Hong Kong Medical Device Regulatory Updates

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Pacific Bridge Medical

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Contents

Facts about Hong Kong

Some Facts about Hong Kong

- Located at China's south coast at Pearl River Delta
- Area of 1,104 km^2
- Consisted of Hong Kong Island, Kowloon Peninsula and the New Territories
- Population at end 2010 is 7.1 million

Economy of Hong Kong

- World's leading international finance centre
- Low taxation and free trade
- Government exercises positive non-interventionism
- One of the Four Asian Tigers: Japan, Taiwan, Korea and Hong Kong
- Extensive trade and investment ties with mainland China
- New Chief Executive in July 2012: Mr. C Y Leung

Business Culture for Medical Device

- Medical device procurement started in 1980's.
- Nowadays, Government procures medical equipment for DH and Government Laboratory
- HA started centralization of procurement of capital medical equipment. The annual budget has been raised from USD 5 million to USD 7.5 million
- Decentralization being enforced to hospital clusters for non-capital medical equipment

Patient Demographics

- There is a strong influx of low income families from the mainland and this causes enormous effect on government subsidy to the healthcare system
- Normal patients rely on medical services of HA hospitals and general out-patient clinics (GOPC)
- Affordable patients have medical consultation and treatment by private medical practitioners and private hospitals

Healthcare System in Hong Kong

Healthcare System in Hong Kong

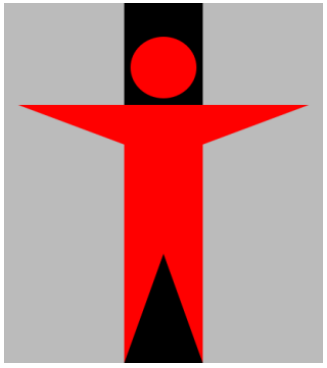
- Food & Health Bureau
  (Permanent Secretary: Dr. York YN Chow)
- Hospital Authority (Chief Executive: Dr. Leung Pak Yin)
- Department of Health (Director: Dr. Lam Bing Yan)
- Centre for Health Protection (Controller: Dr. Thomas Tsang)
- Electrical & Mechanical Services Department (EMSD) to provide support to hospitals and DH on engineering matters

Department of Health (DH)

- Community Health and health policies/strategies such as SARS, Bird Flu, Scarlet Fever and Legionnaires Disease controls
- Community health program, vaccine schemes and education
- The Regulator for pharmaceuticals and drugs, radioactive substances and medical devices
- Licensing for medical professionals, Chinese herbal doctors
- Licensing for 12 private hospitals

Consists of

1. Centre for Health Protection
2. Pharmaceuticals and Drug Control Office
3. Radiation Health Unit
4. Medical Device Control Office



Hospital Authority (HA)

- Consists of 7 Clusters:

  HK East Cluster, HK West Cluster, Kowloon East Cluster, Kowloon Central Cluster, Kowloon West Cluster, New Territories East Cluster and New Territories West Cluster

- Major Acute Hospitals:

1. Pamela Youde Nethersole Eastern Hospital (PYNEH)
2. Queen Mary Hospital (QMH)
3. Queen Elizabeth Hospital (QEH)
4. Princess Margaret Hospital (PMH)
5. United Christian Hospital (UCH)
6. Prince of Wales Hospital (PWH)
7. Tuen Mun Hospital (TMH)

Regulation Controls Relating To Medical Devices

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Regulation Controls Relating to Medical Devices (1)

- Currently, there is no specific legislation to regulate the importation or sale of medical devices in Hong Kong except those containing pharmaceutical products or emitting ionizing radiation
- The **Consumer Goods Safety Ordinance (Cap.456)** provides protection against the supply, manufacture or import of unsafe products, including some medical devices that can be regarded as consumer goods, unless otherwise specified in the Schedule. The **Electrical Products (Safety) Regulation (Cap.406G)** provides protection against the supply of unsafe electrical products including medical devices designed for household use except those products specified otherwise

Regulation Controls Relating to Medical Devices (2)

- The statutory regulation of certain health care professionals, whereby the practitioners are required to ensure the safe and appropriate treatment for patients, also provides incidental control on the use of medical devices
- The **Undesirable Medical Advertisements Ordinance (Cap.231)** prohibits advertisements related to the curative or preventive effects of products on diseases listed in the Ordinance

Regulation Controls Relating to Medical Devices (3)

- Voluntary Medical Device Administrative Control System (MDACS)
- Pharmaceutical and Drugs Control Office
- Radiation Health Unit
- Proprietary Chinese Medicine or Chinese Herbs
- Health food and nutrition supplements

Advantages of Registering for Voluntary Listing

(1) Manufacturers can make device registration whilst product putting to HK market is not affected. No time is lost in the process. Once there is regulation, product cannot be sold until after registration.
(2) According to DH advice, products registered under the voluntary system will be transferred direct to the regulation list without another dossier submission.
(3) Once registered on the voluntary list, there is no need to suffer from long queue when everyone is trying to make application at the mandatory registration.
(4) Applications are being dealt with less pressure since of the voluntary status.

What's More – It's Business !!

