

醫療儀器的規管

Regulation of
Medical Devices

**Overview of
the Medical Device Administrative Control System**

Guidance Notes: GN-01



中華人民共和國

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1. Introduction

1.1 Background

A risk-based framework for regulating the supply of medical devices in Hong Kong was first proposed in the Consultation Document entitled “Regulation of Medical Devices” dated July 2003. It was stated in the document that, pending the enactment of legislation, an administrative control system would be first implemented “to facilitate the transition to the long-term statutory control” (See p. 20 of [1]). Both the long-term statutory control and the administrative control system will largely be based on the recommendations of the Global Harmonization Task Force (GHTF). The proposed administrative control system will feature both a listing system, under which manufacturers and importers of medical devices (except Class I devices) could VOLUNTARILY list their products with the Department of Health, and an adverse incident reporting system, through which the recurrence of adverse incidents could be prevented. The goal of the administrative control system is that, through the listing of medical devices and monitoring of adverse incidents, it can serve to raise public’s awareness of the use of safe medical devices. It is also hoped that this administrative control system would “enable the traders to familiarise themselves with the future mandatory requirements” and will “provide an opportunity to collect more information and feedback from the industry as a reference to fine tune the long-term regulatory framework” (See p. 20 of [1]).

1.2 Phased Implementation of the Medical Device Administrative Control System

Following a public consultation exercise, a decision was made by the Government in early 2004 to implement the proposed administrative control system, hereinafter referred to as the Medical Device Administrative Control System (MDACS), by phases. The implementation will commence with the listing of Class IV medical devices. The listing of Class III and Class II medical devices as well as the listing of importers and local manufacturers will follow in stages. An adverse incident reporting system will also be set up. The whole of the MDACS is to be managed by the Medical Device Control Office (MDCO) in the Department of Health.

1.3 This Booklet

This booklet defines some of the terms used in this booklet (section 2) and gives an overview of the MDACS (section 3). It then goes on to explain in detail the roles of a Local Responsible Person (LRP) within the system (section 4). Sections 5, 6 and 7 give further information about the Listing System, including how to apply for the listing of devices, importers and local manufacturers. Those who are considering to become LRPs are advised to familiarize themselves with the details given in this booklet.

2. Definitions and Abbreviations

Given below are the definitions and abbreviations of some of the terms which will appear in this booklet (including the Appendices) -

2.1 **Medical device** means any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of -

- (a) diagnosis, prevention, monitoring, treatment or alleviation of disease; or
- (b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury; or
- (c) investigation, replacement, modification, or support of the anatomy or of a physiological process; or
- (d) supporting or sustaining life; or
- (e) control of conception (including contraception); or
- (f) disinfection of medical devices; or
- (g) providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body;

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its intended function by such means.

- 2.2 **Manufacturer** means -
- (a) a natural or legal person with responsibility for the design, manufacture, packaging and labelling of a medical device before it is placed on the market under its own name, regardless of whether these operations are carried out by that person himself or on its behalf by a third party; or
 - (b) any other natural or legal person who assembles, packages, processes, fully refurbishes or labels one or more ready-made products or assigns to them their intended purpose as a medical device with a view to their being placed on the market under its own name, apart from a person who assembles or adapts medical devices already on the market to their intended purpose for an individual patient.
- 2.3 **Active medical device** means a device whose operation depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, are not considered to be active medical devices.
- 2.4 **Invasive device** means a device, which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.
- 2.5 **Body orifice** means any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma or permanent tracheotomy.
- 2.6 **Surgically invasive device** means an invasive device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation.
- 2.7 **Implantable medical device** means any device, including those that are partially or wholly absorbed which is intended-
- (a) to be totally introduced into the human body or,
 - (b) to replace an epithelial surface or the surface of the eye,
- by surgical intervention which is intended to remain in place after the procedure. Any device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device.
- 2.8 **Active implantable medical device** means any active medical device, together with any accessories for its proper functioning, which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.
- 2.9 **Central circulatory system** means the major internal blood vessels including the following: pulmonary veins, pulmonary arteries, cardiac veins, coronary arteries, common carotid arteries, cerebral arteries, brachiocephalic artery, aorta, inferior and superior vena cava, renal arteries and common iliac arteries.
- 2.10 **Central nervous system** means the brain, meninges and spinal cord.
- 2.11 **Long-term use** means “normally intended for continuous use for more than 30 days”.
- 2.12 **Short-term use** means “normally intended for continuous use for between 60 minutes and 30 days”.
- 2.13 **Transient use** means “normally intended for continuous use for less than 60 minutes”.
- 2.14 **The Lists** consist of (a) The List of Medical Devices; (b) The List of Importers; and (c) The List of Local Manufacturers. They list respectively the medical devices, importers and local manufacturers conforming to the requirements of the MDACS. These lists are maintained by the MDCO, who may decide to include on The Lists

any other related information considered appropriate and make them available for inspection by the public.

- 2.15 **To list a device (or local manufacturer, etc.)** means to include a device (or local manufacturer, etc.) on The List of Medical Devices (or The List of Local Manufacturers, etc.).
- 2.16 **To delist a device (or local manufacturer, etc.)** means to remove a device (or local manufacturer, etc.) from The List of Medical Devices (or The List of Local Manufacturers, etc.).
- 2.17 **Reportable adverse incidents** means events involving a listed medical device and meeting the reporting requirements of Guidance Notes GN-03.
Note: As a general rule, an incident which involves a listed medical device and which has led to one of the following outcomes is reportable by the LRP -
(a) death of a patient, user or other person;
(b) serious injury of a patient, user or other person; or
(c) no death or serious injury occurred, but the event might lead to death or serious injury of a patient, user or other person if the event recurs.
Where a serious injury under (b) above is defined as either -
(i) life threatening illness or injury;
(ii) permanent impairment of a body function or permanent damage to a body structure; or
(iii) a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.
The reportability of such incidents is subject to the exemption rules listed in section 5 of the Guidance Notes GN-03. However, such incidents are still reportable regardless of the exemption criteria if they involve issues of serious public health concern, or if a change in trend (usually an increase in frequency) or pattern is identified among them.
- 2.18 **Clinical investigation** means any designed and planned systematic study in human subjects undertaken to verify the safety and/or performance of a specific device.
- 2.19 **Label** means information provided upon the medical device itself. Where physical constraints prevent this happening, this term includes information provided on the packaging of each unit or on the packaging of multiple devices.
- 2.20 **Labelling** means written, printed or graphic matter
● affixed to a medical device or any of its containers or wrappers, or,
● accompanying a medical device,
related to identification, technical description, and use of the medical device, but excluding shipping documents and the Special Listing Information specified under clause 4.4.13.
- 2.21 **Instructions for use** means information provided by the manufacturer to inform the device user of the products proper use and of any precautions to be taken.
- 2.22 **Intended use/purpose** means use of a product, process, or service in accordance with the specifications, instructions, and information provided by the manufacturer.
- 2.23 **MDCO** stands for Medical Device Control Office. Address: 18/F., Wu Chung House, 213 Queen's Road East, Wanchai, Hong Kong. Facsimile number: 3157 1286. Telephone number: 2961 8788.
- 2.24 **MDACS** stands for Medical Device Administrative Control System.
- 2.25 **GHTF** stands for Global Harmonization Task Force, which was formed in 1992 by a group of representatives from regulatory authorities and medical device industry. The aim of the GHTF is to harmonize the standards and principles for the regulation of medical devices. The founding members of the GHTF are the USA, the EU, Canada, Australia, and Japan.
- 2.26 **GMDN** stands for Global Medical Device Nomenclature
- 2.27 **LRP** stands for Local Responsible Person.

