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

Medical Device Control Office
Department of Health

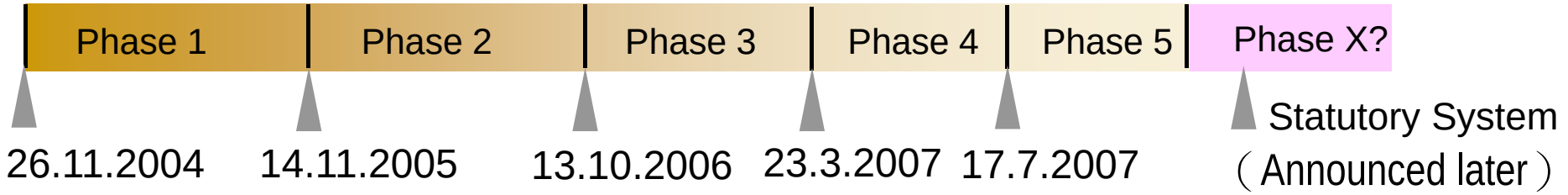
Workshop Agenda

- Medical Device Administrative Control System (MDACS)
- Local Responsible Person（LRP）
- Importer
- Classification of Medical Devices
- Break
- How to Prepare Application Documents
- Q&A

Medical Device Administrative Control System (MDACS)

Background Information

Implemented by phases



Phase 1 (Nov 2004): the MDACS has been open to applications for listing Class IV devices

Phase 2 (Nov 2005): the MDACS has also been open to applications for listing Class II and Class III devices.

Phase 3 (Oct 2006): Recognition of Conformity Assessment Bodies (CABs)

Phase 4 (Mar 2007): the MDACS has been open to applications for listing of Local Manufacturers

Phase 5 (Jul 2007): the MDACS has been open to applications for inclusion on the list of importers

Phase X: (xxx xxxx): Statutory System

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- To be eventually superseded by a statutory system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 – IV)
  - 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)

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
  http://search.mdco.gov.hk/english/sd/sd_ld/sd_ld.php
- Asian Medical Device Nomenclature System (AMDNS)
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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
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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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for the Medical Device Administrative Control System

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the Medical Device Administrative Control System
ation Rules for Medical Devices" given in Appendix 1 of this guidance
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

