GN-02(2004 Edition)

醫療儀器的規管

Regulation of Medical Devices

Guidance Notes for Listing Class IV Medical Devices

Guidance Notes: GN-02 (2004 Edition)

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

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1. Introduction

This booklet is to provide guidance to applicants applying for inclusion of Class IV medical devices into the List of Medical Devices under the Medical Device Administrative Control System (MDACS). It provides detailed information to the applicants for preparing the application submission. Applicants should read this booklet in conjunction with the "Overview of Medical Device Administrative Control System (Guidance Notes GN-01)" to have a thorough understanding of the MDACS before making the submission. Applicants applying for listing medical devices of classes other than Class IV shall make reference to the corresponding Guidance Notes accordingly.

2. Definitions and Abbreviations

Please refer to Section 2 of Guidance Notes GN-01 for the definitions and abbreviations of the terms that appear in this document.

3. The Way to Determine if a Medical Device is a Class IV Medical Device

3.1 Classification of medical devices

By the classification rules of the MDACS (which are in line with those promulgated by the Global Harmonization Task Force), medical devices other than *in vitro* diagnostic medical devices are classified into four categories (Classes I to IV) according to their risk levels, Class IV being the category of the highest risk and Class I the lowest. The classification rules for defining the class of a medical device are given in Appendix 1 of Guidance Notes GN-01.

3.2 Determining Class IV devices by the Classification Rules

3.2.1 The Class IV medical devices could be determined by the classification rules 6, 7, 8, 13, 14 and 16 in Appendix 1 of Guidance Notes GN-01. The examples given in Table 1 illustrate the application of the rules to determine whether a medical device is of Class IV or not.

Table 1 – Examples of Class IV medical devices

Devices	Medical Device Class	Classification Rule
Angioplasty balloon catheter	IV	Rule 6
Neurological catheter	IV	Rule 7
Cardiovascular catheter	IV	Rule 7
Vascular stent	IV	Rule 8
Implantable pacemaker	IV	Rule 8
Breast implant	IV	Rule 8
Heparin-coated catheter	IV	Rule 13
Catgut suture	IV	Rule 14
Intrauterine contraceptive device	IV	Rule 16

3.2.2 Some examples shown in Table 2 are either not medical devices or not Class IV medical devices according to the classification rules.

Table 2 – Examples of not Class IV medical devices

Devices	Medical Device Class	Classification Rule
Urethral stent	III	Rule 5
Bone cement	III	Rule 8
Dental filling material	II	Rule 8
External non-invasive pacemaker	III	Rule 9
Syringe preloaded with vaccine/drug	N.A. (Medicinal Product)	Rule 13 not applicable (medicinal product not ancillary to the device)

4. Persons Eligible to Apply for the Inclusion of a Class IV Medical Device into The List of Medical Devices

Only the Local Responsible Person (LRP) in relation to the device can make the application. Please see Sections 3, 4 and 5 of the Guidance Notes GN-01 for the requirements and obligations of an LRP.

5. Application Procedures

5.1 Application form

All the application forms and guidance notes related to the MDACS can be obtained from the Medical Device Control Office (MDCO) or downloaded from the website http://www.dh.gov.hk. A sample of the Form MD-C4 for Class IV medical devices is given in Appendix 1.

5.2 Submission of applications (hardcopies)

An application for inclusion of a Class IV medical device into The List of Medical Devices must be made on the Form MD-C4. The completed form shall be submitted together with a submission folder containing copies of all the required documents indexed in accordance with the column "Encl." shown in the application form. *The originals of these documents are only required for validation when requested and they shall not be submitted together with the application form or enclosed in the submission folder.* The application form and all documents submitted including enclosures in the submission folder will not be returned. The submission shall be made by hand or by recorded delivery mail to the MDCO.

5.3 Submission of applications (softcopies)

The applicants are encouraged to use softcopies in CD-ROM format for making the application submission as far as possible. If softcopies are used, only the duly signed Application Form MD-C4 and Essential Principles Conformity Checklist (Form MD-CCL) have to be submitted in paper format. The signed forms, together with duplicated copies of other required documents recorded in two separate CD-ROMs, shall be submitted by hand or by recorded delivery mail to the MDCO. Alternatively, an applicant with Hongkong Post e-Cert may submit an application entirely by softcopies (both the completed forms and the other documents in softcopies) to the email address *mdco_app@dh.gov.hk* of the MDCO, provided the total file size of these softcopies is less than 5MB.