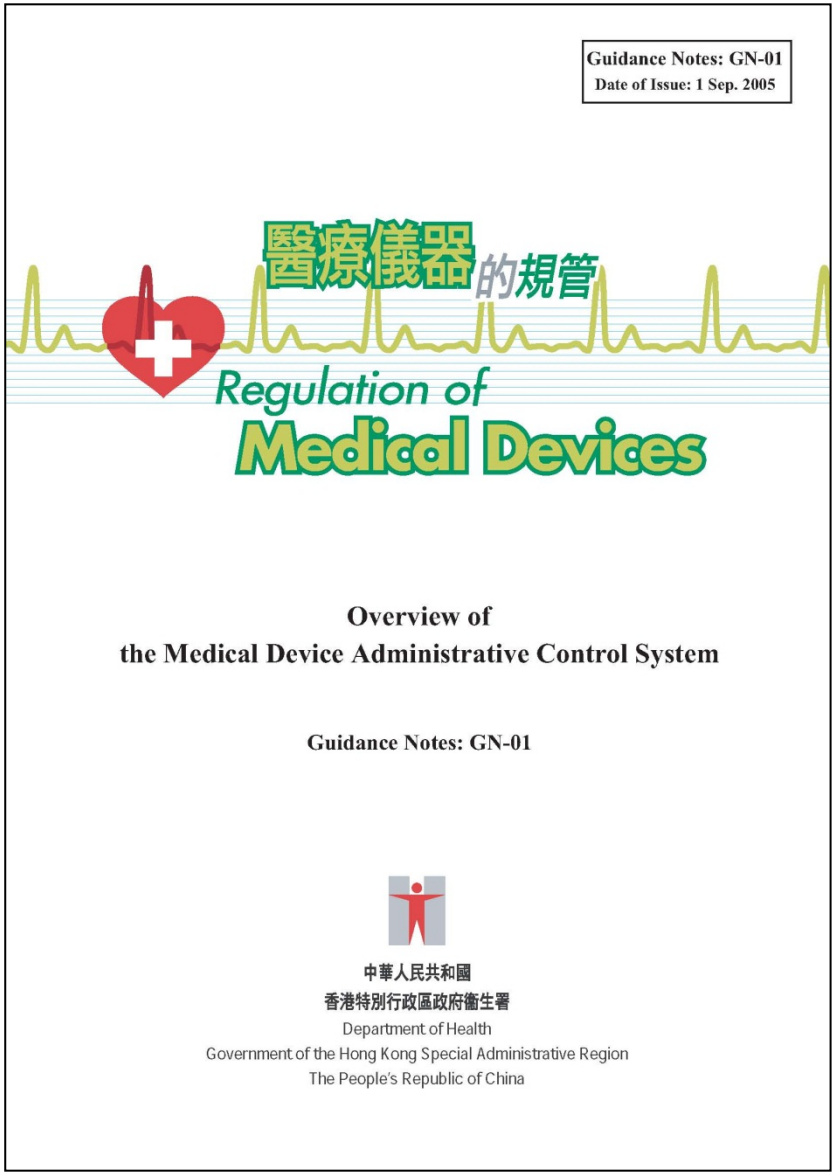
(5) Major procurement in HK comes from Hospital Authority. They are already referring to the voluntary list as a preference for procurement for capital equipment and major purchases of medical equipment and device systems.
(6) Majority of Medical practitioners are HA-trained and hence early application in HA will facilitate future market growth.
(7) Private hospitals in HK all make reference to HA procurement practices.
(8) Mainland China purchases make strong reference to HK registered and listed products.
(9) Hong Kong is a major leader in Asia Harmonization Working Party (AHWP) and a number of Asian countries will make reference to products being registered in HK.

Medical Device Administrative Control System

Regulator: MDCO, DH

- Enforcement of Voluntary MDACS
- Registration and Listing of MD
- Listing of Local Responsible Person (LRP)
- Listing of Local Manufacturers
- Listing of Importers and Suppliers
- Listing of Conformity Assessment Bodies (CAB)
- **Registration to PPO Cap 138 and RO Cap 303** are pre-requisites to registration and listing application to MDCO for a medicinal combinational medical device or an radioactive medical device

Medical Device Administrative Control System (MDACS)



Definition of Medical Devices

A medical device is defined as 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:

1. diagnosis, prevention, monitoring, treatment or alleviation of disease; or compensation for an injury
2. investigation, replacement, modification, or support of the anatomy or of a physiological process; or
3. supporting or sustaining life; or
4. control of conception (including contraception); or
5. disinfection of medical devices; or
6. medical information by means of in vitro examination of human body specimens

Classification of Medical Devices

- Intended Use
- Characteristics of the device
- All Classification rules (TR-003) needed be considered
- The highest class will apply when more than one rule is applicable

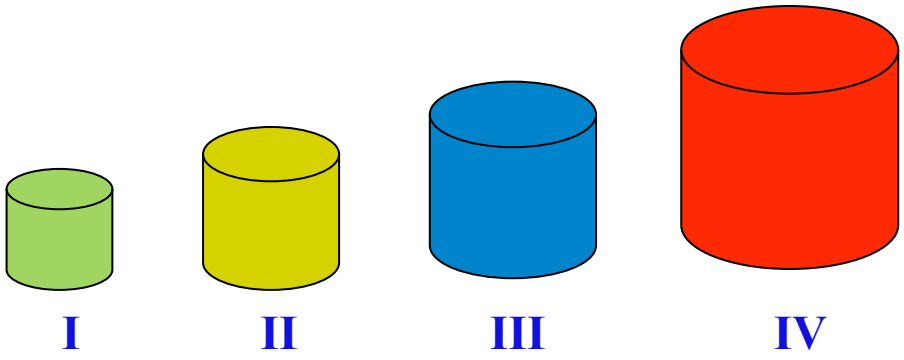
Classification of Medical Devices – Some Definitions

- Active medical device
- Invasive medical device
- Body orifice
- Active implantable medical device
- Transient, short-term and long-term use
- Standalone software
  (Ref Section 2 of GN-00)

Classification of Medical Devices – Some Definitions

- Transient use
  - Continuous use for less than 60 min
- Short-term use
  - Continuous use for between 60 min and 30 days
- Long-term use
  - Continuous use for more than 30 days

Risk Classification of Medical Devices



Class I	Class 1 of EU system
Class II	Class 2a of EU system
Class III	Class 2b of EU system
Class IV	Class 3 of EU system

Phase Development of MDACS

Phase 1 (Nov 2004)	Listing of Class IV devices
Phase 2 (Nov 2005)	Listing of Class II and III devices
Phase 3 (Oct 2006)	Conformity Assessment Framework
Phase 4 (Mar 2007)	Listing of Local Manufacturers
Phase 5 (July 2007)	Listing of Importers
Phase 6 (Dec 2009)	Listing of Class D IVD medical device
Phase 7 (In progress)	Statutory System

Special Features of MDACS

- It is a voluntary system
- Employs a registration framework through Listing
- Follows close to EU GHTF regulatory framework
- Employs a special MD nomenclature system known as Asia Medical Device Nomenclature System (AMDNS)
- Implements an adverse incident reporting system called the SADS (Safety Alert Dissemination System) and is networked to the global GHTF NCAR (National Competent Authority Report) system

Information from MDCO Website (www.mdco.gov.hk)

- Guidance Notes, Code of Practice and Technical Reference http://www.mdco.gov.hk/tc_chi/mdacs/mdacs_gn/mdacs_gn.html
- Application Form
  http://www.mdco.gov.hk/tc_chi/mdacs/mdacs_af/mdacs_af.html
- Listed Medical Device
  http://search.mdco.gov.hk/tc_chi/sd/sd_ld/sd_ld.php
- Asian Medical Device Nomenclature System (AMDNS)
  http://search.mdco.gov.hk/tc_chi/sd/sd_ld/sd_ld.php

Important Roles of Local Responsible Person (LRP)

- LRP makes listing applications for each class II, III and IV medical devices on behalf of the device manufacturer
- LRP is a legal and formal representative of the device manufacturer in the registration and listing of medical device with MDCO
- LRP provides a communication hub among users, manufacturer, importer and the regulator
- LRP ensures the safety and efficacy of the device with the manufacturer and is responsible for adverse incident reporting on the listed device(s)
- LRP provides quality services to the users when required

Who can be an LRP ?

