GN-10:2019(E)

醫療儀器的規管

Regulation of Medical Devices

Guidance Notes for Listing of Local Responsible Persons

Guidance Notes: GN-10

中華人民共和國
香港特別行政區政府衞生署
Department of Health
Government of the Hong Kong Special Administrative Region
The People's Republic of China

Revision History

Edition Number	Date of Revision	Summary of Revision	Reference Number
0	XX May 2019	First issue of GN-10.	GN-10:2019(E)

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1. Introduction

1.1 This document provides general guidance to applicants applying for listing as Local Responsible Persons (LRPs) under the Medical Device Administrative Control System (MDACS).

1.2 Recognising the importance of Local Responsible Persons in applying listing of medical devices and provision of post-market activities, the Medical Device Control Office (MDCO) maintains a List of LRPs under the MDACS.

1.3 LRPs serve as hubs of communication between manufacturers and the users, importers, distributors, the public and the Government such that the LRP can provide quality services to ensure the safe and efficacious use of the devices.

1.4 Application for listing as an LRP is entirely on a voluntary basis.

2. Scope

2.1 Any eligible entities may apply to be included on the List of Local Responsible Persons.

3. Definitions

3.1 For the purpose of this booklet, the definitions given in the Guidance Notes GN-00 (Definitions and Abbreviations for Medical Device Administrative Control System) apply, together with the following.

3.2 A Local Responsible Person of a medical device means a legal person with Hong Kong business registration who places on the Hong Kong market that particular medical device.

3.3 A listed Local Responsible Person of a medical device means the Local Responsible Person who undertakes listing applications for medical devices under MDACS and performing the requirements for listed LRPs.

4. Entities eligible to be Local Responsible Persons

4.1 An LRP shall be a legal person with business registration in Hong Kong.

4.2 In addition, the LRP in respect of a medical device must meet the following requirements:

4.2.1 It is EITHER the manufacturer of the device, OR is supported by the manufacturer of the device to perform the requirements of an LRP for the device; AND

4.2.2 It has placed on market or intends to place on market that medical device.

4.3 To apply for the listing of their medical devices under MDACS, the manufacturers shall either designate third parties as LRPs of their products or take up the roles of LRPs themselves. In the latter case, the manufacturers shall also apply for listing as LRPs under MDACS.

4.4 Entities submitting applications for listing their first medical device under the MDACS shall have applied to be included on the List of Local Responsible Persons. Existing LRPs of listed medical devices do not need to apply.

5. Application procedures

5.1 An eligible entity can apply for the inclusion into the List of Local Responsible Persons beforehand, or submit its application together with its first medical device listing application. The applicants for listing as LRPs are required to complete the application form MD-LRP and send it to the MDCO together with the following documents:

5.1.1 A copy of business registration certificate in Hong Kong; and

5.1.2 A copy of documented procedures as specified in the application form; OR a copy of ISO13485 or ISO9001 certificate for their business covering the documented procedures as specified in the application form and a copy of the corresponding quality manual.

5.2 A sample of a completed MD-LRP form is given in Appendix 1. Provided that the application form is duly completed and all the required documents are submitted

together with the application, it will take around twelve (12) weeks to complete the processing of the application.

5.3 Each LRP in the List of Responsible Persons will be assigned an LRP Listing Number. When applying for medical device listing, the LRP shall quote its Listing Number as appropriate.

6. Requirements for listing of Local Responsible Persons

6.1 Documented procedures and quality management

6.1.1 The LRPs are required to establish documented procedures to cope with pre-market and post-market activities. LRPs are encouraged to implement quality management systems covering the full scope of their business related to the MDACS.

6.2 Efficient communication channels

6.2.1 The LRPs are responsible for communicating between the manufacturers and the users, importers, distributors, the 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.

6.3 Application for listing medical devices

6.3.1 The LRPs are entitled to make applications for listing their medical devices under the MDACS. They are responsible for communicating with the MDCO regarding their applications.

6.4 Keeping of transaction records

6.4.1 The LRP shall establish documented procedures for the keeping of transaction records and maintain an updated list of importers, distributors and transaction records of all their products listed under the MDACS. The transaction records shall include the make, model, batch number, serial

number, and quantity of devices, as appropriate. Such records shall contain sufficient information to trace the sold and distributed medical device(s) and to permit a prompt and complete withdrawal of the device(s) from the market when needed. The transaction records shall be retained for a period of time not less than the service life of the product as defined by the manufacturer, or at least seven (7) years from the date of product distribution, whichever is longer.

