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# Medical Device Administrative Control System (MDACS)

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## Overview of the Medical Device Administrative Control System

### Guidance Notes: GN-01



中華人民共和國

香港特別行政區政府衛生署

Department of Health

The Government of the Hong Kong Special Administrative Region

The People's Republic of China

## Revision History

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0	2004	<ul style="list-style-type: none"> <li>• First issue of GN-01</li> </ul>	GN-01:2004(E)
1.0	1 September 2005	<p><u>In the main text:</u></p> <ul style="list-style-type: none"> <li>• Clauses 2.4, 2.5 and 2.6 have been added;</li> <li>• Clauses 2.4 to 2.13 have been renumbered as Clauses 2.7 to 2.16;</li> <li>• Clause 2.14 has been revised and renumbered as Clause 2.17;</li> <li>• Clauses 2.15 and 2.16 have been renumbered as Clauses 2.18 and 2.19;</li> <li>• Clause 2.17 has been revised and renumbered as 2.20;</li> <li>• Clauses 2.18 to 2.22 have been renumbered as Clauses 2.21 to 2.25;</li> <li>• Clause 2.23 has been revised and renumbered as 2.26;</li> <li>• Clause 2.24 has been renumbered as 2.27;</li> <li>• Clauses 4.2, 4.4.1, 4.4.4, 4.4.8 and 4.4.11.3 have been revised;</li> <li>• Clause 4.4.13 has been added; and</li> <li>• Clauses 5.1, 5.3, 5.5, 8 and 9 have been revised</li> </ul> <p><u>In Appendix 3:</u></p> <ul style="list-style-type: none"> <li>• Clauses 1(h)(ii) and 2.1(a) have been revised</li> </ul>	GN-01:2005(E)
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		<ul style="list-style-type: none"> <li>• Clauses 2 (Definitions and Abbreviations) has been updated. Reference is made to Guidance Notes GN-00 (Guidance Notes for Definitions and Abbreviations for Medical Device Administrative Control System) for definitions</li> <li>• Clause 4.4.3 (Keeping of Supply records) has been updated;</li> <li>• Clause 4.4.7 (Management of product recalls and field safety notices) has been updated;</li> <li>• Clause 5.5 (Submission of applications) has been updated;</li> <li>• Clause 10 (References) has been updated;</li> <li>• Clauses 3.3.2 and 8 have been added;</li> <li>• Appendices 4 and 5 have been renumbered as Appendices 1 and 2; and</li> <li>• Appendix 3, 4 and 5 have been removed.</li> </ul>	
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## 1. Introduction

### 1.1 Background

1.1.1 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”. Both the long-term statutory control and the administrative control system will largely be based on the recommendations of the International Medical Device Regulators Forum (IMRDF) (previously 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 event reporting system, through which the recurrence of adverse events could be prevented. The goal of the administrative control system is that, through the listing of medical devices and monitoring of adverse events, 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”.

### 1.2 Phased Implementation of the Medical Device Administrative Control System

1.2.1 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 general medical devices. The listing of Class II and Class III general medical devices as well as the listing of importers and local manufacturers will follow in stages. An adverse event reporting system will also be set up. The whole of the MDACS is to be managed by the Medical Device Division (MDD) in the Department of Health.

### 1.3 This Document

- 1.3.1 This document 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, 7 and 8 give further information about the Listing System, including how to apply for the listing of devices, importers, local manufacturers and distributors. Those who are considering to become LRPs are advised to familiarize themselves with the details given in this document.

## 2. Definitions and Abbreviations

- 2.1 Please refer to Guidance Notes GN-00 (Guidance Notes for Definitions and Abbreviations for Medical Device Administrative Control System) for the definitions and abbreviations of the terms that appear in this document.

## 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 -

- 3.1.1 *The Listing System.* The MDD 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 performance, as well as a list of importers, a list of distributors, and a list of local manufacturers, that meet the respective requirements. All the lists that the MDD maintains under the Listing System will be accessible to the public.
- 3.1.2 *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 MDD 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 events, the initiation and management of any recall, etc.

- 3.1.3 *Adverse event reporting system.* Under the adverse event reporting system, if a reportable event concerning a listed device happens in Hong Kong, it must be reported by the LRP to the MDD. The responsibility for investigating the event 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 MDD a report detailing its findings and recommendations. The LRP may also be required to provide assistance to the MDD 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 Guidance Notes GN-00 (Guidance Notes for Definitions and Abbreviations for Medical Device Administrative Control System), would not be included into the current scope of the MDACS -
- 3.2.1.1 pharmaceutical products, including those governed by the Pharmacy and Poisons Ordinance (Cap 138);
  - 3.2.1.2 human blood, human blood products, plasma or blood cells of human origin;
  - 3.2.1.3 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;
  - 3.2.1.4 transplants or tissues or cells of human origin or products incorporating or derived from tissues or cells of human origin;
  - 3.2.1.5 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;
  - 3.2.1.6 personal protective equipment (PPE), unless it is intended for protecting the patients;
  - 3.2.1.7 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;

3.2.1.8 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;

3.2.1.9 building services equipment;

3.2.1.10 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

3.2.1.11 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.