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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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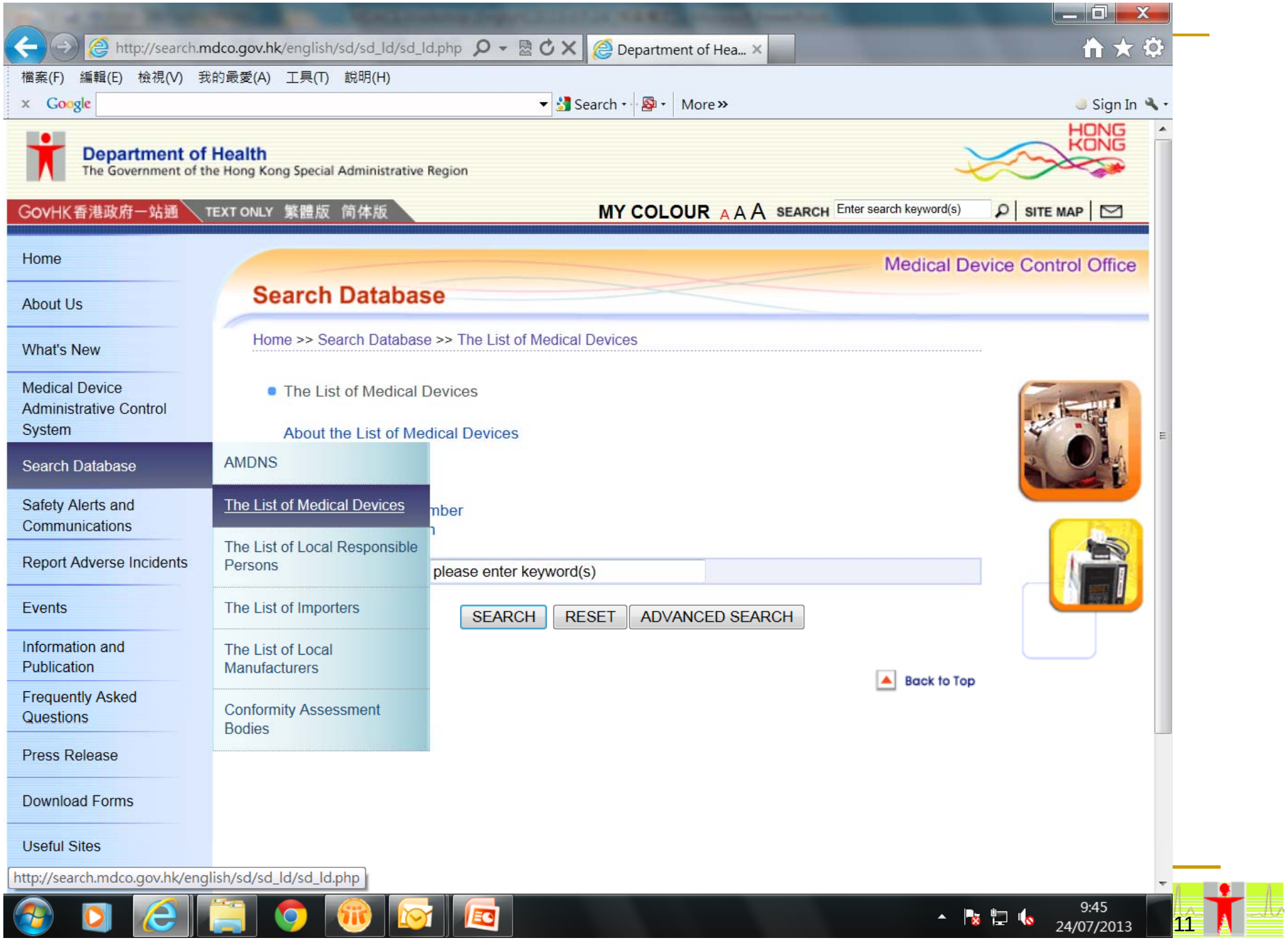
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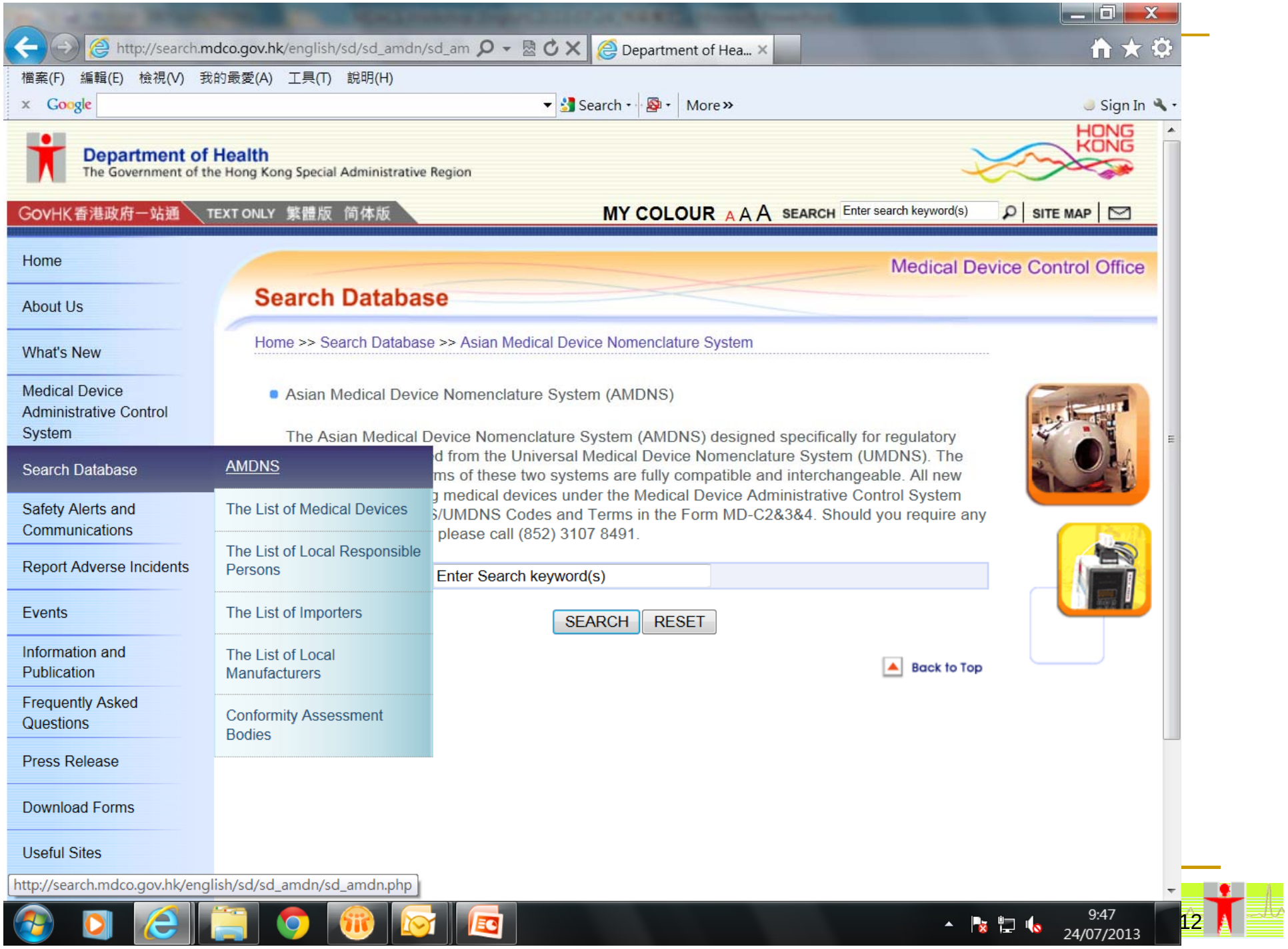
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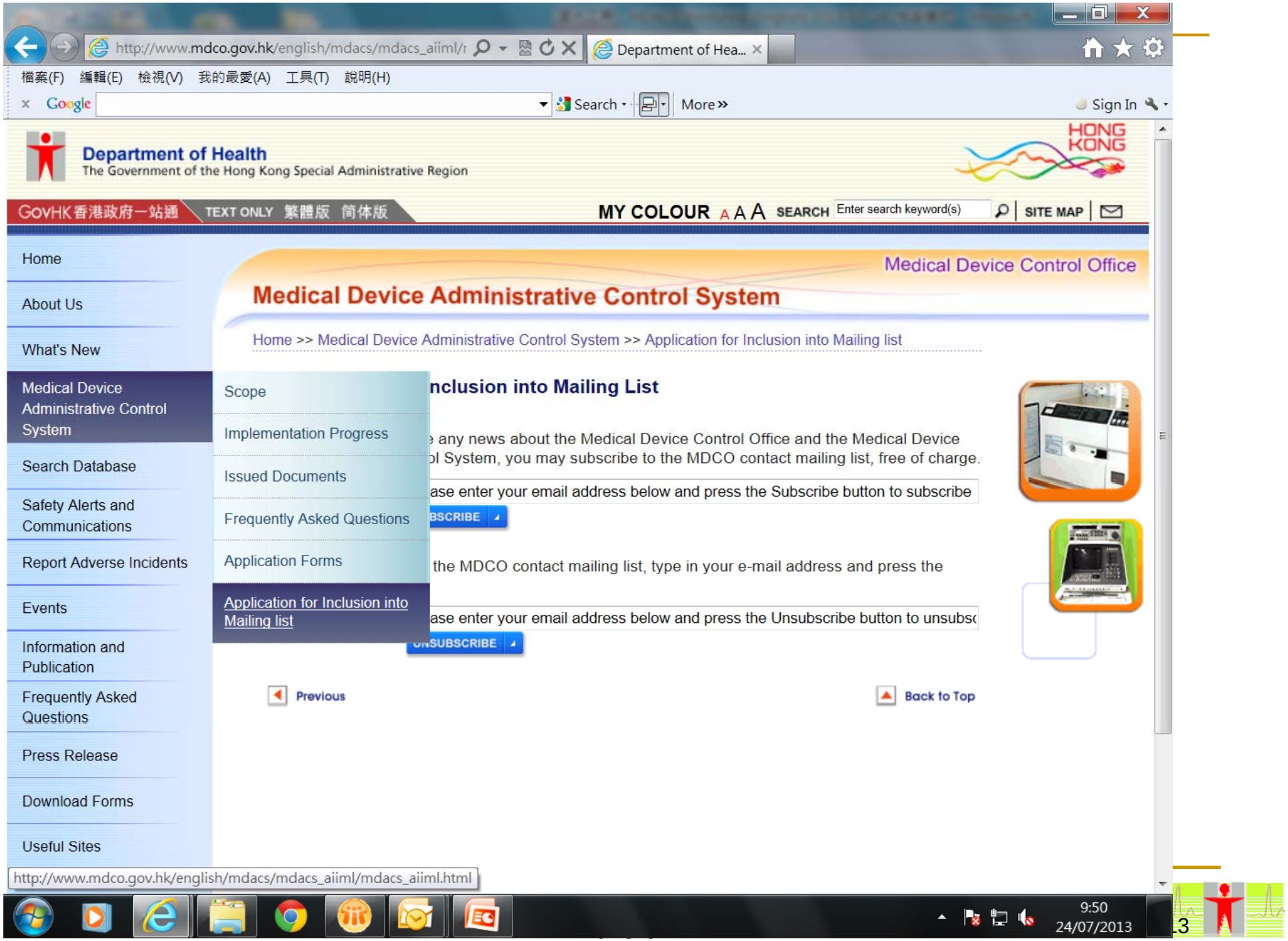
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Issued Documents

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

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

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)

Sample Letter for Designation a Local Responsible Person (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”.
- Manufacturer can “designate” LRPs or becomes LRP by itself.