6.5 Complaint handling

6.5.1 The LRP shall establish documented procedures to handle complaints. The LRP shall provide a telephone number, a fax number and/or an email address to the public for collecting comments and complaints. The LRP shall also provide a 24-hour telephone number for communication with the MDCO in case of emergency. The procedure shall include, but not limited to, the following key activities:

(a) Receiving and evaluating information to determine if the feedback, constitutes a complaint;
(b) Investigating complaints;
(c) Reporting to regulatory authorities as appropriate;
(d) Handling of complaint related devices;
(e) Determining and initiating corrective or preventive actions on the basis of risk; and
(f) Defining requirements for complaint records.

6.6 Tracking of specific medical devices

6.6.1 Clauses 6.6.2 applies to the following categories of high-risk medical devices:

(a) Mechanical heart valves;
(b) Implantable pacemakers, their electrodes and leads;
(c) Implantable defibrillators, their electrodes and leads;
(d) Implantable ventricular support systems; or
(e) Implantable drug infusion systems.

6.6.2 The LRP shall establish documented procedures to have in place a tracking system that tracks those devices 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 devices is possible) The date the device permanently retired from use or (for an implanted device) the date it was explanted.

6.7 Post market surveillance reports

6.7.1 Upon the approval and renewal of listing, the MDCO may notify LRPs to submit surveillance reports of their medical devices at specified time intervals. The LRP shall submit surveillance reports to the MDCO in accordance with the requirements specified. The report shall include, but not limited to, the reporting period, number of devices sold, number of complaints received, number of field safety corrective actions (e.g. product recalls and device modifications, etc.) initiated and number of adverse incidents reported in Hong Kong and overseas. Analyses of complaints (including adverse incidents) and any actions (including field safety corrective actions) taken shall be included in the reports. Information and statistical data could be based on data acquired from local and overseas.

6.7.2 The MDCO may request LRPs to submit surveillance reports of their medical devices from time to time or change the submission schedule on a need basis.

6.8 Management of safety alerts, field safety notices and field safety corrective actions

6.8.1 The LRP shall establish documented procedures to manage safety alerts, field safety notices and field safety corrective actions. Upon the issuance of field safety notices and field safety corrective actions by the manufacturer or safety alerts by 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 ten (10) calendar days after the LRP becomes aware of the issuance. The LRP shall follow up the actions, and shall submit progress

reports to the MDCO as requested until the case is concluded. For matters related to safety alerts, field safety notices and field safety corrective actions, the LRP can contact the MDCO through mdco_alert@dh.gov.hk.

6.9 Managing reportable adverse incidents in Hong Kong

6.9.1 The LRP shall establish documented procedures to manage adverse incidents in Hong Kong. The LRP is required to observe the adverse incident reporting requirements of the Guidance Notes GN-03: (Guidance Notes for Adverse Incident Reporting by Local Responsible Persons) and handle reportable adverse incidents in Hong Kong.

6.9.2 The submission of an adverse incident 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 in accordance with the requirements specified under the Guidance Notes GN-03. The investigation may be done in conjunction with the manufacturer or other parties. In summary, 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 ten (10) calendar days after the LRP becomes aware of the incident. For other reportable or potentially reportable events, the LRP shall, within thirty (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.

6.10 Maintenance and services arrangements

6.10.1 The LRP shall establish documented procedures to handle maintenance and service arrangements, and shall offer or arrange other parties to provide preventive and corrective maintenance, including calibration, provision of spare parts and other services to the users when requested.

6.11 Handling, storage and delivery of medical device

6.11.1 The LRP shall establish documented procedures in handling, storage and delivery of medical devices to fulfill the following requirements:

(a) Protection from environmental conditions that may affect the safety or performance of medical devices;

(b) Identification and appropriate storage, handling and delivery of medical devices that require special storage or transport conditions, for instance the low temperature requirement for IVD medical device;

(c) Stock rotation (first-expiry first-out) for medical devices that have a limited shelf-life or expiry date;

(d) Proper handling of medical devices to prevent damage, deterioration or contamination;

(e) Identification, segregation and control of nonconforming, returned or recalled medical devices to prevent them from being inadvertently sold/issued;

(f) Adequate and sufficient incoming and outgoing inspection to ascertain the safety, performance and quality of the medical devices received and to be issued; and

(g) Delivery procedures, including verification of orders and physical inspection of label description, type and quantity of medical devices to avoid incorrect medical devices from being delivered/received.

6.11.2 The LRP shall also make reference to the “Requirements on storage of pharmaceutical products” from the website of Drug Office, Department of Health (website: http://www.drugoffice.gov.hk/) where applicable for storage of medical devices containing pharmaceutical products and for those having specific storage requirements, such as temperature and humidity. In general, there must be adequate storage facilities with appropriate measures in monitoring the storage conditions (e.g. temperature and humidity).

6.12 Regular checking and review of operation

6.12.1 All operation procedures and records related to the handling and control of medical devices shall be reviewed regularly and documented. In the event of irregularities and/or deficiencies found in the operation procedures and record keeping, the causes of irregularities and/or deficiencies shall be investigated and corrective and preventive measures shall be taken and documented.