### 3.3 Classification Rules for Medical Devices

3.3.1 The MDACS has adopted the classification rules promulgated by the IMDRF. Thus, the MDACS classifies general medical devices into four classes (Classes I, II, III and IV) according to the rules in Technical Reference TR-003 (Classification of General Medical Devices), Class IV being the class with the highest risk and Class I the class with the lowest risk.

3.3.2 The MDACS classifies *in vitro diagnostic* medical devices (IVDMD) into four categories (Classes A to D) according to their risk levels, Class A being the category of the lowest overall risk and Class D the highest. The classification rules for defining the class of an IVDMD are given in Technical Reference TR-006 (Classification of In Vitro Diagnostic (IVD) Medical Devices).

### 3.4 Essential Principles of Safety and Performance of Medical Devices

3.4.1 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 TR-004 as well as the additional labelling requirements in TR-005. For further details about the

Listing System, the reader is referred to sections 5 to 8 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, distributors 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**

4.2.1 Any LRP in relation to a medical device (except a Class I general medical device or a Class A IVDMD) can apply to the MDD 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 MDD webpage. 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**

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

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

AND

4.3.1.2 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*

(a) The LRPs are responsible for communicating with the users, importers, distributors, 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 *Keeping of supply records*

The LRP shall maintain an updated list of importers, distributors and the supply records of the medical devices, including the make, model, batch number, serial number, and quantity of devices, as appropriate, such that the details of devices imported and supplied 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 1 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 1, the LRP shall submit surveillance reports (which may be based on local or overseas data or both) to the MDD at least once a year. The MDD 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 *Managing product recalls and field safety notices*

Upon the issuance of product recalls and field safety notices by the manufacturer or overseas authorities, the LRP shall inform the MDD 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 MDD as requested until the case is concluded. It is preferred that prior arrangements be made such that within four hours of the issuance of product recalls and field safety notices by the manufacturer, the same be also emailed direct to the MDD.

#### 4.4.8 *Managing reportable adverse events in Hong Kong*

The LRP is required to observe the adverse event reporting requirements of the Guidance Notes GN-03 and report all reportable adverse events to the MDD. 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 event. When a reportable or a potentially reportable adverse event that has occurred in Hong Kong is reported to the LRP directly or from other sources, the LRP shall conduct an investigation into the event and report to the MDD as soon as possible. The investigation may be done in conjunction with the manufacturer

or other parties. If the event has caused any death or serious injuries or is of a serious public health concern, the report shall reach the MDD as soon as possible but not later than 10 calendar days after the LRP becomes aware of the event. For other reportable or potentially reportable events, the LRP shall, within 30 calendar days of becoming aware of it, report the event to the MDD. Upon request, the LRP shall provide assistance to the MDD 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 MDD as soon as possible and in no case later than 10 calendar days.

#### 4.4.10 *Making records available for inspection*

The MDD 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 MDD 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 MDD.

#### 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 MDD 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 MDD 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 MDD 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 MDD;
- (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

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

4.5.1 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

4.6.1 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 2). 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

5.1.1 Under the Listing System, the MDD 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 the MDD website.

#### 5.2 Persons eligible to apply for listing a device

5.2.1 Only the LRP in relation to the device can make the application. Please see also para. 3.1.2.

#### 5.3 Methods to obtain the application form and the related Guidance Notes

5.3.1 Application forms can be obtained during office hours from the MDD, or downloaded from the MDD website.

#### 5.4 No application fee to be paid

5.4.1 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

5.5.1 Depending on the class to which the device belongs, an application for listing a medical device must be made on the application form MD-C2&3&4 or MD-IVD 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 MDD. Applicants are encouraged to use soft copy of documents in portable storage devices (PSDs) as far as possible. Alternatively, an applicant with Hongkong Post e-Cert could submit applications to the email address [mdd\\_app@dh.gov.hk](mailto:mdd_app@dh.gov.hk).

## 5.6 Supporting documents to accompany an application

5.6.1 Please refer to GN-02 and GN-06 for the requirements for the listing of Class II/III/IV general medical devices and Class B/C/D in vitro diagnostic medical devices respectively.