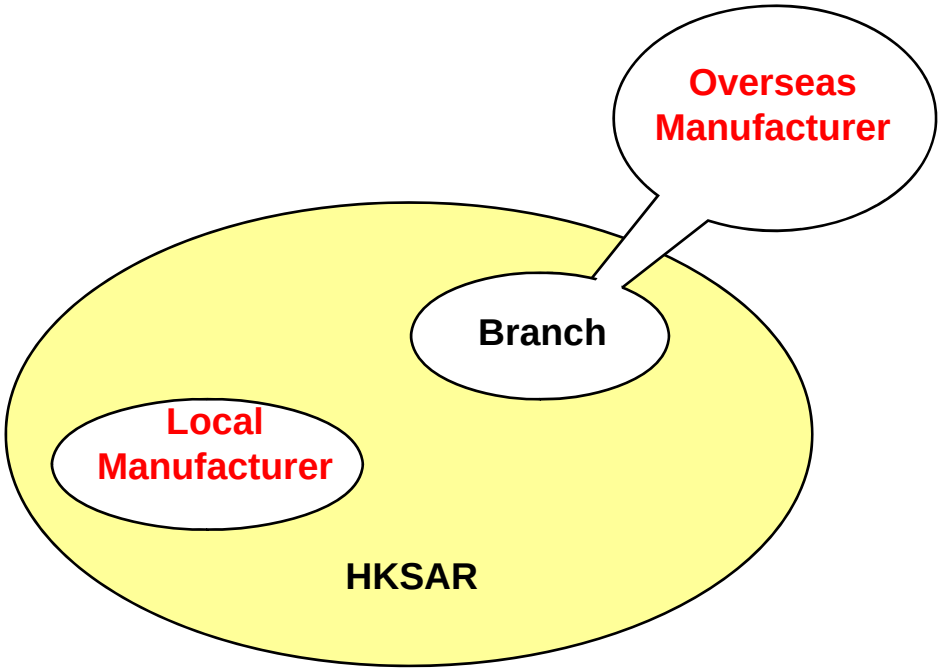


Figure 1

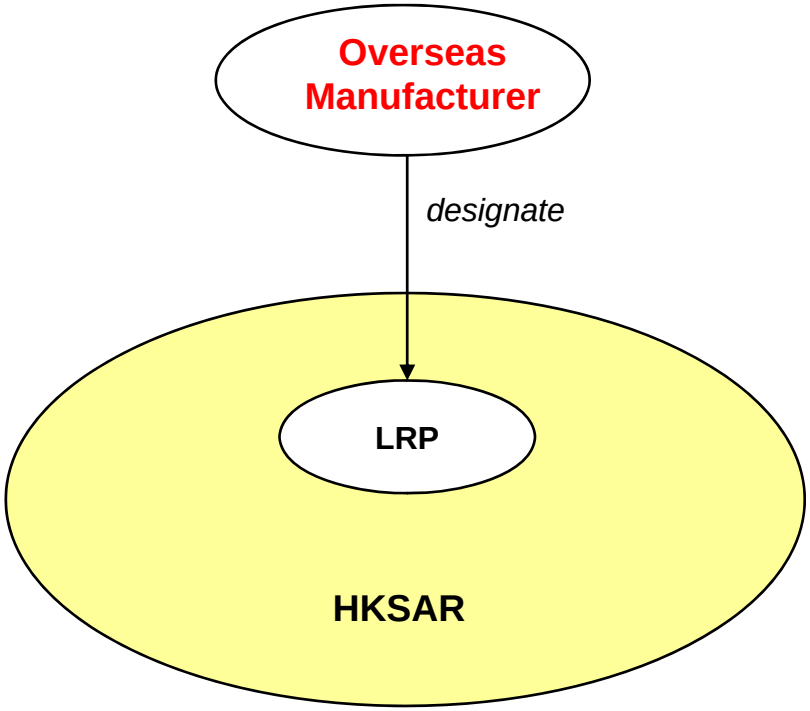
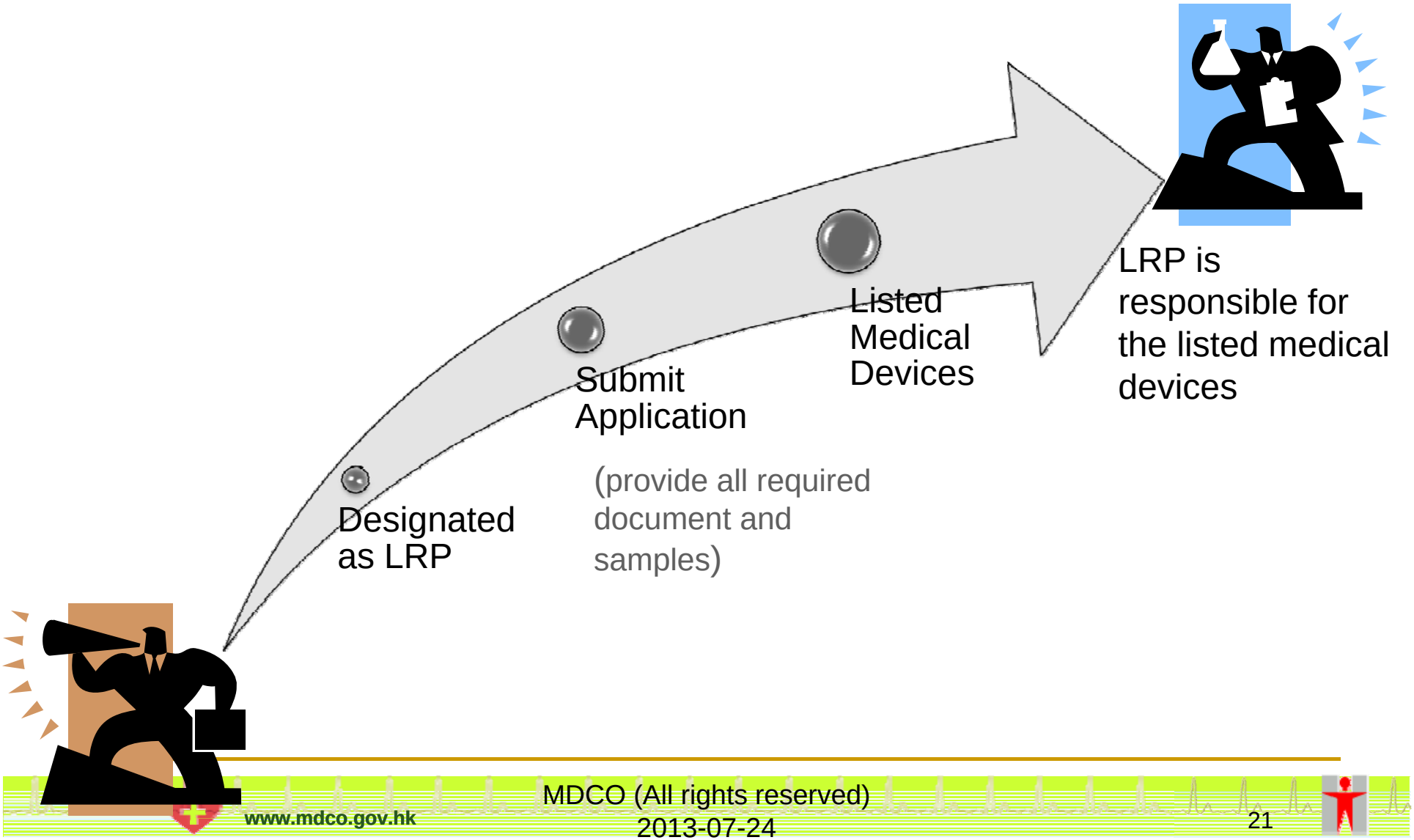


Figure 2

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）	✘	✓

Responsible Person for Listed Medical Devices



LRP's Responsibility

Communications Hub

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

Safe and Efficacious

- Managing reportable adverse incidents in Hong Kong
- 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