- Overseas manufacturer's Hong Kong Branch or
- Company incorporated in Hong Kong or
- Person with business registration in Hong Kong and
  - Itself being the device manufacturer or
  - Supported by the device manufacturer (a designation letter is required from the manufacturer to appoint the LRP in writing)

Duties of Local Responsible Person (LRP)

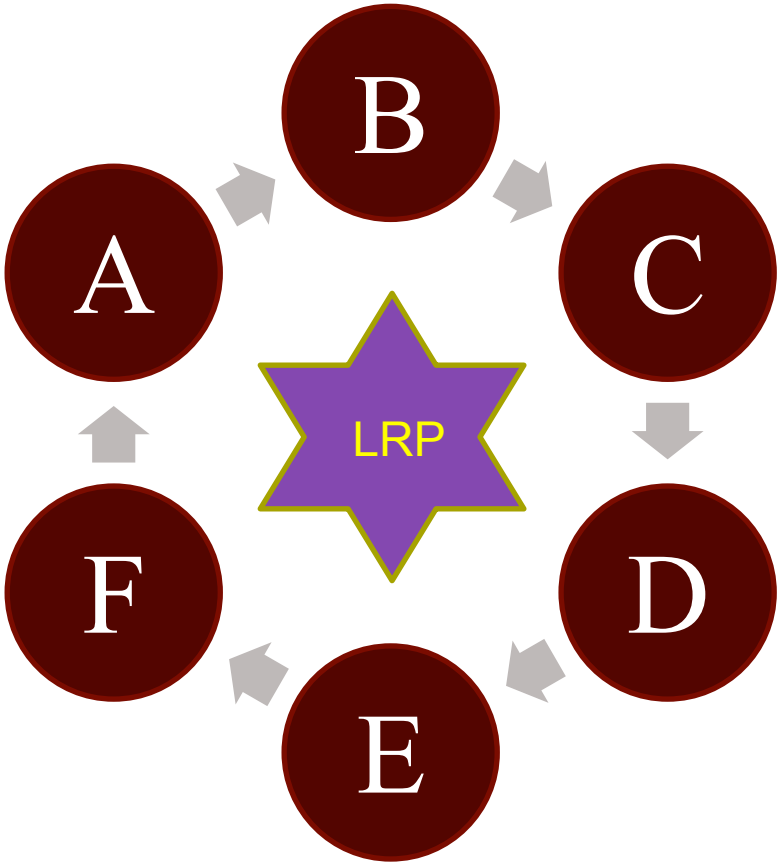
- LRP should have expertise knowledge on the medical device
- LRP should have trust from device manufacturer and be formally designated in writing as LRP
- LRP will submit application for listing of the medical device
- LRP will arrange to provide all required documents and samples so required for in the submission of the application
- Once MD approved for registration and listing, LRP will be the legally responsible person for the listed medical device.

Quality Requirements of LRP

- **Communications Hub**
  - Application for listing
  - Efficient communication channel
  - Reporting changes
  - Making records available for MDCO inspection
  - Maintaining distribution records
- **Safe and Efficacious**
  - Managing reportable adverse incidents in HK
  - Device alerts, modifications and recalls
  - Tracking of specific medical devices
- **Quality of Service**
  - Complaint handling
  - Maintenance and services arrangements

COP Requirement for LRP

A. Keeping of Distribution Records
B. Management of Device Recall and Field Safety Notices
C. Handling of Reportable Adverse Incident in HK
D. Tracking of Specific MD
E. Complaint Handling
F. Maintenance & Service Arrangement



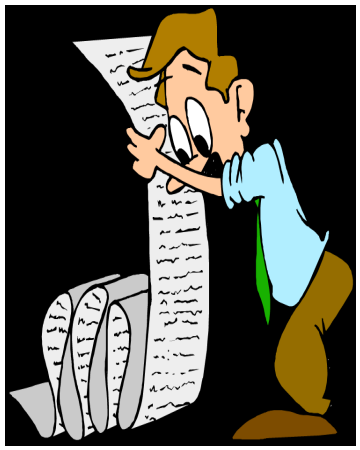
A, B, C and D – COPs already in place

E and F – COP should be ready upon request

Case Study:
An Application for Listing of a Medical Device in Hong Kong

How to fill in an application for listing of a medical device in HK

Part A	Particulars of Manufacturer
Part B	Particulars of LRP
Part C	Particulars of the Device
Part D	Marketing Approvals and Essential Principles
Part E	Declaration
Part F	Personal Data Ordinance



The Listing Application Form MD-C2&3&4

Part A001-004

Medical Device Control Office
Department of Health

Medical Device Administrative Control System
Application for the Listing of Class II/III/IV Medical Devices

For official use only
Date Received: _____ *Application No.:* _____ *Officer:* _____
Date A
PMS R
Remarks: _____

Note	Part A: Particulars of Manufacturer			Encl.
A001	Manufacturer's name*	*in English*	*ABC Medical Ltd.*	
		in Chinese	*N.A.*	
	Address of Head Office*:	*in English*	*1324N. Derby Road, Arlington VA, USA*	
		in Chinese	*N.A.*	
	Post Code: *VA 12345-6789*		Country: *USA*	
	Contact person: *John Smith*		Telephone: *800.332.2354*	
	Fax: *703.276.0314*		E-mail: *jsmith@abcmed.com*	
	Website*: *http://www.abcmedical.com*			
A002	☐ Registered place of business in Hong Kong:			(A1) ☐
	☐ Copy of business registration certificate (with business registration number _____) is enclosed			
	Contact person:		Telephone:	
	Fax:		E-mail:	
A003	Established Quality Management System ☒ Full quality management system covering device design, production, and post-production processes ☐ Partial quality management system covering processes: _____ Standards with which the system complies: ☒ ISO13485:2003 or later edition (ISO13485:_____) ☒ System certified by *CAB Systems Ltd* (certification body), and a copy of the certificate is enclosed			(A2) ☒
A004	Has the manufacturer designated any Local Responsible Person (LRP)? *(N.B. If the manufacturer has no registered place of business in Hong Kong, it must designate a legal person incorporated in Hong Kong or a natural or legal person with a registered place of business in Hong Kong as the LRP.)* ☒ Yes ☐ No, manufacturer itself acts as the LRP			