3. Medical Device Administrative Control System

3.1 Features

The MDACS will consist of a number of administrative control measures. The most prominent of these measures are -

- (a) *The Listing System.* The MDCO will maintain The Lists under the System including a list of medical devices that have been shown to conform to accepted standards of safety and efficacy, as well as a list of local manufacturers, and a list of importers, that meet the respective requirements. All the lists that the MDCO maintains under the Listing System will be accessible to the public.
- (b) *Obligations placed on Local Responsible Persons (LRP).* A manufacturer who wishes to apply for inclusion of a device into The List of Medical Devices must, before the application can be made, designate an LRP if the manufacturer has no registered place of business in Hong Kong. Where the manufacturer has a registered place of business in Hong Kong, it may also designate an LRP; but if it chooses not to, it will be the LRP (see section 4.3). The LRP will be charged with obligations in relation to the application, including the obligation to provide the MDCO with the necessary information and samples to enable its assessment of the application. If the application is successful, the LRP will be taken as the person responsible for placing the device on the market. During the post-market phase, the LRP will be charged with a number of obligations in relation to the device, including the receipt and handling of customer complaints, the reporting and investigation of adverse incidents, the initiation and management of any recall, etc.
- (c) *Adverse incident reporting system.* Under the adverse incident reporting system, if a reportable incident concerning a listed device happens in Hong Kong, it must be reported by the LRP to the MDCO. The responsibility for investigating the incident falls on the LRP, who may perform the investigation in conjunction with, or with assistance from, the manufacturer or other parties. Upon completing the investigation, the LRP must submit to the MDCO a report detailing its findings and recommendations. The LRP may also be required to provide assistance to the MDCO to conduct a separate investigation where considered necessary.

3.2 Scope of the MDACS

3.2.1 The following products, notwithstanding that some of them are classified as medical devices according to para. 2.1 above, would not be included into the current scope of the MDACS -

- (i) pharmaceutical products, including those governed by the Pharmacy and Poisons Ordinance (Cap 138);
- (ii) human blood, human blood products, plasma or blood cells of human origin;
- (iii) devices that, at the time of being placed on the market in Hong Kong, incorporate human blood, blood products, plasma or blood cells of human origin, except for stable derivatives devices;
- (iv) transplants or tissues or cells of human origin or products incorporating or derived from tissues or cells of human origin;
- (v) transplants or tissues or cells of animal origin, unless a device is manufactured utilizing animal tissue which is rendered non-viable or non-viable products derived from animal tissue;
- (vi) *in vitro* diagnostic medical devices;
- (vii) personal protective equipment (PPE), unless it is intended for protecting the patients;
- (viii) any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth or mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, changing their appearance, and/or correcting body

odours, and/or protecting them or keeping them in good condition for cosmetic purposes;

- (ix) household and toiletry products (including domestic products for cosmetic purposes) not intended for diagnosis of disease, management of clinical conditions, control of conception, or disinfection of medical devices;
- (x) building services equipment;
- (xi) equipment specifically for air quality improvement, unless it has been incorporated into a medical device or designed as an accessory to a medical device; and
- (xii) refurbished medical devices.

3.2.2 Please note that a product which is a combination of a medical device and a medicinal product will be treated as a medical device in its own right if –

- (1) the medicinal product actually forms an integral part of the combined product; and
- (2) the action of the medicinal product on the human body is ancillary to that of the device.

Thus, a heparin-coated catheter is a medical device in its own right as conditions (1) and (2) are satisfied, but a pre-loaded syringe is not, as condition (2) is not satisfied for the action of the drug with which the syringe has been pre-loaded is actually the principal action of the product.

3.3 Classification Rules for Medical Devices

The MDACS has adopted the classification rules promulgated by the GHTF (see reference [2]). Thus, the MDACS classifies medical devices other than *in vitro* diagnostic medical devices into four classes (Classes I, II, III and IV) according to the rules in Appendix 1, Class IV being the class with the highest risk and Class I the class with the lowest risk –

Table 1 – Examples of medical devices

Class	Risk level	Examples
I	Low	tongue depressor, bandage, dressing
II	Medium - low	suction pump, gastroscope, transdermal stimulator
III	Medium - high	lung ventilator, orthopaedic implant, X-ray machine, medical laser
IV	High	prosthetic heart valve, implantable cardiac pacemaker, heparin-coated catheter

3.4 Essential Principles of Safety and Performance of Medical Devices

For a medical device to be listed, the LRP, with support from the manufacturer, is responsible for demonstrating that the device conforms to the Essential Principles of Safety and Performance of Medical Devices in Appendix 2 as well as the additional labelling requirements in Appendix 3. For further details about the Listing System, the reader is referred to sections 5 to 7 below and to the respective Guidance Notes on device listing.

4. Local Responsible Persons

4.1 The need for Local Responsible Persons

4.1.1 Most of the medical devices are imported from overseas countries and the manufacturers may or may not have any local offices or representatives in Hong Kong to perform some of the obligations specified in section 4.4 below. As a result, the users may find it difficult to get the required services or to communicate with the overseas manufacturers directly. The LRP can well serve as the hub of communication between the users, manufacturer, importers and the Government, such that the LRP can provide quality services

to the users and the public to ensure the safe and efficacious use of the devices.

4.1.2 Local Manufacturers may decide to take up the roles of LRPs to provide quality services to the users and the public through their local offices, or instead to appoint their LRPs to provide the required services. The local manufacturers are therefore provided with the flexibility either or not to appoint the LRPs for the listing of their medical devices.

4.2 Benefits of having Local Responsible Persons

Any LRP in relation to a medical device (except a Class I device) can apply to the MDCO for inclusion of the device into The List of Medical Devices. Those devices satisfying the requirements will be listed. The information of the devices together with their LRPs will be posted on the webpage <http://www.mdco.gov.hk>. The users and the public can make reference to The List of Medical Devices and contact the LRPs when required.

4.3 Persons eligible to be Local Responsible Persons

The LRP in respect of a medical device must meet the following requirements -

(a) it is EITHER a legal person incorporated in Hong Kong, OR a natural or legal person with business registration in Hong Kong;

AND

(b) it is EITHER the manufacturer of the device, OR is supported by the manufacturer of the device to perform the obligations of an LRP for the device.

4.4 Obligations of the Local Responsible Persons

4.4.1 *Efficient communication channels*

The LRPs are responsible for communicating with the users, importers, public and the Government and to manage the pre-market and post-market matters of the corresponding devices. The LRPs shall maintain efficient communication channels with the manufacturers such that any updated device information can be disseminated to the related parties effectively, while feedbacks can be collected and delivered to the manufacturers for actions.

4.4.2 *Application for listing medical devices*

The LRPs are persons making the applications for listing their medical devices under the MDACS. They are therefore responsible for communication with the Government regarding their applications.

4.4.3 *Distribution records*

The LRP shall maintain an updated list of importers and the distribution records of devices imported, including the make, model, batch number, serial number, and quantity of devices, as appropriate, such that the details of devices sold and distributed in Hong Kong can be traced when needed.