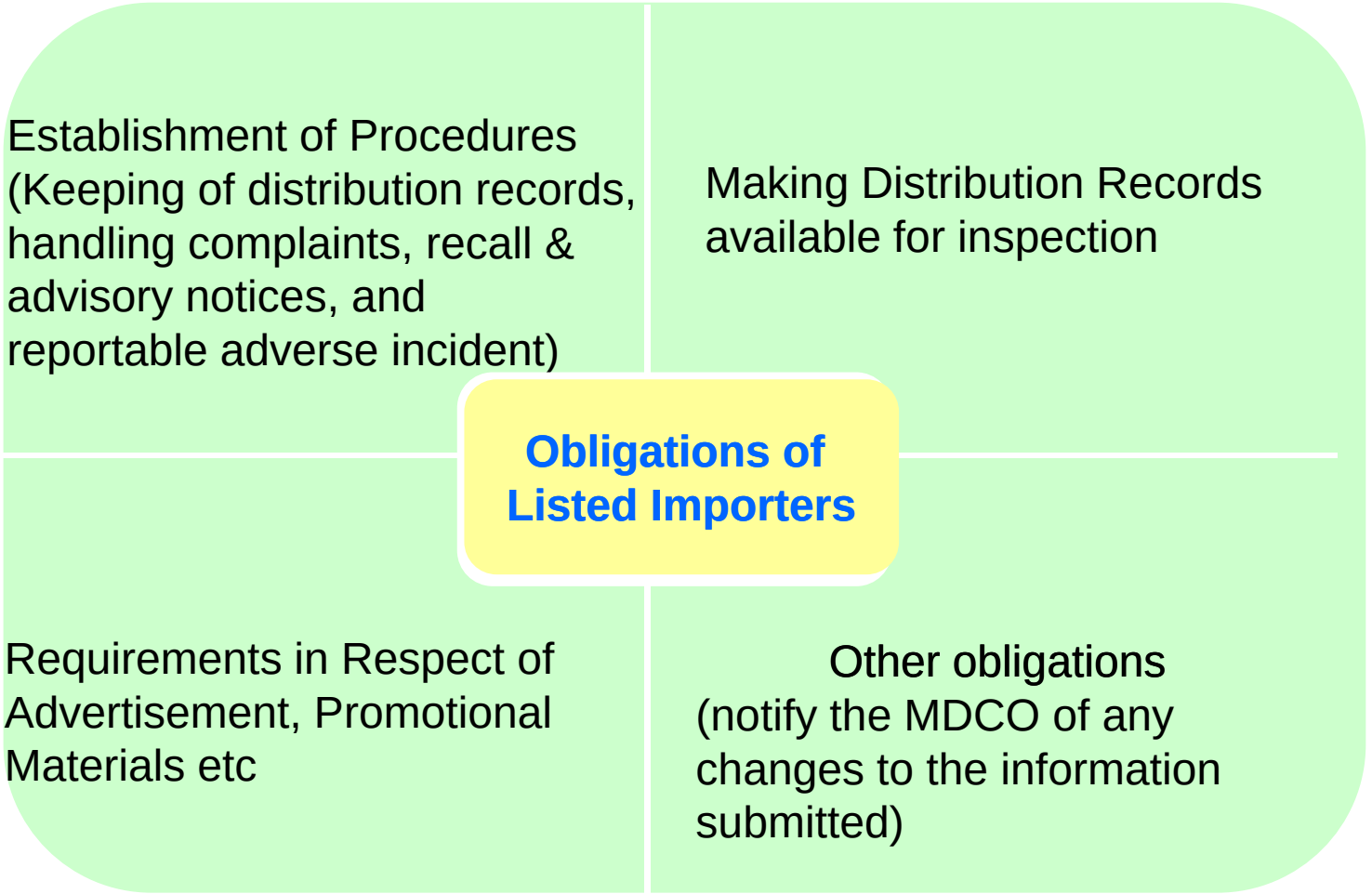
Importer

Listing of Importer
(under voluntary scheme)

(i) A legal or natural person: Business Registration Certificate
Individual : Identification document

(ii) Copy of documented procedures

Obligations of Listed Importers

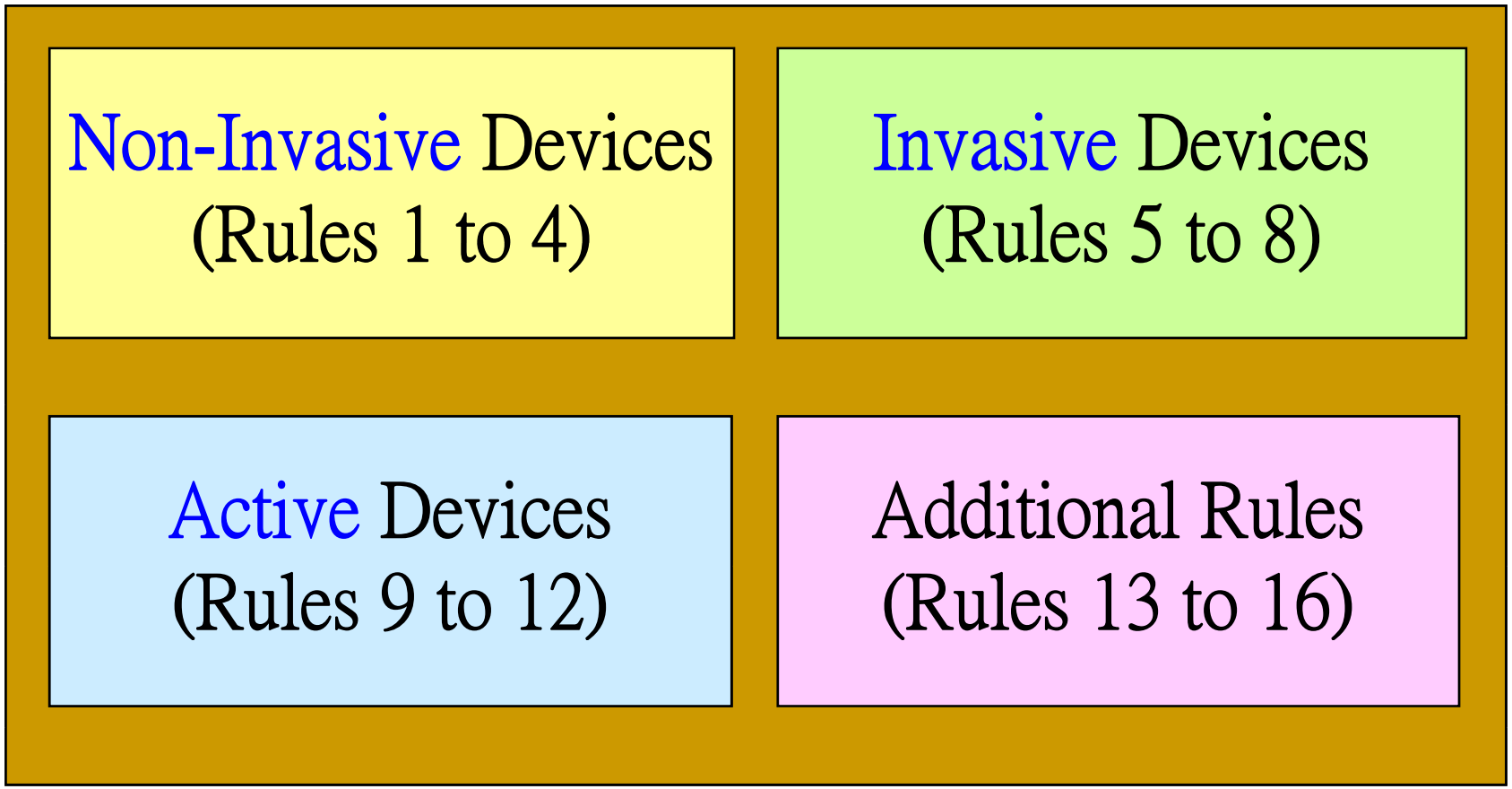


Classification of Medical Devices

Classification of Medical Devices

- Intended Use
- Characteristics of the device
- 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