Form is good for Class II, III and IV

Website address is useful

Requirement for QMS & CAB

Designation for LRP

The Listing Application Form MD-C2&3&4

Part B001-006

Local Contact Person & Nos. are essential

Manufacturer to designate LRP

Nice to have QMS for LRP, But not a must

LRP should have COPs cater for the MD

Note	Part B: Particulars of Local Responsible Person (LRP)			Encl.
B001	LRP's name*	*in English*		(B1) ☐
		in Chinese		
	Address in Hong Kong *(Please give the registered place of business, if any)**	*in English*		
		in Chinese		
	Contact person:		Telephone:	
	Position:		E-mail:	
	Contact telephone for public enquiries * :		Fax :	
	Mobile telephone for urgent use (24 hours) :			
	☐ Copy of business registration certificate (with business registration number: _____) is enclosed			
B002	Date designated as LRP by the manufacturer: ☐ Manufacturer's designation letter is enclosed			(B2) ☐
B003	Established Quality Management System ☐ ISO9001:2000 ☐ ISO9001:2008 or later edition ☐ ISO13485:2003 or later edition ☐ None ☐ System certified by _____ (certification body), and a copy of the certificate is enclosed			(B3) ☐
B004	Documented Procedures Established and Maintained ☐ The applicant does not have any medical device listed under the Medical Device Administrative Control System ☐ The procedures indicated in items (i) to (iv) below are enclosed; AND ☐ The procedures indicated in items (v) to (vi) have been established and will be submitted upon request. (i) Keeping of distribution records (ii) Management of product recalls and field safety notices (iii) Handling of reportable adverse incidents in Hong Kong (iv) Tracking of specific medical devices (if applicable) (v) Complaints handling (vi) Maintenance and service arrangements (if applicable) ☐ The applicant already has one or more medical device listed under the Medical Device Administrative Control System (**LRP number**: _____) ☐ There is no change to the procedures indicated in items (i) to (iv). *(Please go to B005)*; OR ☐ The procedures indicated in items (i) to (iv) have been updated and enclosed.			(B4) ☐
B005	☐ The LRP is also an importer of the device named in Part C Listing No. of Importer: _____ (if applicable)			
B006	☐ The device named in Part C is currently a listed device (under another LRP), with Listing No. _____.			

The Listing Application Form MD-C2&3&4

Part C001-007

Define single, series, family or system

AMDNS Code can be searched on DOH website

Chinese translation not compulsory but preferable

Any YES answers will be excluded

Preferably to have GMDNS / UMDNS code

Do not miss out any accessories or system parts

Note	Part C: Particulars of the Device			Encl.
C001	Make*	*in English*		
		in Chinese		
	Brand Name*	*in English*		
		in Chinese		
	Model*	*in English*		
		in Chinese		
C002	☐ A single medical device ☐ A medical device family ☐ A medical device series ☐ A medical device system For a medical device family, medical device series or a medical device system, please provide the additional information required in a format similar to MDS-01. ☐ Additional information similar to MDS-01 attached			(C1) ☐
C003	Description of the device: *(Please enter the appropriate AMDNS term. If none of the terms in AMDNS appear appropriate, enter a short description of the device.)* AMDNS Code: Other Codes *(Please enter if known):*			
C004	Other common descriptions of the device:			
C005	Intended use of the device*	*in English*		
		in Chinese		
C006	Accessories and parts covered by the Marketing Approvals and Essential Principles Conformity Checklist under Note D001 of Part D. *Please provide its identifier(s) (e.g. part number) and description using a format similar to MDS-02.* ☐ Additional information similar to MDS-02 attached			(C1) ☐
C007	1. The device Yes No ☐ ☐ incorporates, as an integral part, a medicinal product which could act on the human body with action ancillary to that of the device ☐ ☐ is manufactured from or incorporating human cells/tissues/derivatives ☐ ☐ is manufactured from or incorporating animal cells/tissues/derivatives			

Form MD-C2&3&4 (Jul 2011 Edition)

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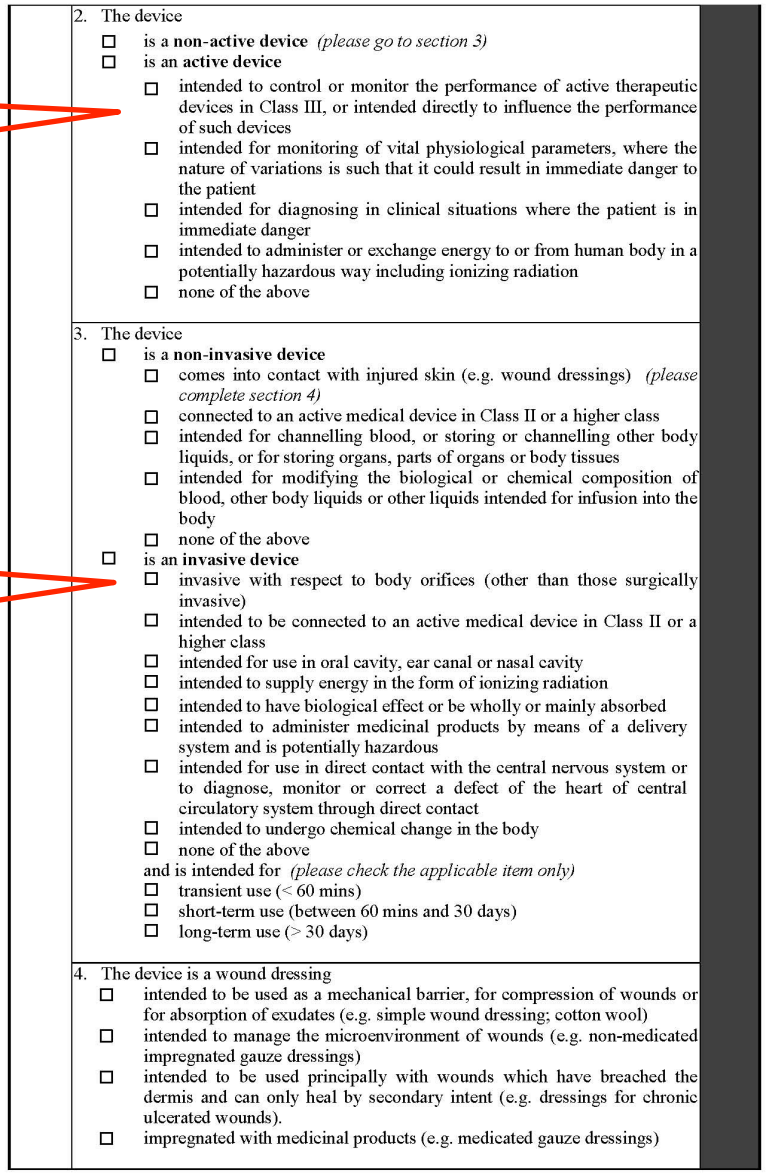
The Listing Application Form MD-C2&3&4