4.4.4 *Complaint handling*

The LRP shall have a documented procedure to handle complaints. A telephone number, a fax number and/or an email address shall be provided to the public for collecting comments and complaints from the users and the public.

4.4.5 *Maintenance and services arrangements*

The LRP shall offer or arrange other parties to provide preventive and corrective maintenance, including calibration, provision of spare parts and other services, if applicable, to the users when requested.

4.4.6 *Tracking of specific medical devices*

4.4.6.1 The LRP shall have in place a tracking system that tracks those high-risk devices specified in Appendix 4 down to patient level. Where this tracking is not possible for any individual devices (e.g. the tracking does not have the patient's consent), the system is

still required (1) to track the devices down to the user-facility level (so that, if a need to recall these devices arises, the recall can still be effected through the assistance of these user facilities) and (2), for each of these devices, to keep track of the following: (a) the date the device was put into service or (for an implantable device) implanted into a patient, and (b) (if tracking of these is possible) the date the device permanently retired from use or (for an implanted device) the date it was explanted.

4.4.6.2 For the categories of devices listed in Appendix 4, the LRP shall submit surveillance reports (which may be based on local or overseas data or both) to the MDCO at least once a year. The MDCO reserves the right to revise the submission schedule as it sees appropriate or necessary, and in case of any such revision the LRP will be notified accordingly.

4.4.7 *Product alerts, modifications and recalls*

Upon the issuance of alerts, modification notices and recalls by the manufacturer or overseas authorities, the LRP shall inform the MDCO of the related details and actions to be taken in Hong Kong as soon as possible, and not later than 10 calendar days after their issuance. The LRP shall follow up the actions, and shall submit progress reports to the MDCO as requested until the case is concluded. It is preferred that prior arrangements be made such that within four hours of the issuance of an alert, recall or modification notice by the manufacturer, the same be also e-mailed direct to the MDCO.

4.4.8 *Managing reportable adverse incidents in Hong Kong*

The LRP is required to observe the adverse incident reporting requirements of the Guidance Notes GN-03 and report all reportable adverse incidents to the MDCO. The submission of a report does not, in itself, represent a conclusion that (1) the content of the report is complete or confirmed, (2) the device failed in any manner, or (3) the device caused or contributed to the incident. When a reportable or a potentially reportable adverse incident that has occurred in Hong Kong is reported to the LRP directly or from other sources, the LRP shall conduct an investigation into the incident and report to the MDCO as soon as possible. The investigation may be done in conjunction with the manufacturer or other parties. If the incident has caused any death or serious injuries or is of a serious public health concern, the report shall reach the MDCO as soon as possible but not later than 10 calendar days after the LRP becomes aware of the incident. For other reportable or potentially reportable events, the LRP shall, within 30 calendar days of becoming aware of it, report the event to the MDCO. Upon request, the LRP shall provide assistance to the MDCO to conduct a separate investigation.

4.4.9 *Reporting changes*

When there is any major change to the information related to the business of the LRP or the listed medical devices, the LRP shall inform the MDCO as soon as possible and in no case later than 10 calendar days.

4.4.10 *Making records available for inspection*

The MDCO has the discretion to inspect the originals or certified copies of records and documents claimed to be in the possession of the LRP or copied to the MDCO by the LRP when considered necessary. The LRP shall produce the required originals or certified copies for inspection within two weeks after receiving the notice from the MDCO.

4.4.11 *Responsibilities in respect of advertisements*

4.4.11.1 The advertisements or other commercial promotional materials shall not contravene the Undesirable Medical Advertisement Ordinance (Cap. 231).

- 4.4.11.2 The MDCO disapproves of references of all kind, in advertisements of medical devices or other commercial promotional materials, to the MDACS, except if the references fall within the permissible exceptions in 4.4.11.3 below. In particular, the MDCO disapproves of any representation that the Government has endorsed the safety, quality, efficacy, or effectiveness of a listed medical device. Such representation may be considered as an unjustified claim for the purpose of clause 5.11(d). The LRP must not publish or cause to be published any advertisement or promotional materials that make references to the MDACS except if the references fall within 4.4.11.3 below.
- 4.4.11.3 Notwithstanding 4.4.11.2, references to the MDACS in lawful advertisements or promotional materials will not be disapproved by the MDCO if they are limited to the following forms and if the presentation of these together with other information in the advertisements or promotional materials is in a legitimately balanced manner:
- (a) a statement to the effect that a certain medical device is listed with the MDCO;
 - (b) mention of the listing number of a listed medical device;
 - (c) pictures or photographs showing a listed device and/or its packaging, and incidentally, its listing number.

4.4.12 *Obligation to indemnify the Government*

The LRP shall sign the declaration as depicted in the application form to indemnify the Government against all losses and claims in relation to any of the following: any act and default of the LRP, any defective device design, any defects in the devices, and any information supplied by the LRP to the Government. The LRP shall consider adopting appropriate measures such as taking out insurance to cover its possible liabilities.

4.4.13 *Special Listing Information*

The Special Listing Information of a medical device comprises (i) and (ii) below:

- (i) The device's Listing Number, and in case the device's instructions for use are available only in English or only in Chinese, a supplementary statement to inform the user of this fact. The information shall be displayed in the applicable format shown in Fig. 1 below.
- (ii) The LRP information including the name, address, and contact telephone / fax numbers in both English and Chinese wherever applicable.

The LRP shall provide the Special Listing Information by complying with either Option (I) or Option (II) below. The LRP will have a grace period of six months after the device is listed to meet this requirement.

Option (I)

- (a) The information (i) shall be displayed on the outer packaging of every device or sales unit; and
- (b) The LRP information (ii) shall be displayed on the outer packaging of every device or sales unit, or on a document delivered together with the device.

Option (II)

- (a) Measures shall be implemented by the LRP such that whenever the listed devices are supplied and delivered to the end-users or user facilities, with or without cost to them, the delivery shall include a document on which the Special Listing Information is printed or

otherwise permanently documented (This requirement does not apply to any subsequent sales from the end-users or user facilities); and

- (b) The LRP shall ensure support from all concerned importers, distributors and retailers to implement the measures in (a). This option shall not be adopted if it cannot be effectively implemented.

HKMD No. xxxxxx

(a)

HKMD No. xxxxxx
Instructions for use in English
not available

(b)

HKMD No. xxxxxx
沒有中文版使用說明

(c)

Note:

“xxxxxx” stands for the device’s Listing Number

Fig. 1. If the instructions for use are available in both English and Chinese languages, the format in figure (a) shall be applied. The format in figure (b) or (c) shall be applied if the instructions for use are available only in Chinese or only in English.

Whenever figure (a), (b) or (c) is applied, it shall be with a printed rectangular border as shown. All the characters shall be of a uniform font size of not less than 2mm high. In (c) the Chinese characters shall be in kaishu (楷書).

4.5 Application for listing as Local Responsible Person

The application shall be made together with the medical devices to be listed. The LRP cannot be listed on its own without representing one or more medical devices.

4.6 Designation of Local Responsible Person

The designation of an LRP by a manufacturer is entirely a matter of agreement between the two parties. The designation must be in writing (e.g. by a letter of the format in Appendix 5). Where the applicant has been designated as an LRP, a copy of the letter or document by which the LRP is designated shall be submitted.