Definitions (Ref.: GN-00)

- **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 :-

  - diagnosis, prevention, monitoring, treatment or alleviation of disease; or

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

Definitions (Ref.: GN-00)

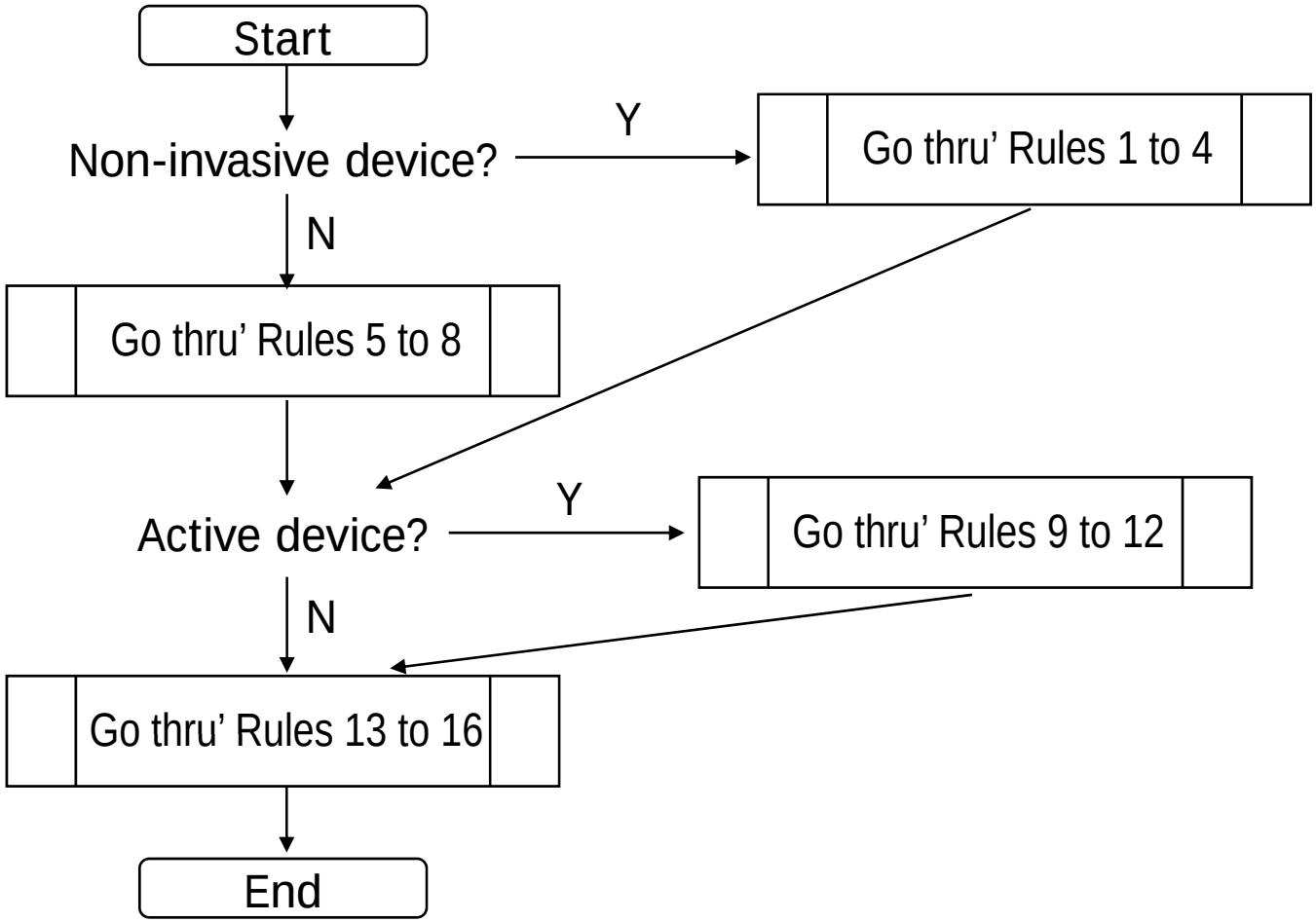
- investigation, replacement, modification, or support of the anatomy or of a physiological process; or
- supporting or sustaining life; or
- control of conception；or
- disinfection of medical devices；or
- providing information for medical purposes by means of in vitro examination of specimens derived 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.

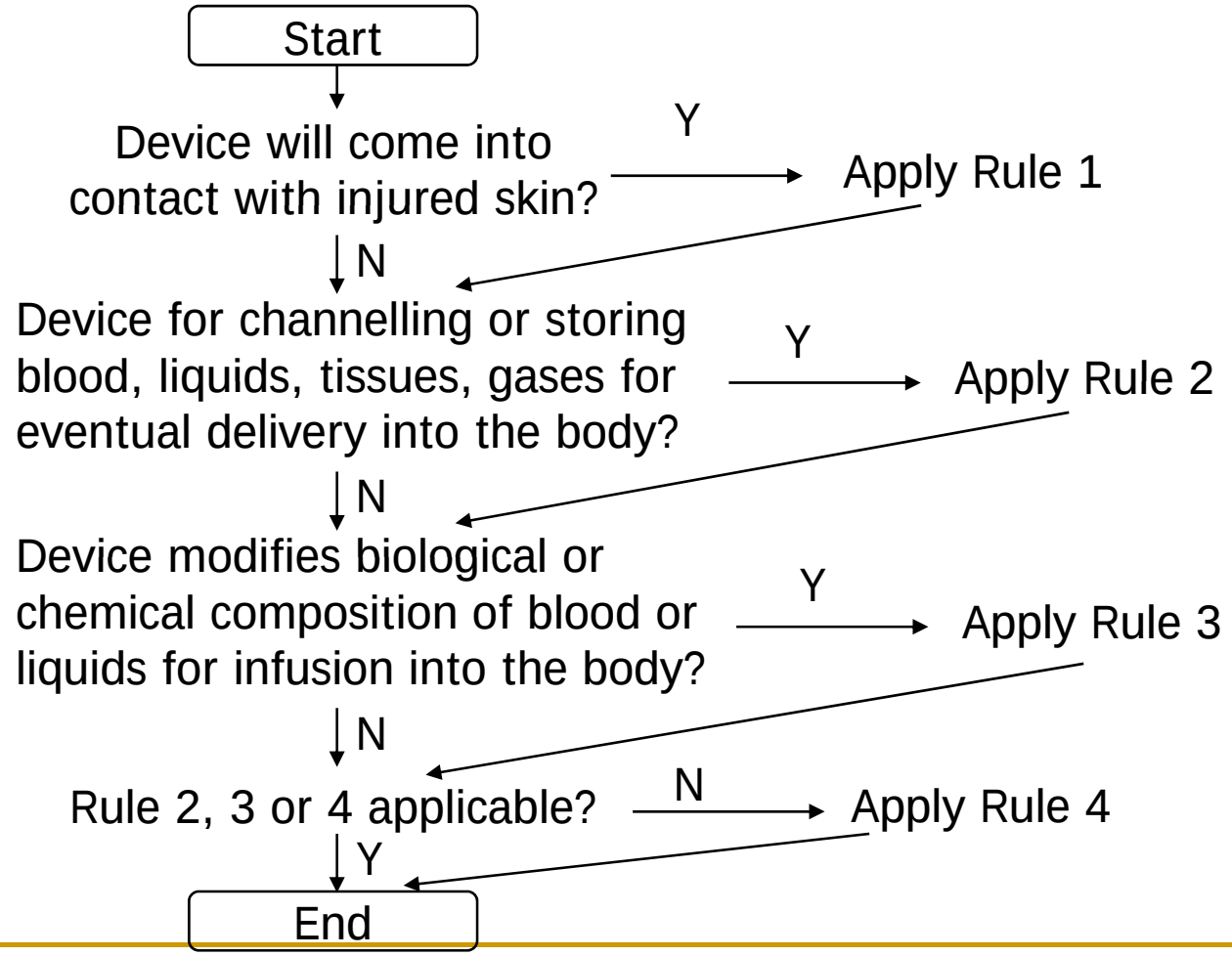
Definitions (Ref.: GN-00)

- 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.

