

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

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Exercise 2
(Post-workshop)

Please complete and return
Exercise 2 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