Part C007

Active or non-active ?

Invasive or non-invasive ?



2. The device
- ☐ is a **non-active device** *(please go to section 3)*
- ☐ is an **active device**
  - ☐ intended to control or monitor the performance of active therapeutic devices in Class III, or intended directly to influence the performance of such devices
  - ☐ intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient
  - ☐ intended for diagnosing in clinical situations where the patient is in immediate danger
  - ☐ intended to administer or exchange energy to or from human body in a potentially hazardous way including ionizing radiation
  - ☐ none of the above

3. The device
- ☐ is a **non-invasive device**
  - ☐ comes into contact with injured skin (e.g. wound dressings) *(please complete section 4)*
  - ☐ connected to an active medical device in Class II or a higher class
  - ☐ intended for channelling blood, or storing or channelling other body liquids, or for storing organs, parts of organs or body tissues
  - ☐ intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body
  - ☐ none of the above
- ☐ is an **invasive device**
  - ☐ invasive with respect to body orifices (other than those surgically invasive)
  - ☐ intended to be connected to an active medical device in Class II or a higher class
  - ☐ intended for use in oral cavity, ear canal or nasal cavity
  - ☐ intended to supply energy in the form of ionizing radiation
  - ☐ intended to have biological effect or be wholly or mainly absorbed
  - ☐ intended to administer medicinal products by means of a delivery system and is potentially hazardous
  - ☐ intended for use in direct contact with the central nervous system or to diagnose, monitor or correct a defect of the heart of central circulatory system through direct contact
  - ☐ intended to undergo chemical change in the body
  - ☐ none of the above

  and is intended for *(please check the applicable item only)*
  - ☐ transient use (< 60 mins)
  - ☐ short-term use (between 60 mins and 30 days)
  - ☐ long-term use (> 30 days)

4. The device is a wound dressing
- ☐ intended to be used as a mechanical barrier, for compression of wounds or for absorption of exudates (e.g. simple wound dressing; cotton wool)
- ☐ intended to manage the microenvironment of wounds (e.g. non-medicated impregnated gauze dressings)
- ☐ intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent (e.g. dressings for chronic ulcerated wounds).
- ☐ impregnated with medicinal products (e.g. medicated gauze dressings)

Form MD-C2&3&4 (Jul 2011 Edition)

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The Listing Application Form MD-C2&3&4

Part C008-013

Records of Previous recalls are essential data required by MDCO

Labeling requirements are essential

C008	Class of the medical device: ☐ Class II ☐ Class III ☐ Class IV Reasons for classifying the device as Class II/III/IV device:	
C009	Manufacturing Site(s) *(Use separate sheet if required)*:	(C1) ☐
C010	History of previous recalls, reportable adverse incidents, banning in other countries or post-market surveillance studies ☐ No ☐ Yes (Please check the appropriate boxes and provide details): ☐ Recalls completed or in progress ☐ Reportable adverse incidents bearing implications to the device ☐ The device banned previously in other countries ☐ Proactive post-market surveillance studies	(C2) ☐
C011	Usage ☐ The device is for single use ☐ The device is supplied as sterile product ☐ Disposal of used device or any part thereof (including any used accessories or consumables) requires special precautions. ☐ The device is intended to be used/operated by healthcare professionals only ☐ The device is intended to be used/operated by laypersons ☐ It is intended for self-use	
C012	Repair and Servicing ☐ The device requires regular servicing/testing/checking/calibration ☐ Repairs and servicing provided by the LRP or appointed party in Hong Kong ☐ All repairs and servicing performed in Hong Kong ☐ Part of the repairs and servicing performed in Hong Kong ☐ Technical support provided by the manufacturer	
C013	Labelling Requirements Instructions for use are available (Note: Devices intended for self-use by consumers must be accompanied by instructions for use written in both English and Chinese): ☐ in English ☐ in Chinese ☐ A set of device labelling copies is enclosed ☐ Sample of Special Listing Information is enclosed Please indicate where in the labelling the following information is given: (1) Indications for use of the device: _____ (2) Contraindications against use of the device: _____ (3) Cleaning, disinfection and/or sterilization procedures: _____ (4) User precautions: _____ (5) Disposal precautions: _____	(C3) ☐

The Listing Application Form MD-C2&3&4

Part C014-017

For combinational products, RO, PPO, AO, DDO shall be pre-requisites

Compliance to Safety standards

Requirements for clinical data

C014	Licencing Requirements The device is subject to provisions under the following ordinances and a copy of the required licence(s) is/are enclosed: Yes No ☐ ☐ Radiation Ordinance (Cap. 303) ☐ ☐ Pharmacy and Poisons Ordinance (Cap. 138) ☐ ☐ Antibiotics Ordinance (Cap. 137) ☐ ☐ Dangerous Drugs Ordinance (Cap. 134)	(C4) ☐
C015	Conformity Assessment ☐ MDACS Conformity Assessment Certificate issued by one of the Conformity Assessment Bodies recognized by MDCO MDACS Conformity Assessment Body number: _____	(C5) ☐
C016	Safety and Risk Analysis International or national safety standards with which the device complies: _____ ☐ Risk analysis conducted: report or summary is enclosed ☐ Type test performed: report or test certificate is enclosed	(C6) ☐
C017	Clinical Evaluation ☐ Clinical investigation report of the device is enclosed ☐ Demonstration of equivalence to another device (equivalent device) where safety and efficacy of which are well established: ☐ Clinical investigation report of the equivalent device and a report of demonstration of equivalence are enclosed ☐ Report demonstrating full equivalence to a well established product is enclosed	(C7) ☐