6.13 Reporting changes

6.13.1 When there is any major change to the information that has been submitted in relation to the listed LRP (e.g. change of LRP's address, change of documented procedures related to the MDACS, etc.) or the listed devices (e.g. change of model number, change of device design, etc.), the LRP shall notify the MDCO as soon as possible and in no case later than ten (10) calendar days. It is at the discretion of the MDCO to require the LRP to submit a new application for the device based on the information submitted.

6.14 Making local facilities and records available for inspection

6.14.1 The MDCO has the discretion to inspect the local facilities of the LRP, original records and supporting documents claimed to be in the possession of the LRP or copied to the MDCO by the LRP when considered necessary. The LRP shall accommodate the request of on-site inspection raised by the MDCO and produce the original records and supporting documents for inspection within two (2) weeks after receiving the notice from the MDCO. The MDCO may conduct announced or unannounced on-site inspection to the LRP.

6.15 Responsibilities in respect of advertisements

6.15.1 The LRP shall not publish or cause to be published any advertisements or other commercial promotional materials that contravene applicable ordinances such as the Undesirable Medical Advertisement Ordinance (Cap. 231).

6.15.2 Where any document, statement, information, claim, advertisement, promotional material (or any other communication by any means) published to the public, customers or potential customers includes any representation that the LRP is a listed Local Responsible Person, or that the LRP is in compliance with the MDACS requirements on listed Local Responsible Person, it shall at the same time include a statement to the effect that:

(a) The listing of a Local Responsible Person carries no implication that its medical devices are listed; and

(b) Clearly state whether any of the medical devices presented in the

same article are listed under the MDACS or not.

6.15.3 Where the representation that the LRP is a listed Local Responsible Person, or that the LRP is in compliance with the MDACS requirements on listed Local Responsible Person, is in writing, then the statements required by 6.15.2(a) and 6.15.2(b) above shall be in the same format (in terms of font size, colour, etc.) as the aforesaid representation.

6.15.4 All advertised claims of a listed medical device shall align with the indications and instructions for use as listed with the MDCO. Information that has not been listed or which may potentially or indirectly extend the usage of a listed medical device must not be included in advertisements. This is to ensure information provided in the advertisement falls within the scope of the listed uses of the medical device.

6.16 Special listing information

6.16.1 The Special Listing Information of a medical device comprises (a) and (b) below:

(a) 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.

(b) The LRP information including the name, address, and contact telephone / fax numbers in both English and Chinese wherever applicable.

6.16.2 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 (6) months after the device is listed to meet this requirement.

6.16.2.1 Option (I)

(a) The information 6.16.1(a) shall be displayed on the outer packaging of every device or sales unit; and

(b) The LRP information 6.16.1(b) shall be displayed on the outer packaging of every device or sales unit, or on a document delivered together with the device.

6.16.2.2 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 6.16.2.2(a). This option shall not be adopted if it cannot be effectively implemented.

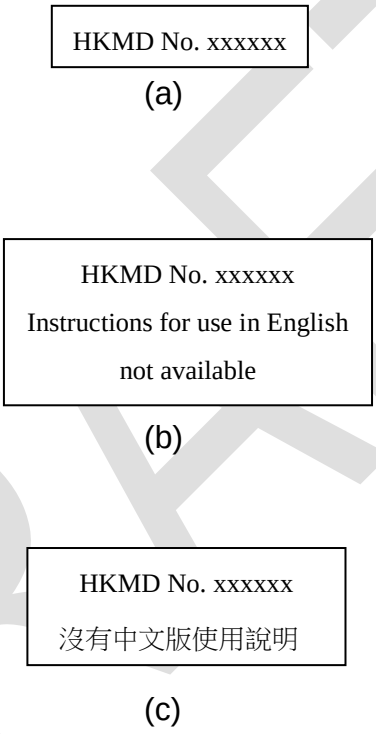

Fig. 1. If the instructions for use are available in both English and Chinese languages, the format in figure (a) shall be applied. The format in figure (b) or (c) shall be applied if the instructions for use are available only in Chinese or only in English.

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).

7. Administrative provisions

7.1 Validity of approval

7.1.1 If an application for inclusion on the List of Local Responsible Person is approved, the applicant will be included on the List for three (3) years. The listed LRP should apply for renewal of its current inclusion on the List of Local Responsible Persons (current listing) not less than three (3) months before its expiry through the submission of a renewal application form and requisite documents as specified by the MDCO. If the current listing expires prior to a decision of its application for renewal is made by the MDCO, its current listing shall remain in effect until there is a decision.