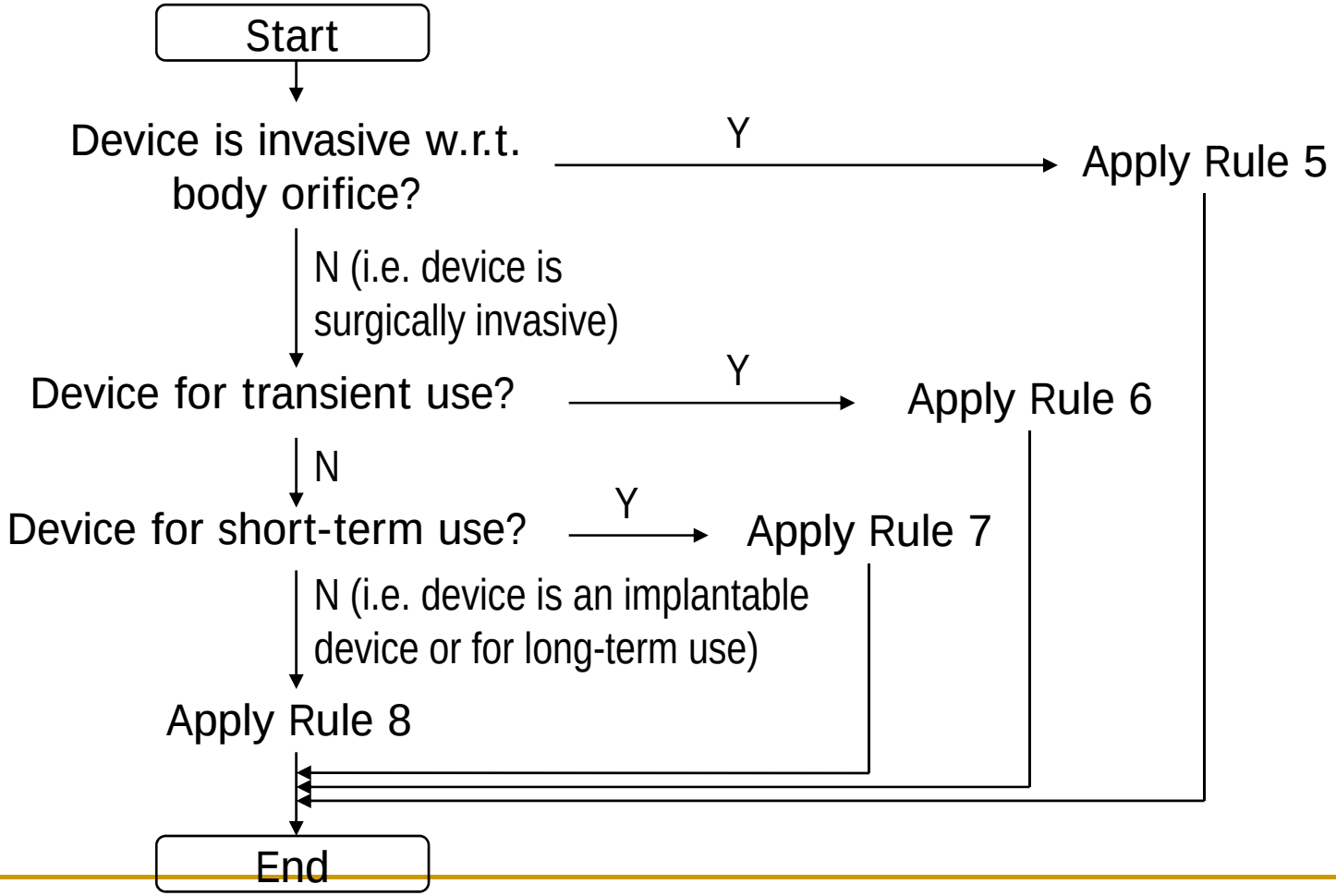
Classification of Medical Devices



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



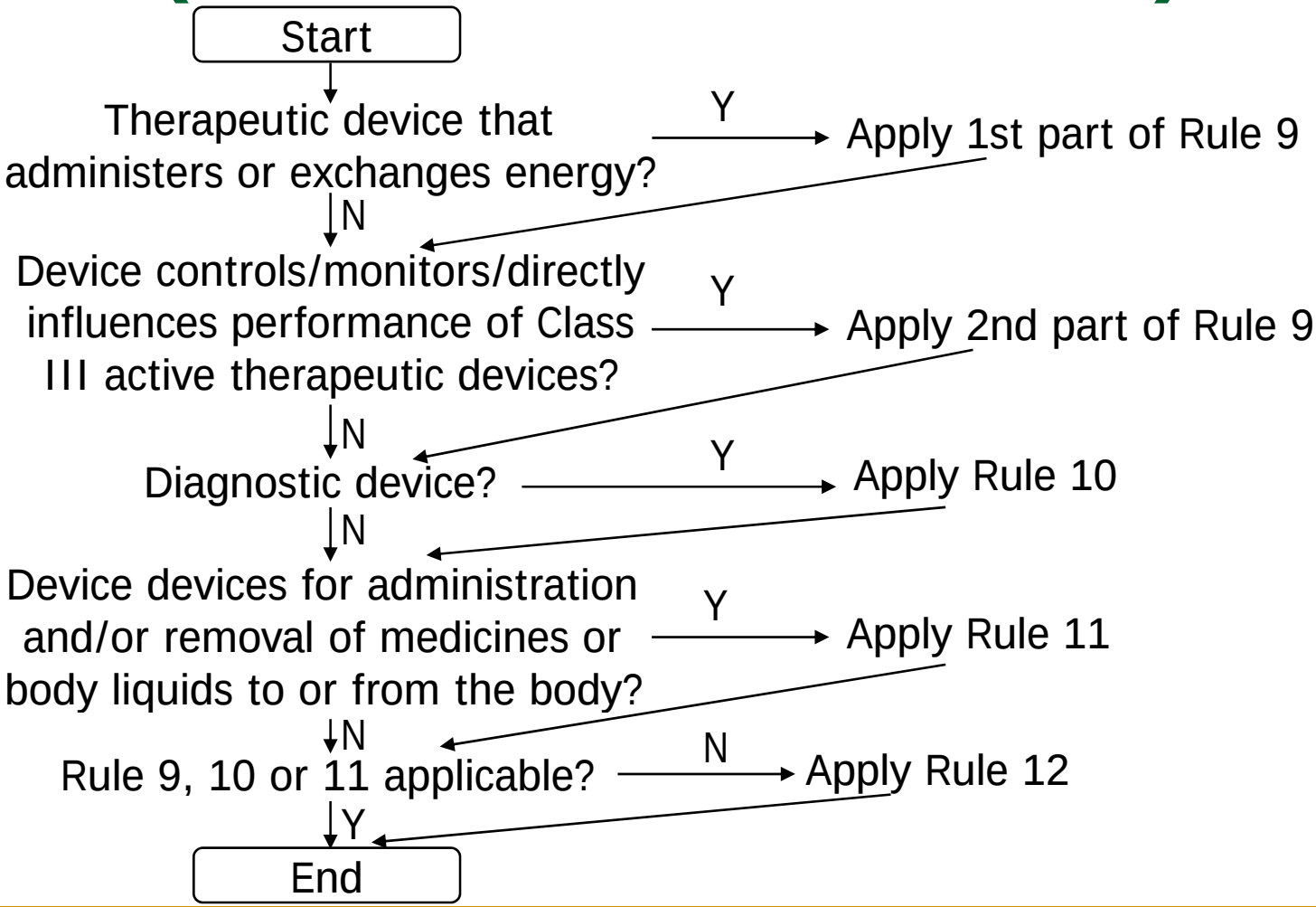
Go thru' Rules 5 to 8 (if the device is invasive)