The Listing Application Form MD-C2&3&4

Part D001

Market Approval of any US or EU countries can be referred as support for application

Note	Part D: Marketing Approvals and Essential Principles	Encl.
D001	Marketing Approvals in Foreign Countries ☐ Approval obtained for the medical device to be placed on the market of the following countries: ☐ Australia (The Therapeutic Goods Administration) ☐ Canada (Health Canada) ☐ Member countries of European Union that have implemented the European Council Directives 90/385/EEC and 93/42/EEC and a copy of the EC Declaration of Conformity is enclosed ☐ Japan (Ministry of Health, Labour and Welfare) ☐ United States of America (U.S. Food and Drug Administration) ☐ Earliest approval obtained on or before 31 December 2004 ☐ Earliest approval obtained on or after 1 January 2005 ☐ Essential Principles Conformity Checklist MD-CCL is enclosed; OR ☐ Essential Requirements Checklist in accordance with the EU Medical Device Directives and Essential Principles Declaration of Conformity are enclosed	(D1) ☐

Complete MD-CCL form or use EP in EU submission to simplify paperwork

Form MD-C2&3&4 (Jul 2011 Edition)

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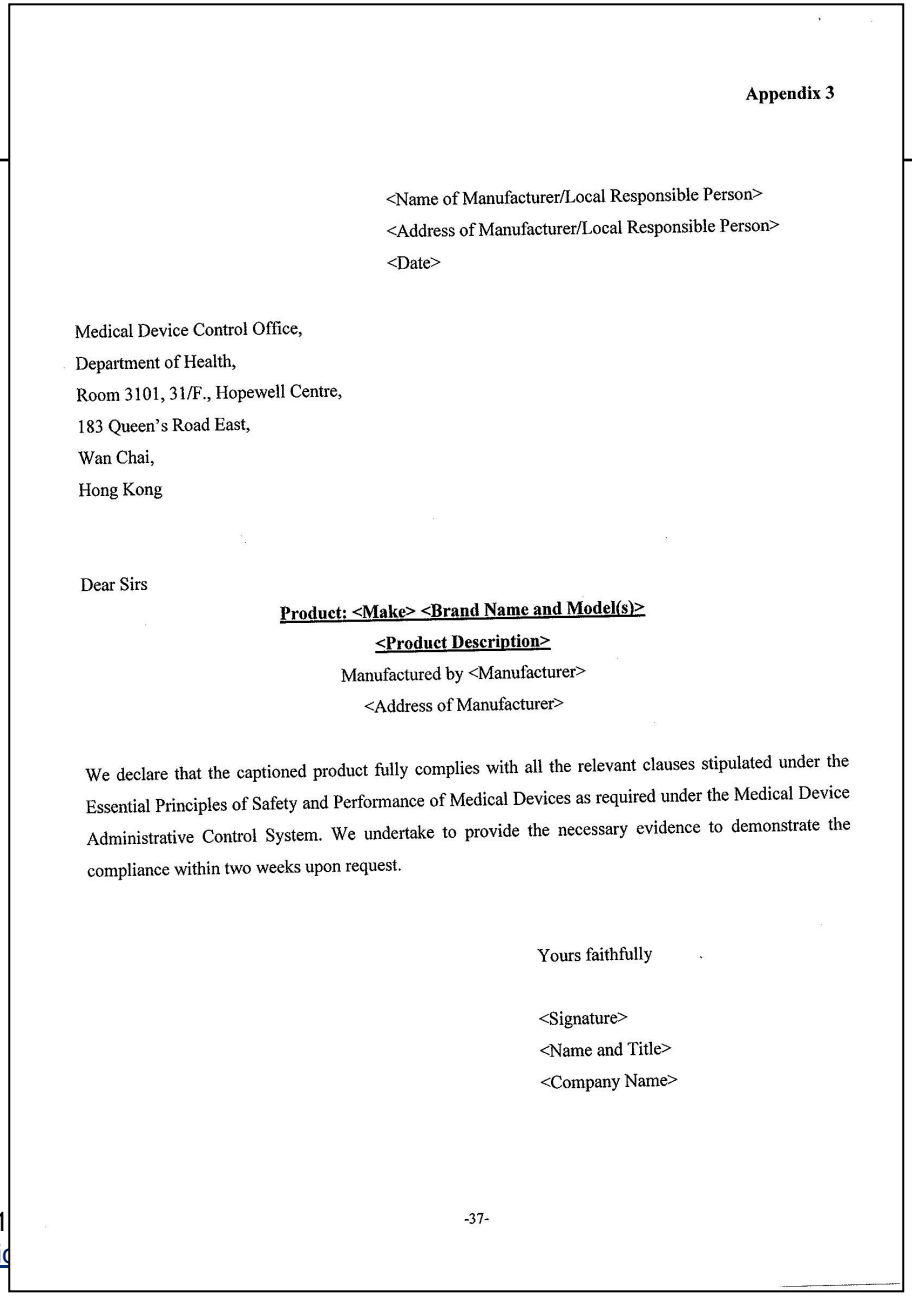
MDACS Essential Principles Conformity Checklist

1. General requirements of QMS, risk management and technical tests to provide for high level of protection of health and safety dedicated for the intended purpose of the medical device.
2. Conformance to safety and risk hazard control,
3. Designed, manufactured and packaged to meet intended function and performance
4. Characteristics and performances should not be adversely affected under stress conditions during normal conditions of use.
5. Characteristics and performances should not be adversely affected under transport and storage conditions
6. The benefits must be undermined to outweigh any undesirable side effects for the performance intended
7. Chemical, physical and biological properties

MDACS Essential Principles Conformity Checklist (Cont'd)

8. Infection and microbial contamination
9. Manufacturing and environmental properties
10. Devices with a diagnostic or measuring function
11. Protection against radiation
12. Requirements for MD connected to or equipped with an energy source
13. Protection against mechanical risks
14. Protection against risks posed to the patient by supplied energy or substances
15. Protection against risks posed to the patient for devices for self-testing or self-administration
16. Information provided by the manufacturer
17. Performance evaluation, where appropriate, clinical evaluation