7.2 Fees

7.2.1 No fee will be charged by the Government for the application or in relation to the inclusion of an LRP on the List of Local Responsible Persons.

7.3 Undertaking by Applicant

7.3.1 The applicant shall, on the terms set out in the Undertaking in the Application Form, undertake inter alia to indemnify the Government of the Hong Kong Special Administrative Region against any loss or claim that flows from any of the following:

(a) any act or default of the applicant,

(b) any defective design of the medical device products of the applicant,

(c) any defect in such products, and

(d) any information supplied by the applicant to the Government.

7.4 Delisting of LRP

7.4.1 A listed LRP may be permanently or temporarily removed from the List of Local Responsible Persons at the discretion of the MDCO, where any of the following circumstances arises:

(a) the listed LRP has been wound up, dissolved or otherwise has ceased to exist;

(b) where the inclusion into the List of Local Responsible Persons or the inclusion of devices into the List of Medical Devices has been

approved on certain special conditions, failure of the LRP to comply with any of those conditions;

(c) the delisting is requested by the listed LRP;

(d) the listed LRP fails to comply with any of the MDACS requirements including but not limited to the LRP requirements as stipulated in Section 6;

(e) the listed LRP fails to address or adequately address a situation that gives rise or that might give rise to a hazard of its medical device products or to a public health or public safety concern;

(f) the MDCO considers the delisting necessary for public health or safety considerations; or

(g) where the listed LRP has made an untrue or unjustified claim for the medical devices represented by the LRP, 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.

7.4.2 If an LRP is permanently removed from the List of Local Responsible Persons, all the listed medical devices represented by the LRP, if any, are automatically de-listed. However, the LRP shall continue the post-market surveillance, field safety corrective actions and vigilance activities for the listed devices already marketed. In the case that the de-listing is temporary, the MDCO has the discretion to suspend all the medical devices listed by the LRP and the LRP cannot submit any new applications for device listing until the de-listing is over. All post-market surveillance, field safety corrective actions and vigilance activities for the listed devices already marketed shall be continued by the LRP.

7.5 The List of Local Responsible Persons

7.5.1 For each listed LRP, the entries on the List may include:

(a) the name, telephone number and address of the LRP; and

(b) the LRP Listing Number assigned to the LRP.

7.5.2 The List of Local Responsible Persons will be publicly accessible.

7.6 Appeal against a decision to reject or conditional approval of an application of listing of LRP

7.6.1 Any appeal against a decision to reject of an application for inclusion or renewal of inclusion on the List of Local Responsible Persons or to delist a listed LRP must be lodged by the applicant/listed LRP within fourteen (14) calendar days of receiving the notification of decision.

7.6.2 Where an application for inclusion of an LRP into The List of LRPs has only been conditionally approved, an appeal as to the conditions imposed may be submitted by the LRP within fourteen (14) calendar days of receiving the notification of conditional approval.

7.6.3 To lodge the appeal, the applicant/listed LRP must write to the Secretary to Medical Device Administration Appeal Committee, c/o Medical Device Control Office, stating its grounds of appeal.

7.6.4 Where a decision of the MDCO is appealed against under Section 7.6.1 or 7.6.2, the lodging of the appeal does not suspend the decision unless the MDCO decides otherwise.

7.6.5 An appeal lodged after the time limit will not be considered.

7.7 Appeal against a decision to delist a LRP

7.7.1 A decision of the MDCO to delist an LRP permanently or temporarily may be appealed against by the LRP within fourteen (14) calendar days of being notified of the decision.

7.7.2 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.

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

7.7.4 An appeal lodged after the time limit specified in Section 7.7.1 will not be considered.

7.8 Application for taking over the listing of medical devices from another LRP

7.8.1 An LRP can apply to take over the listing of medical devices from another LRP only if

(a) The applicant undertakes to assume all the responsibilities and

requirements for the existing LRP of the listed medical devices including field safety corrective actions (e.g. product recalls and device modifications, etc.), adverse incidents reporting, etc. for products already and/or to be placed on market and to comply with all the applicable requirements of the MDACS; and

(b) The existing LRP of the listed medical devices undertakes to provide the applicant with all necessary support and information (e.g., distribution and maintenance records etc.) required for taking up the LRP requirements of the devices already placed on market; and

(c) The manufacturer of the listed medical devices undertakes to provide the applicant with all the necessary information and support so as to enable the applicant to become the new LRP and fulfil its requirements for listed LRP under MDACS.

7.8.2 The applicant should arrange with the existing LRP and manufacturer of the listed medical devices to be taken over to complete the form MD-LRP Change, a Transfer Form and submit the application to the MDCO. A sample of a completed MD-LRP Change form and Transfer Form is given in Appendix 2 and Appendix 3 respectively.