5. Listing of Medical Devices

5.1 General

Under the Listing System, the MDCO will maintain a list of medical devices that have been shown to conform to the requirements under the MDACS. The List of Medical Devices will include the make and model of the device and, alongside this information, the names and contact details of the manufacturer and the LRP. For convenient access by the public, The List of Medical Devices will be posted at

- <http://www.mdco.gov.hk>. A hard copy of The List of Medical Devices will also be made available at the MDCO for inspection.
- 5.2 Persons eligible to apply for listing a device
Only the LRP in relation to the device can make the application. Please see also para. 3.1(b).
- 5.3 Methods to obtain the application form and the related Guidance Notes
Application forms can be obtained during office hours from the MDCO, or downloaded from the website <http://www.mdco.gov.hk>.
- 5.4 No application fee to be paid
No fee will be charged by the Government for inclusion of devices into The Lists of Medical Devices or in respect of applications for such inclusion. However the applicant or the manufacturer must take into account any other costs incurred to them such as those charged by conformity assessment bodies for the certification of conformity to Essential Principles of Safety and Performance of Medical Devices.
- 5.5 Submission of applications
Depending on the class to which the device belongs, an application for listing a medical device must be made on the application form MD-C4 or MD-C2&3 as appropriate. The completed application form together with the supporting documents (please refer to the respective Guidance Notes on device listing) and labelling samples (please see section 5.7 below) must be submitted, by hand or by recorded delivery mail, to the MDCO. Applicants are encouraged to use softcopies of documents in CD-ROM format as far as possible. Alternatively, an applicant with Hongkong Post e-Cert could submit applications to the email address mdco_app@dh.gov.hk if the total file size of the application is less than 5MB.
- 5.6 Supporting documents to accompany an application
Please refer to the respective Guidance Notes on listing of devices of different classes.
- 5.7 Labelling samples to accompany an application
An application for listing a device must be sent in together with samples of the device labelling. These must include, but not be limited to, the operation and service manuals for the device, and must be sufficient to demonstrate that the labelling for the device meets the Essential Principles and the Additional Device Labelling Requirements set out in Appendices 2 and 3 respectively.
- 5.8 Time for vetting and approving an application
The vetting and approval of an application for listing a device should normally be completed within 12 weeks following the submission of the application and all the required supporting information, including labelling samples.
- 5.9 Obligations of the LRP in relation to the application
The LRP must ensure that the application and all the associated submissions have been properly prepared before they are submitted to the MDCO. The LRP has the obligation to submit further information or further labelling samples related to the application if this is requested by the MDCO. Whether during or after the application process, the LRP cannot refuse any request by the MDCO for inspection of the originals or certified true copies of the documents referred to in the application and any other relevant documents (including documents prepared and/or being kept by the manufacturer). Within two weeks of receiving such a request, the LRP must produce the required originals or certified true copies for inspection by the MDCO.
- 5.10 Notification of approval or rejection of application
An application for inclusion of a device into The List of Medical Devices may either be rejected, approved, or approved conditionally. If the application is approved or conditionally approved, a listing number will be assigned to the device. The LRP will be notified of the rejection, approval, or conditional approval, along with any listing number assigned to the device (in the case of approval or conditional approval), by letter. Where the application is approved conditionally, this letter will also specify the special conditions (e.g. one requiring the manufacturer to conduct certain post-market

surveillance studies) on which the approval is given. Failure of the manufacturer or the LRP to comply with those conditions can result in their names and the device being removed from The Lists (see para. (b) of section 5.11 below).

5.11 Causes for delisting a device

A device on The List of Medical Devices may be permanently or temporarily delisted or removed from The List of Medical Devices at the discretion of the MDCO, where any of the following circumstances arises -

- (a) failure of the manufacturer or the LRP to comply with the requirements of the MDACS; or
- (b) where the inclusion of the device into The List of Medical Devices has been approved on certain special conditions (section 5.10 above), failure of the manufacturer or the LRP to comply with any of those conditions; or
- (c) the manufacturer or the LRP fails to address or to adequately address a hazard of the device; or
- (d) where the manufacturer or the LRP has made an unjustified claim in an advertisement for the device, the LRP fails to comply fully with an instruction from the Department of Health requiring the LRP to publicize a statement to withdraw the claim. The instruction from the Department of Health may specify the way in which the statement must be publicized (e.g. by placing advertisements in at least four Chinese language newspapers and one English language newspaper in Hong Kong); or
- (e) the manufacturer or the LRP has been wound up or has ceased to exist; or
- (f) the MDCO considers the delisting necessary for public health or safety considerations; or
- (g) the delisting is requested by the manufacturer or LRP.

When a device is delisted, all entries on The List of Medical Devices related to the device (including the names and contact details of the manufacturer and the LRP) will be removed from The List of Medical Devices.

5.12 Appeal against a decision to reject or conditionally approve an application

5.12.1 A decision of the MDCO to reject an application for inclusion of a device into The List of Medical Devices may be appealed against by the LRP within 4 weeks of receiving the notification of rejection.

5.12.2 Where an application for inclusion of a device into The List of Medical Devices has only been conditionally approved, an appeal as to the conditions imposed may be submitted by the LRP within 4 weeks of receiving the notification of conditional approval.

5.12.3 To appeal, the LRP must write to the Secretary to Medical Device Administration Appeal Committee, c/o Medical Device Control Office, stating its grounds for appeal.

5.12.4 Where a decision of the MDCO is appealed against under section 5.12.1 or 5.12.2, the lodging of the appeal does not suspend the decision unless the MDCO decides otherwise.

5.12.5 An appeal lodged after the corresponding time limit specified above will not be considered.

5.13 Appeal against a decision to delist a device

5.13.1 A decision of the MDCO to permanently or temporarily remove a device from The List of Medical Devices may be appealed against by the LRP within 4 weeks of being notified of the decision.

5.13.2 To appeal, the LRP must write to the Secretary to Medical Device Administration Appeal Committee, c/o Medical Device Control Office, stating its grounds for appeal.

5.13.3 The lodging of an appeal against a decision of the MDCO to delist a device does not suspend the decision unless the MDCO decides otherwise.

5.13.4 An appeal lodged after the time limit specified in section 5.13.1 will not be considered.

5.14 Change of Particulars

Both during the application process and after an application is approved or conditionally approved, when there is any major change to the information that has been submitted in relation to the application (e.g. change of LRP's address, change of model number, change of device design etc.), the LRP shall notify the MDCO as soon as possible. It is the discretion of the MDCO to require the LRP to submit a new application for the device based on the information submitted.

5.15 Validity of Listing Approval

An approval or conditional approval for listing a device will be valid for five years. The LRP must submit an application for continuation of the listing to the MDCO at least 3 months before the expiry of this five-year validity period. Unless the application for continuation of the listing reaches the MDCO within this time frame, the device may be delisted after the five-year validity period.

6. Listing of Importers

Importers of medical devices may apply for becoming Listed Importers under the MDACS. Please refer to the Guidance Note GN-07 for the details.

7. Listing of Local Manufacturers

Local manufacturers of medical devices may apply for becoming Listed Local Manufacturers under the MDACS. Please refer to the Guidance Note GN-08 for the details.