The Manufacturer's Declaration of Essential Principles Conformity



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>

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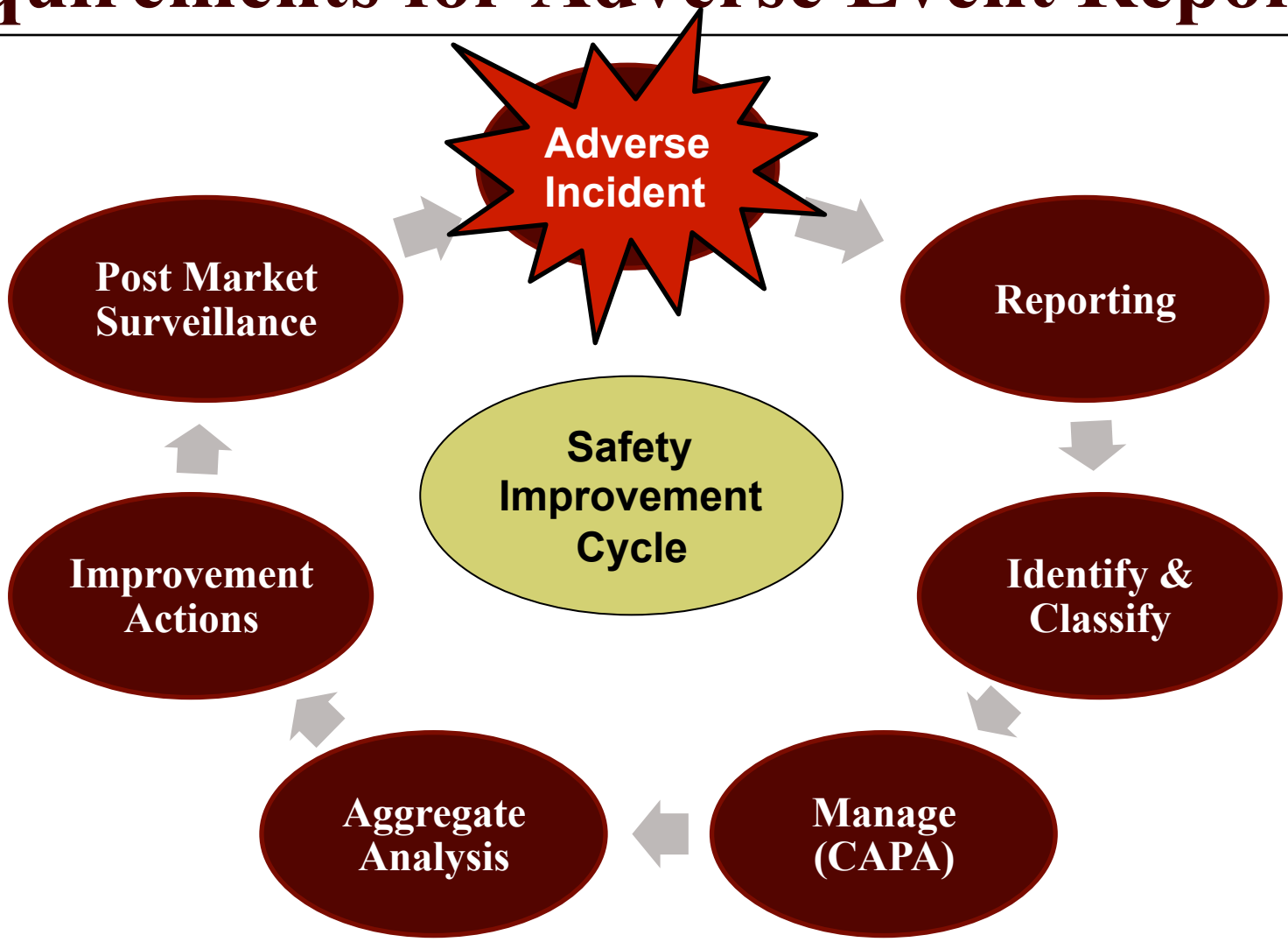
Part E & Part F

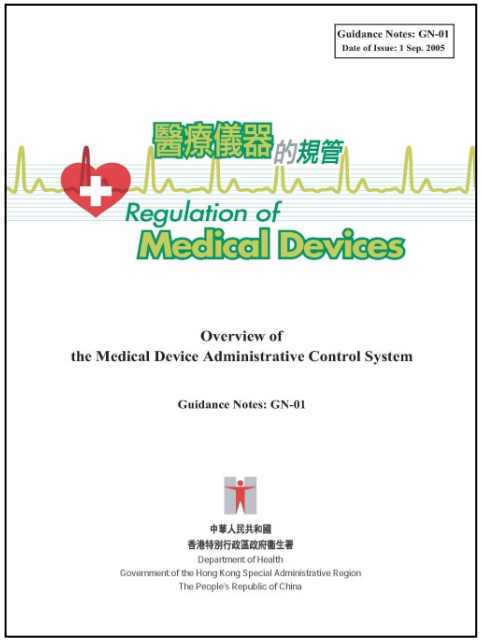
Declaration for Application
Personal Data (Privacy) Ordinance

Requirements for Adverse Event Reporting



Adverse Incidents to be Reported under MDACS

- The LRP is required to report and manage adverse incidents happening in Hong Kong concerning medical devices listed under his/her name.



(Section 4.4.8 of Guidance Notes GN-01 refers)

Adverse Incidents to be Reported under MDACS

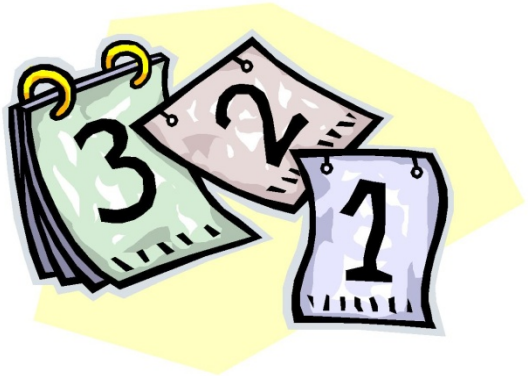
- Incidents occurring in Hong Kong need to be reported
- Incidents occurring outside Hong Kong do not need to be reported
- Reportable if the incidents in (1) lead to Corrective actions or preventive actions (CAPA)
- To report on details and actions to be taken in HK not later than 10 calendar days after the manufacturer has initiated the actions