7.8.3 The existing LRP shall continue to comply with all the requirements, stipulated in Section 6, for the related products until the approval for the taking over is granted. The applicant shall then assume all the requirements for the LRP and becomes the new LRP of the related products.

7.8.4 The existing listing certificates of related products will be superseded by the new ones issued to the new LRP. The superseded listing certificates shall be returned to MDCO immediately.

8. Points to note

8.1 The inclusion of an individual, person, company or partnership on the List of Local Responsible Persons is not an endorsement in support or any recommendation whatsoever of that individual, person, company or partnership as an LRP of medical devices by the Department of Health. Nor does the inclusion imply that the supply of medical devices by that individual, person, company or partnership is in compliance with the applicable laws or has the necessary regulatory approvals. The

responsibility for ensuring the legality of the supply rests with the LRP.

9. Enquiries

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

Medical Device Control Office, Department of Health.

Facsimile number: 3157 1286

Telephone number: 3107 8484

E-mail address: mdco@dh.gov.hk

Medical Device Control Office
Department of Health

Medical Device Administrative Control System
Application for the Listing of Local Responsible Person

For official use only

Date Received: _____ *Application No.:* _____ *Officer:* _____
Date Approved/Rejected: _____ *LRP Listing No.:* _____
Remarks: _____

Please read this section carefully before completing the form

1. Please note that information included in those parts that are marked with asterisks (*) may be included on The List of Local Responsible Persons if this application is approved. They include (i) the LRP's name, (ii) address in Hong Kong, and (iii) contact telephone number for public enquiries. The details will normally appear on The List of Local Responsible Persons as they appear on this form. Where under an item both the prompts "in English" and "in Chinese" appear, the entry for that item shall be given in both languages wherever applicable such that they could be accordingly recorded on The List of Local Responsible Persons for the reference of the public.
2. Please check the corresponding boxes in the "Encl." column if any document is enclosed under respective indexes of the submission folder.
3. Submitted documents not in Chinese or English shall be accompanied by Chinese or English translations.
4. Please check the boxes as appropriate.

Note	**Particulars of Applicant**			**Encl.**
1001	Name of Business*	*in English*	***Cardio Supplies Limited***	(A1) ☒
		in Chinese	*心臟儀器供應有限公司*	
	Address in Hong Kong *(Please give the registered place of business, if any)**	*in English*	***32/F, Metropolitan Centre, 123 Merry Street, Causeway Bay, Hong Kong***	
		in Chinese	*香港銅鑼灣喜樂街都市中心32樓*	
	Contact person: ***CHAN Tai-man***		Telephone: ***2800 0000***	
	Fax: ***2900 0000***		E-mail: ***tcchan@cardio.com.hk***	
	Contact telephone for public enquiries (if different from the number given above)*: ***2000 0000***			
	Mobile telephone for urgent use (24 hours): ***9012 3456***			
	☒ Copy of business registration certificate (with business registration number: ***12345678-000-01-09-4***) is enclosed			

1002	☒ The applicant is a listed importer of medical device under MDACS Listed Importer No. ***IMP07009***	
1003	☒ The applicant is a listed distributor of medical device under MDACS Listed Distributor No. ***DIS07009***	
1004	☒ The applicant is a listed local manufacturer of medical device under MDACS Local Manufacturer Listing No. ***LM07009***	
1005	Address of storage / maintenance / other facilities (if different from item 1001) and kind of activities conducted in each facility: Nil	
	Quality Management and Documented Procedures	
2001	Established Quality Management System (QMS) ☐ ISO9001 ☐ ISO13485 ☒ none ☐ System certified by _____ (certification body), and a copy of the certificate and quality manual are enclosed.	(B1) ☐
2002	Documented Procedures Established The applicant has established documented procedures for their medical devices described below and copies of these procedures are enclosed. (Note: Submission of documented procedures is not required if ISO13485 / ISO9001 certificate covering below documented procedures and the corresponding quality manual are enclosed.) ☒ Keeping of transaction records ☒ Complaint handling ☒ Management of safety alerts, field safety notices and field safety corrective actions ☒ Tracking of specific medical devices ☒ Managing reportable adverse incidents in Hong Kong ☒ Maintenance and service arrangements ☒ Handling and storage and delivery of medical devices	(B2) ☒

Undertaking by Applicant

Date: 1 April 2010

To the Government of the Hong Kong Special Administrative Region (hereinafter "the Government"):

I/We have read the latest editions of the Guidance Notes GN-01 (with all appendices), GN-10 (with all appendices) and COP-01 issued by the Department of Health in relation to the Medical Device Administration Control System (MDACS) and the listing of Local Responsible Persons thereunder.