## 5.7 Labelling samples to accompany an application

5.7.1 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 TR-004 and TR-005 respectively.

## 5.8 Time for vetting and approving an application

5.8.1 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

5.9.1 The LRP must ensure that the application and all the associated submissions have been properly prepared before they are submitted to the MDD. The LRP has the obligation to submit further information or further labelling samples related to the application if this is requested by the MDD. Whether during or after the application process, the LRP cannot refuse any request by the MDD

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 MDD.

#### 5.10 Notification of approval or rejection of application

5.10.1 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

5.11.1 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 MDD, where any of the following circumstances arises -

5.11.1.1 failure of the manufacturer or the LRP to comply with the requirements of the MDACS; or

5.11.1.2 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

5.11.1.3 the manufacturer or the LRP fails to address or to adequately address a hazard of the device; or

5.11.1.4 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

5.11.1.5 the manufacturer or the LRP has been wound up or has ceased to exist; or

5.11.1.6 the MDD considers the delisting necessary for public health or safety considerations; or

5.11.1.7 the delisting is requested by the manufacturer or LRP.

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

5.12.1 A decision of the MDD 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 Division, stating its grounds for appeal.

5.12.4 Where a decision of the MDD is appealed against under section 5.12.1 or 5.12.2, the lodging of the appeal does not suspend the decision unless the MDD 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 MDD 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 Division, stating its grounds for appeal.

5.13.3 The lodging of an appeal against a decision of the MDD to delist a device does not suspend the decision unless the MDD 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

5.14.1 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 MDD as soon as possible. It is the discretion of the MDD to require the LRP to submit a new application for the device based on the information submitted.

#### 5.15 Validity of Listing Approval

5.15.1 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 MDD at least 12 weeks before the expiry of this five-year validity period. Unless the application for continuation of the listing reaches the MDD within this time frame, the device may be delisted after the five-year validity period.

### **6. Listing of Importers**

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

### **7. Listing of Local Manufacturers**

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

### **8. Listing of Distributors**

8.1 Distributors of medical devices may apply for becoming Listed Distributors under the MDACS. Please refer to the Guidance Notes GN-09 for the details.

### **9. Enquiries**

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

Medical Device Division,  
Department of Health,  
Telephone number: 3107 8484  
Facsimile number: 3157 1286  
Email address: [mdd@dh.gov.hk](mailto:mdd@dh.gov.hk)  
Website: [www.mdd.gov.hk](http://www.mdd.gov.hk)

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

## 10. References

- 10.1 Department of Health. Regulation of Medical Devices – Consultation Document. <https://www.dh.gov.hk> accessed on 30 October 2004.
- 10.2 Global Harmonization Task Force. Principles of Medical Devices Classification. Proposed Document SG1/N015R22. <http://www.ghtf.org> accessed on 30 October 2004.
- 10.3 Global Harmonization Task Force. Principles of In Vitro Diagnostic (IVD) Medical Devices Classifications. Final Document GHTF/SG1/N045:2008. <http://www.imdrf.org> accessed on 23 June 2020.
- 10.4 Department of Health. Guidance Notes for Definitions and Abbreviations for Medical Device Administrative Control System. Guidance Notes GN-00.
- 10.5 Department of Health. Guidance Notes for Listing Class II/III/IV General Medical Devices. Guidance Notes GN-02.
- 10.6 Department of Health. Guidance Notes for Adverse Event Reporting by Local Responsible Persons. Guidance Notes GN-03.
- 10.7 Department of Health. Guidance Notes for Listing Class B, C and D In Vitro Diagnostic Medical Devices. Guidance Notes GN-06.
- 10.8 Department of Health. Guidance Notes for Listing of Importers of Medical Devices. Guidance Notes GN-07.
- 10.9 Department of Health. Guidance Notes for Listing of Local Manufacturers of Medical Devices. Guidance Notes GN-08.
- 10.10 Department of Health. Guidance Notes for Listing of Distributors of Medical Devices. Guidance Notes GN-09.
- 10.11 Department of Health. Classification of General Medical Devices. Technical

Reference TR-003.

10.12 Department of Health. Essential Principles of Safety and Performance of Medical Devices. Technical Reference TR-004.

10.13 Department of Health. Additional Medical Device Labelling Requirements. Technical Reference TR-005.

10.14 Department of Health. Classification of In Vitro Diagnostic (IVD) Medical Devices. Technical Reference TR-006.

## 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

## 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 events and post market surveillance.

Yours faithfully,

(signature)

(name and title of official signing this letter)

(official chop (if any) of the manufacturer)