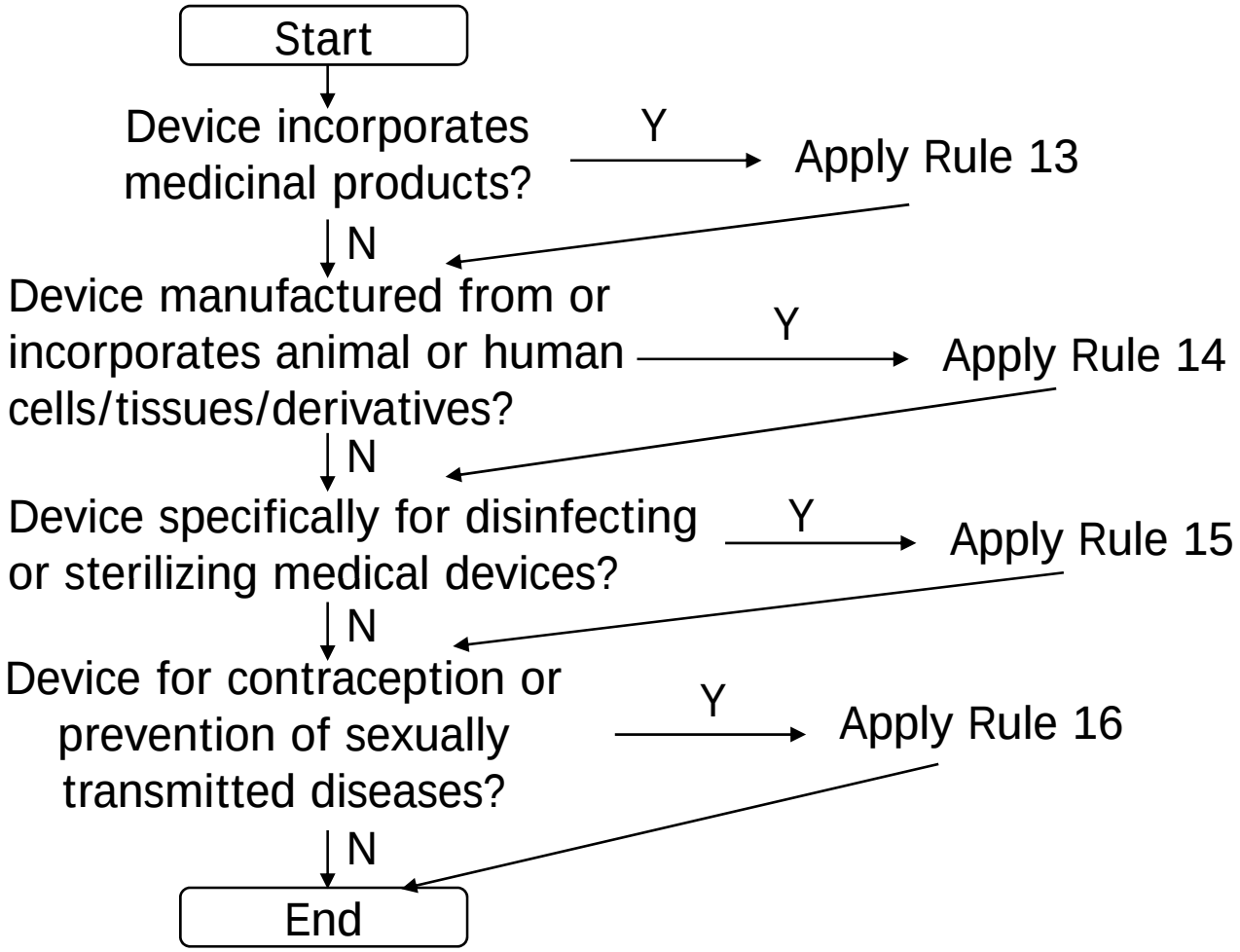
Classification of Medical Devices

	Duration of use
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

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



Go thru' Rules 13 to 16



Classification

- **Trial software for classification for trial by LRPs**
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最新消息

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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

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最新消息

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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

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医疗仪器管制办公室

最新消息

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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

This medical device is classified as:

Class IV

(Rule 13)

- END -

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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 accuracy of the above classification programme.

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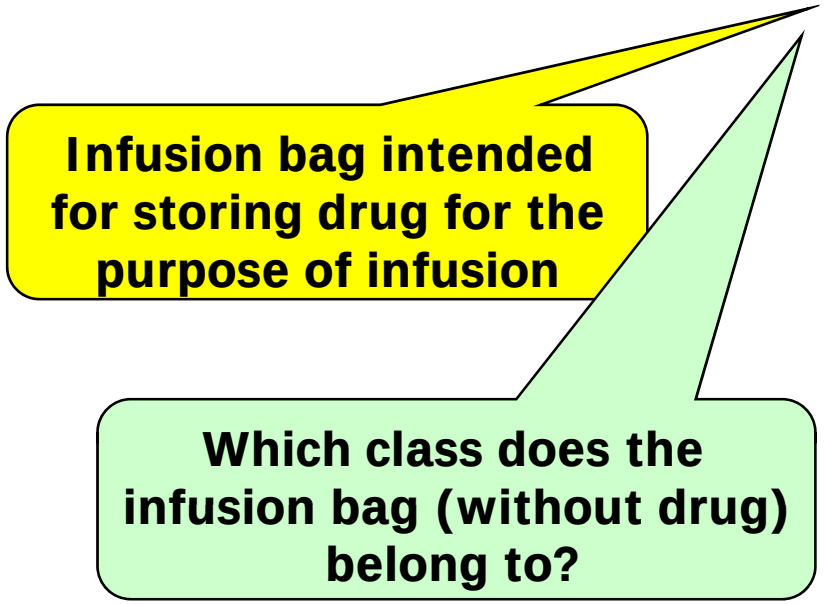
Classification of Medical Devices – Exercise 1a



Which class does the device belong to?	
Classification rules	**Which rule applies?**
1 to 4 (for non-invasive devices)	
5 to 8 (for non-invasive devices)	
9 to 12 (for active devices)	
13 to16 (additional rules)	

Classification of Medical Devices – Exercise 1b

Which Class does an intravenous (IV) set belong to?

Which class does the device belong to?	
Classification rules	**Which rule applies?**
1 to 4 (for non-invasive devices)	
5 to 8 (for non-invasive devices)	
9 to 12 (for active devices)	
13 to16 (additional rules)	

Classification of Medical Devices – Exercise 1c

The IV cannula is used to give medical personnel access to a patient's vein for insertion of medicine

Which class does IV cannula belong to?