In consideration of the promise of the Government in the Guidance Notes GN-10 to proceed with the processing of this application under the MDACS, I/we Cardio Supplies Limited, 32/F, Metropolitan Centre, 123 Merry Street, Causeway Bay, Hong Kong [name and address of the Applicant], undertake, acknowledge and agree in favour of the Government as follows:

1. To the maximum extent permitted by law I/we agree to exempt, relieve, exonerate, indemnify and hold harmless, and to keep indemnified and harmless, as the case may be, the Government from and/or against any and all losses, claims, demands and proceedings (including but not limited to all costs, charges and expenses) whatsoever and howsoever suffered or incurred by, or made or issued against, the Government, as the case may be, by any third party in respect of any loss of or damage to any property or injury to or death of any person arising out of and/or relating and/or incidental to:
   a. any act, neglect or default on my/our part or on the part of my/our employees or agents;
   b. any defect in the design, material, workmanship or installation in relation to my/our medical device product or products;
   c. any use of any of the information supplied by me/us or my/our employees or agents in relation to this application or to my/our medical device product or products, whether or not such information has materially contributed to the inclusion of the applicant on the List of Local Responsible Persons or the inclusion of any of my/our product or products on the List of Medical Devices and whether or not such information is misleading, wrong or inaccurate.
2. I/We also agree and accept that:
   a. the Government, its employees or agents shall not be liable to me/us for any loss of or damage to property caused by the act, default or neglect of the Government or its employees or agents in the processing of my/our application, the inclusion or non-inclusion of any of my/our information and/or product or products on the Lists being maintained under the MDACS (including but not limited to the List of Local Responsible Persons and the List of Medical Devices) or any cause whatsoever arising out of or in connection with the implementation and management of the MDACS;
   b. neither the Government nor any of its employees or agents makes any representation, statement, warranty or guarantee, express or implied, that any of my/our products (including any spares or replacement parts), whether or not they are included on the List of Medical Devices, are of merchantable quality or are fit for the purposes for which they are commonly bought, used and/or applied and that the spares or replacement parts are readily available.
3. I/We undertake that the information contained in my/our application is true and correct and that my/our medical device product or products (including any spares or replacement parts) are of merchantable quality and are fit for the purposes for which they are commonly bought, used and/or applied.
4. I/We fully understand and agree that any future changes or additions to the requirements of the MDACS can be imposed by the Department of Health without prior notice. I/We hereby undertake to comply with the latest requirements of the MDACS that are in force.
5. I/We undertake that I/we have neither amended any wording in this form, nor otherwise altered the form in any material manner, apart from filling in the appropriate blanks / boxes.

Each of the provisions of this Undertaking is severable and distinct from the others and, if one or more of such provisions or any part thereof is or becomes illegal, invalid or unenforceable, the legality and enforceability of the remainder of this Undertaking shall not be affected or impaired in any way.

The Government shall be entitled to enforce any or all of its rights under this Undertaking.

This Undertaking shall be governed by and construed according to the laws of Hong Kong and the parties irrevocably submit to the non-exclusive jurisdiction of the Courts of Hong Kong.

As witness whereof, this Undertaking has been entered into the day, month and year first above written

SIGNED BY	)	
	)	
Chan Tai-man (name of Applicant or its representative*)	)	**<*Signature of Chan***
General Manager (position)	)	***Tai-man*>**
	)	
[for and on behalf of	)	
	)	
Cardio Supplies Limited (name of Applicant)	)	**<*Company chop of***
(who hereby warrant(s) that the signatory above has	)	***Cardio Supplies Limited*>**
the authority to bind ~~the above firm and the partners~~	)	
~~therein for the time being~~ / the above company* to	)	
this Undertaking)]#	)	
	)	
in the presence of	)	
	)	
Chan Siu-man (name)	)	**<*Signature of Chan***
32/F, Metropolitan Centre, 123 Merry Street, Causeway Bay,	)	***Siu-man*>**
Hong Kong (address)	)	

* Delete where appropriate
# Delete if the applicant is an individual

Personal Data (Privacy) Ordinance
Statement of Purposes

1. Purpose of Collection
The personal data that you provide the Department of Health ("the Department") in connection with the Medical Device Administrative Control System (MDACS) or with this application in particular will be used by the Department for the management and implementation of the MDACS.

2. Class of Transferees
The personal data are mainly for use by the Department, but may also be disclosed to other Government bureaux/departments or other parties for the purpose stated in para. 1 above or for the purpose of a related matter. Apart from this, the data may only be disclosed to parties where you have given consent to such disclosure or where it is allowed under the Personal Data (Privacy) Ordinance.

3. Access to Personal Data
You have a right of access and correction with respect to personal data as provided for in sections 18 and 22 and Principle 6 of Schedule 1 of the Personal Data (Privacy) Ordinance. Your right of access includes the right to obtain a copy of your personal data. A fee may be imposed for complying with a data access request.