8. Enquiries

Enquiries concerning this booklet and the MDACS should be directed to:

Medical Device Control Office,
Department of Health,
18/F, Wu Chung House,
213 Queen's Road East,
Wanchai, Hong Kong
Facsimile number: 3157 1286
Telephone number: 2961 8788
E-mail address: mdco@dh.gov.hk

Latest versions of the Guidance Notes for the MDACS and the application forms for listing are available at the website: <http://www.mdco.gov.hk>

9. References

- [1] Department of Health. Regulation of Medical Devices – Consultation Document. <http://www.mdco.gov.hk> accessed on 30 October 2004.
- [2] Global Harmonization Task Force. Principles of Medical Devices Classification. Proposed Document SG1/N015R22. <http://www.ghtf.org> accessed on 30 October 2004.
- [3] Department of Health. Guidance Notes for Listing Class IV Medical Devices. Guidance Notes GN-02 (2004 Edition).
- [4] Department of Health. Guidance Notes for Adverse Incident Reporting by Local Responsible Person. Guidance Notes GN-03 (2005 Edition).

Appendix 1

Classification Rules for Medical Devices^a

The actual classification of each device depends on the precise claims made by the manufacturer and on its intended use. While the provision of examples in the table that follows is helpful when interpreting the purpose of each rule, it must be emphasized that the **actual classification of a particular device** must be considered individually, taking account of its design and intended use.

Where a medical device has features that place it into more than one class, conformity assessment should be based on the highest class indicated.

RULE	ILLUSTRATIVE EXAMPLES OF DEVICES THAT MAY CONFORM WITH A RULE
➤ NON-INVASIVE DEVICES	
1. All non-invasive devices are in Class I, unless Rule 2, 3 or 4 applies.	These devices either do not touch the patient or contact intact skin only. <u>Examples:</u> urine collection bottles; compression hosiery; non-invasive electrodes, hospital beds. NOTE: Non-invasive devices that are <u>indirectly</u> in contact with the body & can influence internal physiological processes by storing, channelling or treating blood, other body liquids or liquids which are returned or infused into the body or by generating energy that is delivered to the body are outside the scope of this rule.
2. All non-invasive devices intended for channelling or storing blood, body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in Class I,	Such devices are ‘indirectly invasive’ in that they channel or store liquids that will eventually be delivered into the body (see comment for Rule 1). <u>Examples:</u> administration sets for gravity infusion; syringes without needles.
unless they may be connected to an active medical device in Class II or a higher class, in which case they are Class II;	<u>Examples:</u> syringes and administration sets for infusion pumps; anaesthesia breathing circuits. NOTE: “Connection” to an active device covers those circumstances where the safety and performance of the active device is influenced by the non-active device and <i>vice versa</i> .
unless they are intended for use of storing or channeling blood or other body liquids or for storing organs, parts of organs or body tissues, in which case they are Class II.	<u>Examples:</u> tubes used for blood transfusion.
3. All non-invasive devices intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body are in Class III,	Such devices are indirectly invasive in that they treat or modify substances that will eventually be delivered into the body (see comment for Rule 1). They are normally used in conjunction with an active device within the scope of either Rule 9 or 11. <u>Examples:</u> haemodialyzers; devices to remove white blood cells from whole blood. NOTE: for the purpose of this part of the rule, ‘modification’ does not include simple, mechanical filtration or centrifuging which are covered below.
unless the treatment consists of filtration, centrifuging or exchanges of gas or of heat, in which case they are in Class II.	<u>Examples:</u> devices to warm or cool blood; devices to remove carbon dioxide; particulate filters in an extracorporeal circulation system.
4. All non-invasive devices which come into contact with injured skin:	Devices covered by this rule are extremely claim sensitive.

^a These have been adopted from [2]. Classes I, II, III and IV are referred to respectively as Classes A, B, C and D in [2].

- are in Class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates;	<u>Examples:</u> simple wound dressings; cotton wool.
unless intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent, in which case they are in Class III.	Devices used to treat wounds where the subcutaneous tissue is at least partially exposed and the edges of the wound are not sufficiently close to be pulled together. The device manufacturer claims that they promote healing through physical methods other than providing a barrier are in Class III. <u>Examples:</u> dressings for chronic ulcerated wounds; dressings for severe burns.
- are in Class II in all other cases, including devices principally intended to manage the microenvironment of a wound.	<u>Examples:</u> non-medicated impregnated gauze dressings.
➤ INVASIVE DEVICES	
5. All invasive devices with respect to body orifices (other than those which are surgically invasive) and which: a) are not intended for connection to an active medical device or b) are intended for connection to a Class I medical device	Such devices are invasive in body orifices and are not surgically invasive. Devices tend to be diagnostic and therapeutic instruments used in ENT, ophthalmology, dentistry, proctology, urology and gynaecology. Classification depends on the time of invasion and the sensitivity (or vulnerability) of the orifice to such invasion.
- are in Class I if they are intended for transient use;	<u>Examples:</u> dental impression materials; examination gloves; enema devices.
- are in Class II if they are intended for short-term use;	<u>Examples:</u> contact lenses, urinary catheters, tracheal tubes.
unless they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity, in which case they are in Class I,	<u>Examples:</u> dentures intended to be removed by the patient; dressings for nose bleeds.
- are in Class III if they are intended for long-term use;	<u>Example:</u> urethral stent; contact lenses for long-term continuous use (for this device, removal of the lens for cleaning or maintenance is considered as part of the continuous use).
unless they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear-drum or in a nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in Class II.	<u>Examples:</u> orthodontic wire, fixed dental prosthesis.
All invasive devices with respect to body orifices (other than those which are surgically invasive) that are intended to be connected to an active medical device in Class II or a higher class, are in Class II.	<u>Examples:</u> tracheal tubes connected to a ventilator; suction catheters for stomach drainage; dental aspirator tips. NOTE: independent of the time for which they are invasive.
6. All surgically invasive devices intended for transient use are in Class II,	A majority of such devices fall into three major groups: those that create a conduit through the skin (e.g. syringe needles; lancets), surgical instruments (e.g. single-use scalpels; surgical staplers; surgical gloves; single-use aortic punch) and various types of catheter /sucker etc. NOTE: a surgical instrument (other than those in Class IV) is in Class I if reusable and in Class II if supplied sterile and intended for single use. Also, a surgical instrument connected to an active device is in a higher class than Class I. NOTE: if the device incorporates a medicinal substance in a secondary role refer to Rule 13.
unless they are reusable surgical instruments, in which case they are in Class I;	<u>Examples:</u> Manually operated surgical drill bits and saws.
unless intended to supply energy in the form of ionizing radiation, in which case they are in Class III;	<u>Example:</u> catheter incorporating/ containing sealed radioisotopes.
unless intended to have a biological effect or be wholly or mainly absorbed, in which case they are in Class III;	NOTE: the 'biological effect' referred to is an intended one rather than unintentional. The term 'absorption' refers to the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body.