Information to be Reported

1. description of the medical device, the make and model,
2. serial numbers or other identification (batch or lot numbers) of the medical devices concerned,
3. the actions to be taken and the respective reasons,
4. the distribution volume and listing (if available) of the concerned medical device in Hong Kong.
5. the contact details of personnel responsible for corrective action in Hong Kong, for MDCO and those for the general public,
6. any advice regarding possible hazards, and
7. any consequent actions to be taken

Timeframes for Submission of Adverse Incident Reports

- Adverse Incidents that result in death or serious injury or of a serious public health concern must be reported by the LRP to the MDCO not later than 10 calendar days after the LRP becomes aware of the incident.
- All other reportable adverse incidents – not later than 30 calendar days



Examples of Reportable Adverse Incidents (1)

1. On an X-ray vascular system during patient examination, the C arm had uncontrolled motion. The patient was hit by the image intensifier and his nose was broken.
2. It was reported that a monitor suspension system fell from the ceiling when the bolts holding the swivel joint broke off. Nobody was injured in the surgical theater at that time but a report is necessary (near incident).
3. An infusion pump stops, due to a malfunction, but fails to give an alarm. Patient receives under-infusion of needed fluids and requires extra days in hospital to correct.
4. Premature revision of an orthopedic implant due to loosening.

Examples of Reportable Adverse Incidents (2)

5. Manufacturer of a pacemaker released on the market identified a software bug and the risk assessment showed the likelihood of occurrence of a serious injury is not remote.
6. It was reported that during implant of a heart valve, the sewing cuff is discovered to be defective. The valve was abandoned and a new valve was implanted and pumping time during surgery was extended.
7. During the use of an external defibrillator on a patient, the defibrillator failed to deliver the programmed level of energy due to malfunction. Patient died.
8. After delivery of an orthopedic implant, errors were discovered in heat treatment records leading to non-conforming material properties, which resulted in risk to public health.

Urgent Contacts and Enquiries with MDCO

- Office hours
  - Medical Device Control Office, Department of Health
  - Address: Room 3101, 31/F Hopewell Centre, 183 Queen's Road East, Wanchai, Hong Kong
  - Tel No.: (852) 3107 8484
  - Fax No.: (852) 3157 1286
  - Email: mdco@dh.gov.hk
  - Website: http://www.mdco.gov.hk

- Outside office hours
  - DH Duty Officer
  - Pager No.: (852) 7116 3300 asking for No. 9178

Other Issues

Reimbursement for Medical Devices

Reimbursement Relating to Medical Devices

HA Drug Formulary (HADF) – Mainly drugs

- Implemented in 2005
- supply on a limited basis self-financed drug items
- Safety net: no one will be denied adequate healthcare because of lack of means
- HA Drug Advisory Committee systematically appraises new drugs every three months and includes them into the Formulary

HA Standard Drugs provided by HA Pharmacies

- General Drugs List and
- Specific Drugs List

Plus Non-HA standard drugs (safety net items and some non safety items)

Reimbursement Relating to Medical Devices

Samaritan Fund – Drugs and Medical Devices

- Established in 1950, Managed by HA since 1990
- 30% Private Donation and 70% Government Subsidy
- Fund needy patients on Privately Purchased Medical Items (PPMI) or new MD technologies
- About 5,000 cases, totaling over USD 20M a year
- Allocated government donation of USD 1.3 billion (2012 – 22) to meet additional 2,000 – 3,000 new cases
- Apply to Samaritan Fund Office, Director (Cluster Services), Hospital Authority

Reimbursement Relating to Medical Devices

Samaritan Fund – Reimbursable items include

- Expensive drugs
- Expensive medical items, such as prostheses and consumables
- Items purchased by patients for home use, such as wheelchairs and home use ventilators
- Costly medical treatment not provided in public hospitals, such as gamma knife treatment and Automatic Implantable Cardioverter Defibrillator
- Evaluated by Financed Medical Technologies Committee (PFMT Committee)
- Application Guide: http://www.ha.org.hk/hadf/en_pep.html

Other Issues

Import/Export Controls
and
Country of Origin

Import / Export Controls

Devices are subject to import/export (I/E) controls / licenses as follows:

(1) Medical devices in general currently **no (I/E) controls**

(2) Devices with biological material – (I) control by Port Health Unit, DH

(3) Devices with Chinese Herbs content – (I/E) control by DH

(4) Devices with controlled chemicals – (I/E) control by C&ED

(5) Devices with pharmaceutical, medicine or drugs – (I/E) control by DH

(6) Devices with radioactive substance/irradiating apparatus – (I) control by RHU, DH

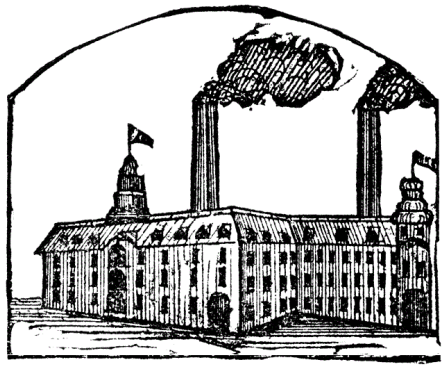
(7) Devices with radio transmitting parts – (I/E) control by OFTA

(8) Devices of Strategic Commodities such as defense thermal imaging systems – (I/E) control by Trade & Industry Dept (TID)

Export License

- Export license is applicable for pharmaceuticals and drugs controlled under the Pharmaceutical and Poisons Ordinance (PPO) (Cap 138)
- For medical device, MDACS is implementing voluntary registration of importers and there is not yet a control on export license for medical device.
- Exports of medical device in recent years amounted to HKD 10 billions and mainly re-exports. Local industry mainly engaged in
  - mechano-therapy appliances/massage apparatus,
  - electro-diagnostic apparatus and
  - miscellaneous medical instruments and appliances
- Certificate of Origin is in place of Export License for Medical Device

Country of Origin



Refer C009 – **Whether in US or in other countries, all manufacturing sites of major assemblies should be listed and be covered by the Corporate Quality Management System ISO 13485.**

This is to ensure that the design, manufacture and package of the device meets the quality requirement, safety, the intended functions and performance stipulated for in the Conformity for Essential Principles.

Country of origin is therefore not a major issue for product registration in Hong Kong. But it is important to have manufacturing sites certified for ISO 13485 by FDA or EU listed Notified Bodies.

Thank you for your consideration!

Pacific Bridge Medical

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