4. Enquiries
Enquiries in relation to the personal data, including requests for making access or corrections to the data, should be addressed to the Medical Device Control Office, Department of Health (facsimile number 3157 1286; telephone number 3107 8484, e-mail address: mdco@dh.gov.hk). Please quote your application number when you make the enquiries.

Medical Device Control Office
Department of Health

Medical Device Administrative Control System
Application for Taking Over the Listing of Medical Devices

For official use only

Date Received: _____ *Application No.:* _____ *Officer:* _____
Date Approved/Rejected: _____ *HKMD No(s).:* _____
Remarks: _____

Please read this section carefully before completing the form

1. Please note that information included in those parts that are marked with asterisks (*) may also be included on The List of Local Responsible Persons and The List of Medical Device if this application is approved. Where under an item both the prompts "in English" and "in Chinese" appear, the entry for that item shall be given in both languages wherever applicable such that they could be accordingly recorded on The List of Local Responsible Persons for the reference of the public.
2. Please check the corresponding boxes in the "Encl." column if any document is enclosed under respective indexes of the submission folder.
3. Submitted documents not in Chinese or English shall be accompanied by Chinese or English translations.
4. Please check the boxes as appropriate.

Note	Part A: Particulars of Applicant			Encl.
1001	Name	*in English*	***Cardio A Company Limited***	(A1) ☒
		in Chinese	***N/A***	
	☒ Copy of business registration certificate (with business registration number: *12345678-000-01-09-4*) is enclosed.			
1002	Is the applicant a listed LRP? ☒ Yes and LRP Listing Number ***LRP9999*** ☐ No (please submit LRP application form MD-LRP)			
1003	Date designated as LRP by the manufacturer: ***2 February 2010*** The manufacturer's designation letter is enclosed.			(A1) ☒

	Part B: Particulars of the listed Medical Devices to be taken over			
2001	Listing Number(s) of medical device(s) to be taken over: ***040025, 040098***			
2002	Name of existing LRP of the listed device(s)	*in English*	***Cardio B Company Limited***	
		in Chinese	***N/A***	
2003	Special Listing Information: A sample of special listing information is enclosed.			(B1) ☒
	Part C: Undertakings for the taking over			
3001	☒ Agreement has been reached among the applicant, the existing LRP and the manufacturer for the taking over and the Transfer Form is enclosed.			(C1) ☒

Undertaking by Applicant

Date: ***26 March 2010***

To the Government of the Hong Kong Special Administrative Region (hereinafter "the Government"):

I/We have read the latest editions of the Guidance Notes GN-01 (with all appendices), GN-10 (with all appendices) and COP-01 issued by the Department of Health in relation to the Medical Device Administration Control System (MDACS) and the listing of Local Responsible Persons thereunder.

In consideration of the promise of the Government in the Guidance Notes GN-10 to proceed with the processing of this application under the MDACS, I/we ***Cardio A Company Limited, 23/F, 234 Hung To Road, Kwun Tong, Kowloon, Hong Kong*** [name and address of the Applicant], undertake, acknowledge and agree in favour of the Government as follows:

1. To the maximum extent permitted by law I/we agree to exempt, relieve, exonerate, indemnify and hold harmless, and to keep indemnified and harmless, as the case may be, the Government from and/or against any and all losses, claims, demands and proceedings (including but not limited to all costs, charges and expenses) whatsoever and howsoever suffered or incurred by, or made or issued against, the Government, as the case may be, by any third party in respect of any loss of or damage to any property or injury to or death of any person arising out of and/or relating and/or incidental to:
   a. any act, neglect or default on my/our part or on the part of my/our employees or agents;
   b. any defect in the design, material, workmanship or installation in relation to my/our medical device product or products;
   c. any use of any of the information supplied by me/us or my/our employees or agents in relation to this application or to my/our medical device product or products, whether or not such information has materially contributed to the inclusion of the applicant on the List of Local Responsible Persons or the inclusion of any of my/our product or products on the List of Medical Devices and whether or not such information is misleading, wrong or inaccurate.
6. I/We also agree and accept that:
   a. the Government, its employees or agents shall not be liable to me/us for any loss of or damage to property caused by the act, default or neglect of the Government or its employees or agents in the processing of my/our application, the inclusion or non-inclusion of any of my/our information and/or product or products on the Lists being maintained under the MDACS (including but not limited to the List of Local Responsible Persons and the List of Medical Devices) or any cause whatsoever arising out of or in connection with the implementation and management of the MDACS;
   b. neither the Government nor any of its employees or agents makes any representation, statement, warranty or guarantee, express or implied, that any of my/our products (including any spares or replacement parts), whether or not they are included on the List of Medical Devices, are of merchantable quality or are fit for the purposes for which they are commonly bought, used and/or applied and that the spares or replacement parts are readily available.
7. I/We undertake that the information contained in my/our application is true and correct and that my/our medical device product or products (including any spares or replacement parts) are of merchantable quality and are fit for the purposes for which they are commonly bought, used and/or applied.
8. I/We fully understand and agree that any future changes or additions to the requirements of the MDACS can be imposed by the Department of Health without prior notice. I/We hereby undertake to comply with the latest requirements of the MDACS that are in force.
9. I/We undertake that I/we have neither amended any wording in this form, nor otherwise altered the form in any material manner, apart from filling in the appropriate blanks / boxes.