unless intended to administer medicines by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which they are in Class III.	<u>Example:</u> insulin pen for self-administration. NOTE: the term ‘administration of medicines’ implies storage and/or influencing the rate/volume of medicine delivered not just channelling. The term ‘potentially hazardous manner’ refers to the characteristics of the device and not the competence of the user.
unless intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class IV.	<u>Examples:</u> angioplasty balloon catheters and related guide wires; dedicated disposable cardiovascular surgical instruments.
7. All surgically invasive devices intended for short-term use are in Class II,	Such devices are mostly used in the context of surgery or post-operative care, or are infusion devices, or are catheters of various types. <u>Examples:</u> clamps; infusion cannulae; temporary filling materials; non-absorbable skin closure devices; tissue stabilisers used in cardiac surgery. NOTE: includes devices that are used during cardiac surgery but do not monitor or correct a defect. NOTE: if the device incorporates a medicinal substance in a secondary role refer to Rule 13.
unless they are intended to administer medicines, in which case they are in Class III;	NOTE: the term ‘administration of medicines’ implies storage and/or influencing the rate/volume of medicine delivered not just channelling.
unless they are intended to undergo chemical change in the body (except if the devices are placed in the teeth), in which case they are in Class III;	<u>Example:</u> surgical adhesive.
unless they are intended to supply energy in the form or ionizing radiation, in which case they are in Class III;	<u>Example:</u> brachytherapy device.
unless they are intended to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class IV;	<u>Example:</u> absorbable suture; biological adhesive. NOTE: the ‘biological effect’ referred to is an intended one rather than unintentional. The term ‘absorption’ refers to the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body.
unless they are intended specifically for use in direct contact with the central nervous system, in which case they are in Class IV;	<u>Example:</u> neurological catheter.
unless they are intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class IV.	<u>Examples:</u> cardiovascular catheters; temporary pacemaker leads; carotid artery shunts.
8. All implantable devices, and long-term surgically invasive devices, are in Class III,	Most of the devices covered by this rule are implants used in the orthopaedic, dental, ophthalmic and cardiovascular fields. <u>Example:</u> maxilla-facial implants; prosthetic joint replacements; bone cement; non-absorbable internal sutures; posts to secure teeth to the mandibula bone (without a bioactive coating). NOTE: if the device incorporates a medicinal substance in a secondary role refer to Rule 13.
unless they are intended to be placed into the teeth, in which case they are in Class II;	<u>Examples:</u> bridges; crowns; dental filling materials.
unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class IV;	<u>Examples:</u> prosthetic heart valves; spinal and vascular stents.
unless they are intended to be life supporting or life sustaining, in which case they are in Class IV;	
unless they are intended to be active implantable medical devices, in which case they are Class IV;	<u>Example:</u> pacemakers, their electrodes and their leads; implantable defibrillators.

unless they are intended to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class IV;	<u>Example:</u> implants claimed to be bioactive. NOTE: hydroxy-apatite is considered as having biological effect only if so claimed and demonstrated by the manufacturer.
unless they are intended to administer medicines, in which case they are in Class IV;	<u>Example:</u> rechargeable non-active drug delivery system.
unless they are intended to undergo chemical change in the body (except if the devices are placed in the teeth), in which case they are in Class IV.	NOTE: bone cement is not within the scope of the term 'chemical change in the body' since any change takes place in the short rather than long term.
unless they are breast implants, in which case they are in Class IV.	
➤ ACTIVE DEVICES	
9. All active therapeutical devices intended to administer or exchange energy are in Class II,	Such devices are mostly electrically powered equipment used in surgery; devices for specialised treatment and some stimulators. <u>Examples:</u> muscle stimulators; TENS devices; powered dental hand pieces; hearing aids; neonatal phototherapy equipment; ultrasound equipment for physiotherapy.
unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, including ionizing radiation, taking account of the nature, the density and site of application of the energy, in which case they are in Class III.	<u>Examples:</u> lung ventilators; baby incubators; electrosurgical generators; external pacemakers and defibrillators; surgical lasers; lithotriptors; therapeutic X-ray and other sources of ionizing radiation. NOTE: the term 'potentially hazardous' refers to the type of technology involved and the intended application.
All active devices intended to control or monitor the performance of active therapeutical devices in Class III, or intended directly to influence the performance of such devices, are in Class III.	<u>Examples:</u> external feedback systems for active therapeutical devices.
10. Active devices intended for diagnosis are in Class II:	Such devices include equipment for ultrasonic diagnosis/imaging, capture of physiological signals, interventional radiology and diagnostic radiology.
- if they are intended to supply energy which will be absorbed by the human body (except for devices used solely to illuminate the patient's body, with light in the visible or near infra-red spectrum, in which case they are Class D), or	<u>Examples:</u> magnetic resonance equipment; diagnostic ultrasound in non-critical applications; evoked response stimulators.
- if they are intended to image <i>in vivo</i> distribution of radiopharmaceuticals, or	<u>Example:</u> gamma/nuclear cameras.
- if they are intended to allow direct diagnosis or monitoring of vital physiological processes,	<u>Example:</u> electronic thermometers, stethoscopes and blood pressure monitors; electrocardiographs.
unless they are specifically intended for: a) monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of central nervous system, or b) diagnosing in clinical situations where the patient is in immediate danger, in which case they are in Class III.	<u>Example:</u> monitors/alarms for intensive care; biological sensors; oxygen saturation monitors; apnoea monitors. <u>Example:</u> ultrasound equipment for use in interventional cardiac procedures.
Active devices intended to emit ionizing radiation and intended for diagnostic and/or interventional radiology, including devices which control or monitor such devices, or those which directly influence their performance, are in Class III.	<u>Example:</u> diagnostic X-ray source; devices for the control, monitoring or influencing of the emission of ionizing radiation.
11. All active devices intended to administer and/or remove medicines, body liquids or other substances to or from the body are in Class II,	Such devices are mostly drug delivery systems, or anaesthesia equipment. <u>Examples:</u> feeding pumps; jet injectors.

unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application, in which case they are in Class III.	<u>Examples:</u> infusion pumps; anaesthesia equipment; dialysis equipment; hyperbaric chambers.
12. All other active devices are in Class I.	<u>Examples:</u> examination lamps; surgical microscopes; powered hospital beds & wheelchairs; powered equipment for the recording, processing, viewing of diagnostic images; dental curing lights.
➤ ADDITIONAL RULES	
13. All devices 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, are in Class IV.	These devices cover combination devices that incorporate medicinal substances in a secondary role. <u>Examples:</u> antibiotic bone cements; heparin-coated catheters; wound dressings incorporating antimicrobial agents to provide ancillary action on the wound.
14. All devices manufactured from or incorporating animal or human cells/tissues/derivatives thereof, whether viable or non-viable, are Class IV,	NOTE: Please note that the following products do not fall within the current scope of the MDACS and will not be listed at this stage: 1. devices that incorporate human blood, blood products, plasma or blood cells of human origin, except for stable derivatives devices; 2. transplants or tissues or cells of human origin or products incorporating or derived from tissues or cells of human origin 3. transplants or tissues or cells of animal origin, unless a device is manufactured utilizing animal tissue which is rendered non-viable or non-viable products derived from animal tissues.
unless such devices are manufactured from or incorporate non-viable animal tissues or their derivatives that come in contact with intact skin only, where they are in Class I.	<u>Examples:</u> leather components of orthopaedic appliances.
15. All devices intended specifically to be used for disinfecting or sterilising medical devices are in Class II,	<u>Examples:</u> disinfectants intended to be used with medical devices; washer disinfectors. NOTE: This rule does not apply to products that are intended to clean medical devices other than contact lenses by means of physical action e.g. washing machines.
unless they are intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses, in which case they are in Class III.	<u>Examples:</u> contact lens solutions. -
16. All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class III,	<u>Examples:</u> condoms; contraceptive diaphragms.
unless they are implantable or long-term invasive devices, in which case they are in Class IV.	<u>Example:</u> intrauterine contraceptive device.