Which class does the device belong to?	
Classification rules	**Which rule applies?**
1 to 4 (for non-invasive devices)	
5 to 8 (for non-invasive devices)	
9 to 12 (for active devices)	
13 to16 (additional rules)	

Classification of Medical Devices – Exercise 2

Electronic thermometer

Which class does the device belong to?	
Classification rules	**Which rule applies?**
1 to 4 (for non-invasive devices)	
5 to 8 (for non-invasive devices)	
9 to 12 (for active devices)	
13 to16 (additional rules)	

Classification of Medical Devices – Exercise 3

- **Example 3：Pulse Oximeter**

Intended Use :
Intended for monitoring, recording and alarming of patient SpO_2 in acute care settings in health care facilities.

Which class does the device belong to?	
Classification rules	**Which rule applies?**
1 to 4 (for non-invasive devices)	
5 to 8 (for non-invasive devices)	
9 to 12 (for active devices)	
13 to16 (additional rules)	

Classification of Medical Devices – Exercise 4

Surgical Laser

Which class does the device belong to?	
Classification rules	**Which rule applies?**
1 to 4 (for non-invasive devices)	
5 to 8 (for non-invasive devices)	
9 to 12 (for active devices)	
13 to16 (additional rules)	

Exercise/ Group Discussion

1. Which of the following item(s) is/ are Medical Devices?
   a) condom
   b) a torch used by a doctor for examination of patients in a clinic
   c) contact lens solution
   d) all of the above
   e) non of the above
2. Is it mandatory to list Medical Devices under HK MDACS?
3. Which class/classes of medical devices can be listed under HK MDACS?
4. What is the highest risk class of medical devices?
5. What is the duration of **short-term** use of a medical device?

Contact us

Department of Health

Medical Device Control Office

Address： Room 3101, 31/F, Hopewell Centre,
183 Queen's Road East, Wan Chai

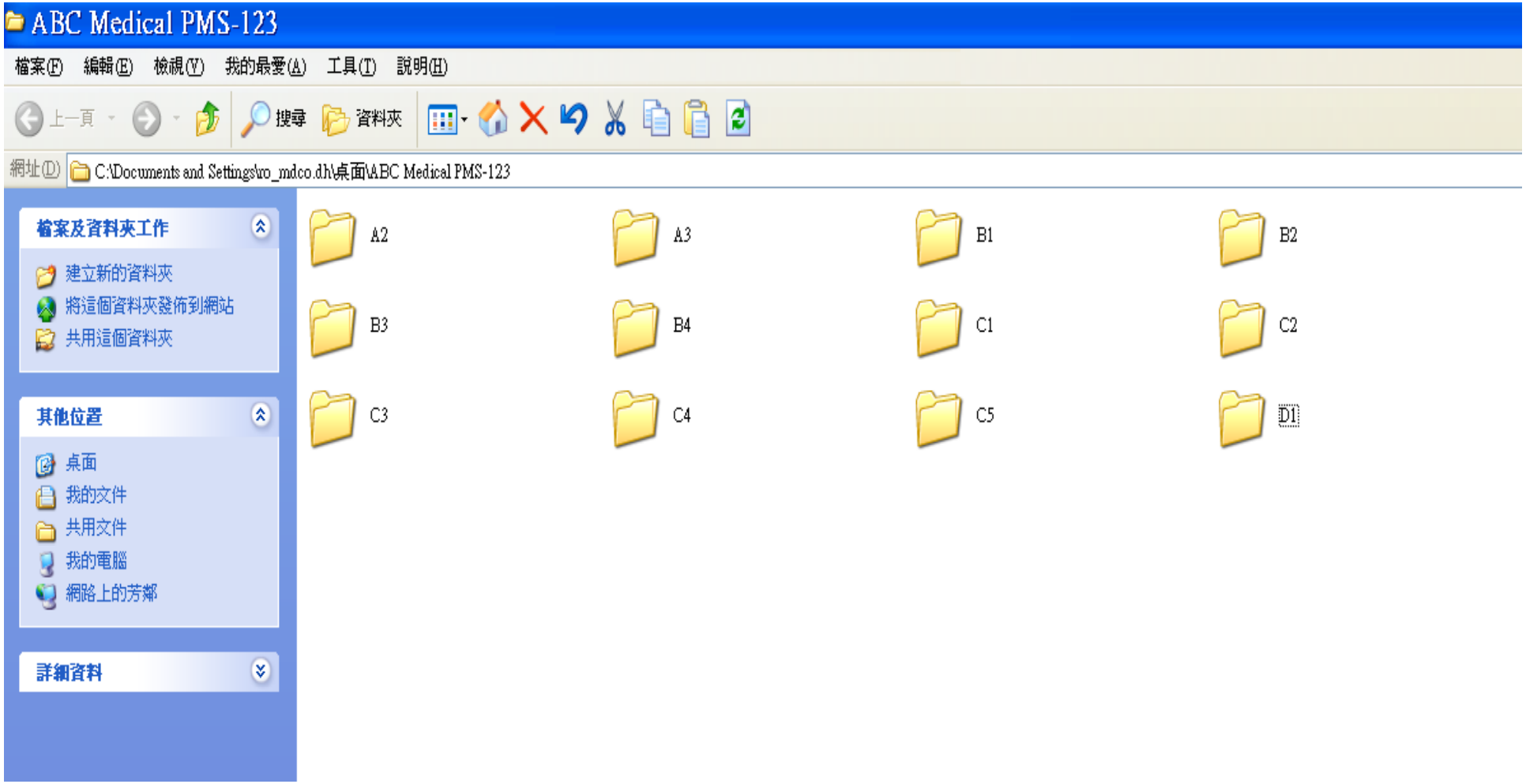
Telephone： 3107 8484

Fax： 3157 1286

Email： mdco@dh.gov.hk

Website： www.mdco.gov.hk

How to prepare an application



Manufacturer:

- ISO 13485 certificate (A2)

Local Responsible Person (LRP):

- Business Registration Certificate (B1)
- Manufacturer’ s letter for designation of LRP (B2)
- ISO 13485/ ISO 9001 if any (B3)

LRP

Documented Procedures:

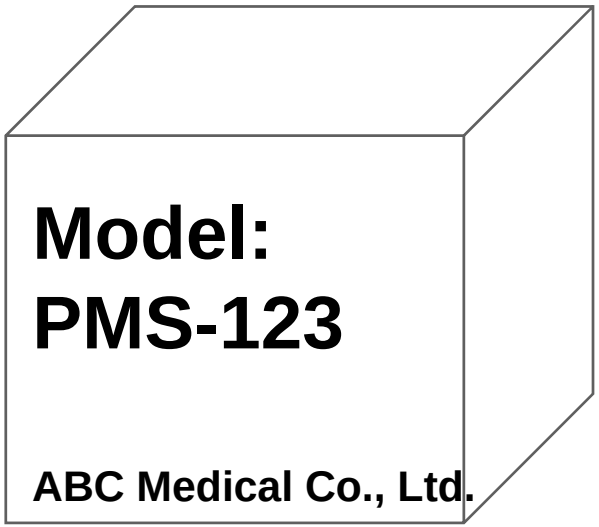
- Management of product recalls & field safety notices

- Handling of reportable adverse incidents

- Keeping of distribution records

(B4)

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)

HK MDACS Conformity Assessment Certificate if applicable

(C5)

Type Test Certificate/Report

Risk Analysis Report

(C6)

Clinical evaluation report

(C7)

Medical Device (D1) EU Approval

Declaration of Conformity (DoC)	
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

Thank you!

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