Each of the provisions of this Undertaking is severable and distinct from the others and, if one or more of such provisions or any part thereof is or becomes illegal, invalid or unenforceable, the legality and enforceability of the remainder of this Undertaking shall not be affected or impaired in any way.

The Government shall be entitled to enforce any or all of its rights under this Undertaking.

This Undertaking shall be governed by and construed according to the laws of Hong Kong and the parties irrevocably submit to the non-exclusive jurisdiction of the Courts of Hong Kong.

As witness whereof, this Undertaking has been entered into the day, month and year first above written

SIGNED BY	)	
	)	
Cheung Mei-fong (name of Applicant or its representative*)	)	***<Signature of***
Manager (position)	)	***Cheung Mei-fong>***
	)	
[for and on behalf of	)	
	)	
Cardio A Company Limited (name of Applicant)	)	***<Company Chop of***
(who hereby warrant(s) that the signatory above has	)	***Cardio A Company***
the authority to bind the above firm and the partners	)	***Limited>***
therein for the time being / the above company* to	)	
this Undertaking)]#	)	
	)	
in the presence of	)	
	)	
Cheung Siu-fong (name)	)	***<Signature of***
	)	***Cheung Siu-fong>***
23/F, 234 Hung To Road, Kwun Tong, Kowloon (address)	)	

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Transfer Form for the Taking Over of the Listing of Medical Devices under the Medical Device Administrative Control System

We, the following parties (Party 1, Party 2 and Party 3),

Party 1

Name of applicant: ***Cardio A Company Limited***

Address: ***23/F, 234 Hung To Road, Kwun Tong, Kowloon, Hong Kong***

Party 2

Name of existing Local Responsible Person (LRP): ***Cardio B Company Limited***

Address: ***32/F, Metropolitan Centre, 123 Merry Street, Causeway Bay, Hong Kong***

Party 3

Name of manufacturer: ***ABC Medical Incorporation***

Address: ***1234N, Derby Road, Arlington, VA54321 USA***

hereby agree that:

1. The Local Responsible Person (LRP) of the following listed medical devices under the MDACS is to be changed from Party 2 to Party 1 with effect from the taking over date approved by the Director of Health, Hong Kong. The proposed taking over date is (dd/mm/yyyy) ***02/06/2010***.

Make	Model	Medical Device Listing No. (HKMD No.)
ABC Medical	***HeartAid PL3000***	***040025***
ABC Medical	***HeartAssist PX900***	***040098***

2. The applicant (Party 1) undertakes to (i) assume all the responsibilities and obligations of the existing LRP (Party 2) including pre-market and post-market requirements and activities related to the medical devices depicted in Section 1 above; and (ii) comply with all the requirements of being a Local Responsible Person of the related products under the Medical Device Administrative Control System.

3. The existing LRP (Party 2) undertakes to provide the applicant (Party 1) with all necessary support and information including distribution and maintenance records etc. required for taking up the LRP obligations of the devices depicted in Section 1. The existing LRP also undertakes that it will continue with all the LRP obligations of the related products until the taking over date approved by the Director of Health, Hong Kong.
4. The manufacturer (Party 3) undertakes to provide the applicant with all the necessary information and support so as to enable the applicant (Party 1) to fulfil its LRP obligations under the Medical Device Administrative Control System.

For and on behalf of the applicant (Party 1)

Signature: <***Signature of Cheung Mei-fong***> Date: ***3 February 2010***
Name: ***Cheung Mei-fong*** Company Chop: < ***Chop of Cardio***
Position: ***Manager*** ***A Company Limited***>
Company Name: ***Cardio A Company Limited***

For and on behalf of the existing LRP (Party 2)

Signature: <***Signature of Chan Tai-man***> Date: ***10 February 2010***
Name: ***Chan Tai-man*** Company Chop: < ***Chop of Cardio***
Position: ***General Manager*** ***B Company Limited***>
Company Name: ***Cardio B Company Limited***

For and on behalf of the manufacturer (Party 3)

Signature: <***Signature of John Smith***> Date: ***20 February 2010***
Name: ***John Smith***
Position: ***International Regulatory Affairs Manager***
Company name: ***ABC Medical Incorporation***