Appendix 2

Essential Principles of Safety and Performance of Medical Devices

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.
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 risk(s) so that the residual risk(s) 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.
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.
4. The characteristics and performances referred to in Clauses 1, 2 and 3 should not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.
5. The devices should be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected under transport and storage conditions (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.
6. The benefits must be determined to outweigh any undesirable side effects for the performances intended.

Design and Manufacturing Requirements

7. Chemical, physical and biological properties
 - 7.1 The devices should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Clauses 1 to 6 of the 'General Requirements'. Particular attention should be paid to:
 - the choice of materials used, particularly as regards toxicity and, where appropriate, flammability,
 - the compatibility between the materials used and biological tissues, cells, body fluids, and specimens, taking account of the intended purpose of the device.
 - the choice of materials used should reflect, where appropriate, matters such as hardness, wear and fatigue strength.
 - 7.2 The devices should be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to patients, taking account of the intended purpose of the product. Particular attention should be paid to tissues exposed and to the duration and frequency of exposure.

- 7.3 The devices should be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they should be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.
- 7.4 Where a device incorporates, as an integral part, a substance which, if used separately, is considered to be a pharmaceutical and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and usefulness of the substance should be verified, taking account of the intended purpose of the device.
- 7.5 The devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks posed by substances that may leach or leak from the device.
- 7.6 Devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate risks posed by the unintentional ingress or egress of substances into or from the device taking into account the device and the nature of the environment in which it is intended to be used.
8. Infection and microbial contamination
- 8.1 The devices and manufacturing processes should be designed in such a way as to eliminate or to reduce as far as reasonably practicable and appropriate the risk of infection to patients, users and, where applicable, other persons. The design should:
- allow easy handling,
- and, where necessary:
- reduce as far as reasonably practicable and appropriate any microbial leakage from the device and/or microbial exposure during use,
 - prevent microbial contamination of the device, or specimen where applicable, by the patient, user or other person.
- 8.2 Where a device incorporates substances of biological origin, the risk of infection must be reduced as far as reasonably practicable and appropriate by selecting appropriate sources, donors and substances and by using, as appropriate, validated inactivation, conservation, test and control procedures.
- 8.3 Where a device incorporates tissues, cells and substances of non-human origin, such tissues, cells and substances should originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. Information on the geographical origin of the animals should be retained. Processing, preservation, testing and handling of tissues, cells and substances of animal origin should be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.
- 8.4 Where a device incorporates human tissues, cells and substances, the selection of sources, donors and/or substances of human origin, the processing, preservation, testing and handling of tissues, cells and substances of such origin should be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.
- 8.5 Devices labelled as having a special microbiological state should be designed, manufactured and packed to ensure they remain so when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.
- 8.6 Devices delivered in a sterile state should be designed, manufactured and packed in a non-reusable pack, and/or according to appropriate procedures, to ensure that they are sterile when placed on the market and remain sterile, under the transport and storage conditions indicated by the manufacturer, until the protective packaging is damaged or opened.
- 8.7 Devices labelled either as sterile or as having a special microbiological state should have been processed, manufactured and, if applicable, sterilized by appropriate, validated methods.
- 8.8 Devices intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.

8.9 Packaging systems for non-sterile devices should keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system should be suitable taking account of the method of sterilization indicated by the manufacturer.

8.10 The packaging and/or label of the device should distinguish between identical or similar products placed on the market in both sterile and non-sterile condition.

9. Manufacturing and environmental properties

9.1 If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system should be safe and should not impair the specified performance of the devices. Any restrictions on use applying to such combinations should be indicated on the label and/or in the instructions for use.

9.2 Devices should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate:

- the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;
- risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, pressure, humidity, temperature or variations in pressure and acceleration;
- the risks connected to their use in conjunction with materials, substances and gases with which they may come into contact during normal conditions of use;
- the risks of accidental penetration of substances into the device;
- the risk of incorrect identification of specimens;
- the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given;
- risks arising where maintenance or calibration is not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.

9.3 Devices should be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention should be paid to devices whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.

9.4 Devices must be designed and manufactured in such a way as to facilitate the safe disposal of any waste substances.

10. Devices with a diagnostic or measuring function

10.1 Devices with a measuring function, where inaccuracy could have a significant adverse effect on the patient, should be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose of the device. The limits of accuracy should be indicated by the manufacturer.

10.2 Diagnostic devices should be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended use, based on appropriate scientific and technical methods. In particular the design should address sensitivity, specificity, trueness, repeatability, reproducibility, control of known relevant interference and limits of detection, as appropriate.

10.3 Where the performance of devices depends on the use of calibrators and/or control materials, the traceability of values assigned to such calibrators and/or control materials should be assured through a quality management system.

10.4 Any measurement, monitoring or display scale should be designed in line with ergonomic principles, taking account of the intended purpose of the device.

10.5 Wherever possible values expressed numerically should be in commonly accepted, standardised units, and understood by the users of the device.

11. Protection against radiation

11.1 *General*

11.1.1 Devices should be designed and manufactured and packaged in such a way that exposure of patients, users and other persons to any emitted radiation should be reduced as far as practicable and appropriate, compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.

11.2 *Intended radiation*

11.2.1 Where devices are designed to emit hazardous, or potentially hazardous, levels of visible and/or invisible radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it should be possible for the user to control the emissions. Such devices should be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance.

11.2.2 Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they should be fitted, where practicable, with visual displays and/or audible warnings of such emissions.

11.3 *Unintended radiation*

11.3.1 Devices should be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as practicable and appropriate.

11.4 *Instructions for use*

11.4.1 The operating instructions for devices emitting radiation should give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.

11.5 *Ionizing radiation*

11.5.1 Devices intended to emit ionizing radiation should be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and energy distribution (or quality) of radiation emitted can be varied and controlled taking into account the intended use.

11.5.2 Devices emitting ionizing radiation intended for diagnostic radiology should be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimising radiation exposure of the patient and user.

11.5.3 Devices emitting ionizing radiation, intended for therapeutic radiology should be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the energy distribution of the radiation beam.

12. Requirements for medical devices connected to or equipped with an energy source

12.1 Devices incorporating electronic programmable systems, including software, should be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition in the system, appropriate means should be adopted to eliminate or reduce as far as practicable and appropriate consequent risks.

12.2 Devices where the safety of the patients depends on an internal power supply should be equipped with a means of determining the state of the power supply.

12.3 Devices where the safety of the patients depends on an external power supply should include an alarm system to signal any power failure.

12.4 Devices intended to monitor one or more clinical parameters of a patient should be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.

- 12.5 Devices should be designed and manufactured in such a way as to reduce as far as practicable and appropriate the risks of creating electromagnetic interference which could impair the operation of this or other devices or equipment in the usual environment.
- 12.6 Devices should be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.
- 12.7 *Protection against electrical risks*
- Devices should be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed and maintained as indicated by the manufacturer.
13. Protection against mechanical risks
- 13.1 Devices should be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance to movement, instability and moving parts.
- 13.2 Devices should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.
- 13.3 Devices should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.
- 13.4 Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle should be designed and constructed in such a way as to minimize all possible risks.
- 13.5 Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings should not attain potentially dangerous temperatures under normal use.
14. Protection against the risks posed to the patient by supplied energy or substances
- 14.1 Devices for supplying the patient with energy or substances should be designed and constructed in such a way that the delivered amount can be set and maintained accurately enough to guarantee the safety of the patient and of the user.
- 14.2 Devices should be fitted with the means of preventing and/or indicating any inadequacies in the delivered amount which could pose a danger. Devices should incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.
- 14.3 The function of the controls and indicators should be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information should be understandable to the user and, as appropriate, the patient.
15. Protection against the risks posed to the patient for devices for self-testing or self-administration
- 15.1 Such devices should be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to users and the influence resulting from variation that can reasonably be anticipated in user's technique and environment. The information and instructions provided by the manufacturer should be easy for the user to understand and apply.
- 15.2 Such devices should be designed and manufactured in such a way as to reduce as far as practicable the risk of use error in the handling of the device and, if applicable, the specimen, and also in the interpretation of results.
- 15.3 Such devices should, where reasonably possible, include a procedure by which the user can verify that, at the time of use, that the product will perform as intended by the manufacturer.
16. Information supplied by the manufacturer

- 16.1 Users should be provided with the information needed to identify the manufacturer, to use the device safely and to ensure the intended performance, taking account of their training and knowledge. This information should be easily understood.
- 17. Performance evaluation including, where appropriate, clinical evaluation
- 17.1 All data generated in support of performance evaluation should be obtained in accordance with the relevant requirements applicable in the countries where the data are gathered.
- 17.2 Clinical investigations on human subjects should be carried out in accordance with the spirit of the Helsinki Declaration. This includes every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results.

Appendix 3

Additional Medical Device Labelling Requirements

1 General Principles

Labelling serves to communicate safety and performance related information to users of medical devices and/or patients as well as to identify individual devices. Such information may appear on the device itself, on packaging (or as a packaging insert), or as instructions for use:

- a) Each device must be accompanied by the information needed to use it safely, taking account of the training and knowledge of the potential users.
- b) As far as it is practical and appropriate, the information needed to identify and use the device safely shall be provided on the device itself, and /or on the packaging for each unit, and / or on the packaging of multiple devices. If individual packaging of each unit is not practicable, the information shall be set out in the leaflet, packaging insert or other media supplied with, or applicable to, one or multiple devices.
- c) The format, content and location of labelling shall be appropriate to the particular device and its intended purpose.
- d) Instructions for use shall be written in terms and languages readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams.
- e) Instructions for use shall be provided with the device. However, they may not be needed or may be abbreviated for devices of Class I and Class II if the devices can be used safely and as intended by the manufacturer without any such instructions.
- f) Labelling may be provided to the user in various media and by several means such as printed documents, through a display screen incorporated into the device, downloaded from the manufacturer's web site using the Internet, magnetic or optical media. Whatever the media or the means, information should be targeted to the anticipated user population. Upon request from the user paper copies of labelling shall be made available.
- g) Where appropriate, the information can take the form of symbols or colours, provided that device safety is not compromised by a lack of understanding on the part of the patient or user. Where the meaning of the symbol or colour is not obvious to the device user, an explanation shall be provided in the documentation supplied with the device.
- h) The languages to be used in the labelling information shall be as follows-
 - (i) The contact details of the manufacturers and Local Responsible Persons shall be in both English and Chinese wherever applicable.
 - (ii) The instructions for use such as user manuals provided shall be in both Chinese and English. If any one of the two languages is not available, it shall be specified as per the requirements of Special Listing Information stipulated in section 4.4.13 and Fig. 1 of these Guidance Notes.
 - (iii) Other labelling information such as maintenance manuals provided shall preferably be in both English or Chinese and shall at least be in one of these two languages.

2 Contents of Labelling

2.1 In general:

- a) The names or trade names and addresses of the manufacturer shall be given in the labelling.

Furthermore, the instructions for use and/or the device itself shall preferably be labelled with the device's Listing Number and LRP information in the same format as specified under section 4.4.13 and Fig. 1 of these Guidance Notes.

- b) Sufficient details for the user to identify the device and, where these are not obvious, its intended purpose, user and patient population of the device; also, where relevant, the contents of any packaging.

- c) An indication of either the batch code/lot number (e.g. of single-use disposable devices) or the serial number (e.g. of electrically powered medical devices), where relevant, and to allow appropriate actions to trace and recall the devices and detachable components.
- d) An indication of the date until which the device may safely be used (i.e. put into service), expressed at least as the year and month (e.g. on single-use disposable devices) where this is relevant.
- e) For devices other than those covered by (d) above, and as appropriate to the type of device, an indication of the date of manufacture. This indication may be included in the batch code or serial number.
- f) Any special storage and /or handling conditions at the appropriate packaging level.
- g) Any warnings, precautions, limitations or contraindications.
- h) The performance intended by the manufacturer and, where relevant, any undesirable side effects.
- i) The information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature, and frequency of preventative and regular maintenance, replacement of consumable components, and calibration needed to ensure that the device operates properly and safely during its intended life.
- j) Details of any further treatment or handling needed before the device can be used (e.g. sterilization, final assembly, calibration, preparation of reagents and/or control materials, etc.).

2.2 Where applicable:

- k) An indication that the device is sterile and necessary instructions in the event of damage to sterile packaging and, where appropriate, description of methods of re-sterilization.
- l) An indication that the device has been specified by the manufacturer for single-use only.
- m) An indication that the device is for use by a single individual and has been manufactured according to a written prescription or pattern (i.e. it is custom-made).
- n) An indication that the device is intended for premarket clinical investigation or, for *in vitro* diagnostic medical devices, performance evaluation only.
- o) An indication that the device is intended only for presentation or demonstration purposes.
- p) If the device is to be installed with or connected to other medical devices or equipment, or with dedicated software, in order to operate as required for its intended use, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination.
- q) If the device is implantable, information regarding any particular risks in connection with its implantation.
- r) Information regarding the risks of reciprocal interference posed by the reasonably foreseeable presence of the device during specific investigations, evaluations, treatment or use (e.g. electromagnetic interference from other equipment).
- s) If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of re-sterilization and any restriction on the number of reuses. Where a device is supplied with the intention that it is sterilized before use, the instructions for cleaning and sterilization should be such that, if correctly followed, the device will still comply with the *Essential Principles of Safety and Performance of Medical Devices*.
- t) If the device emits radiation for medical purposes, details of the nature, type and where appropriate, the intensity and distribution of this radiation.

- 2.3 The instructions for use should also include, where appropriate, details allowing the medical staff to brief the patient on any contra-indications, warnings and any precautions to be taken. These details should cover in particular:

- u) Precautions to be taken in the event of changes in the performance, or malfunction, of the device including a contact telephone number, if appropriate.
- v) Precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, temperature, humidity, acceleration, thermal ignition sources, proximity to other devices, etc.
- w) Adequate information regarding any medicinal product or products, which the device in question is, designed to administer, including any limitations in the choice of substances to be delivered.
- x) Precautions to be taken against any special, unusual risks related to the disposal of the device.
- y) Any medicinal substances or biological material incorporated into the device as an integral part of the device.
- z) Degree of accuracy claimed for devices with a measuring function.
- aa) Any requirement for special facilities, or special training, or particular qualifications of the device user.

Appendix 4

List of Medical Devices Requiring Tracking

1. Mechanical heart valves
2. Implantable pacemakers, their electrodes and leads
3. Implantable defibrillators, their electrodes and leads
4. Implantable ventricular support systems
5. Implantable drug infusion systems

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)