5.4 Acknowledgement of Application

On receiving an application the MDCO will acknowledge the receipt of it. If an applicant does not receive the acknowledgement within 2 weeks after sending in an application, he may contact the MDCO to check if the submission has reached the MDCO.

6. Guide to Application Form MD-C4

The following table explains how to fill in the application form MD-C4 for Class IV medical devices. Given in Appendix 1 is a sample of a completed form MD-C4. The number under the leftmost column "Note" in the form is used as an identifier for the notes given below (Table 3), while the rightmost column "Encl." indicates the indexes in the submission folder where the required documents shall be enclosed. Under an item in the form where more than one box is applicable, all the applicable boxes should be selected and checked and all the related documents should be provided. 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 recorded accordingly for the reference of the public.

Table 3 – Guidance for Completing the Application Form MD-C4

Note	Explanation
0001	♦ The make and model of the device shall be specified in English and/or Chinese and they will be used as the identifier of the device. This information is considered essential for the application.
1001	♦ Particulars of the manufacturer including the name (in English and/or Chinese), address of head office (in English and/or Chinese), post code, country, contact person, telephone number, fax number, email address and the website shall be provided. This information is considered essential for the application.
1002	♦ If the manufacturer has a registered place of business in Hong Kong, both boxes shall be checked with a copy of the business registration enclosed under index (A1) in the submission folder. The contact person, telephone number, fax number and email address of the Hong Kong office shall be provided.
1003	♦ If the manufacturer has implemented a quality management system, the appropriate box shall be checked to indicate whether it is a full quality management system or a partial system. If it is a partial system, the processes covered shall be specified. The boxes corresponding to the relevant standards and, where appropriate, the box corresponding to the item on certification body of the quality management system shall also be checked, and a copy of the certificate(s) issued by the certification body shall be enclosed under index (A2) in the submission folder. This information is considered essential for the application.
1004	♦ If the manufacturer has any recall system or device tracking mechanism, the appropriate box shall be checked. ♦ Copies of the documented procedures for tracking of specific medical device (if applicable) and managing recalls shall be enclosed under index (A3) in the submission folder.
1005	♦ The Local Responsible Person (LRP) must either be a legal person incorporated in Hong Kong or a natural or legal person with a registered place of business in Hong Kong e.g. a company, a solicitor firm. ♦ If the manufacturer has a registered place of business in Hong Kong, it could decide either to be the LRP by itself or to designate another body to be the LRP. If the manufacturer has no registered place of business in Hong Kong, it must designate another body meeting the requirements of an LRP to make the application.
2001	♦ The details of the LRP including the name (in English and/or Chinese), address (in English and/or Chinese), contact person, telephone numbers, fax number and email address shall be provided. The details must include, among other things, a telephone number that the public may call for enquiries, as well as a telephone number through which the LRP may be contacted by the MDCO after office hours. ♦ A copy of the Hong Kong business registration, if any, shall be enclosed under index (B1) of the submission folder.
2002	♦ The date of designation as the LRP of the device shall be quoted and a copy of the corresponding letter issued by the manufacturer shall be enclosed under index (B2) of the submission folder. This information is considered essential for the application.
2003	♦ If the LRP has implemented any quality management system, the system and the certification body shall be specified. A copy of the certificate of the quality management system shall be enclosed under index (B3) of the submission folder.
2004	♦ If the LRP has developed documented procedures (no matter under the quality management system or not) for distribution records; complaints handling;

	maintenance and service arrangements; tracking of specific medical devices (see paragraph 4.4.6 and Appendix 4 of Guidance Notes GN-01); recalls; alerts and modifications; and/or reportable adverse incidents in Hong Kong, the corresponding boxes shall be checked. This information is considered essential for the application. ♦ Copies of the documented procedures for tracking of specific medical device (if applicable) and managing recalls shall be enclosed under index (B4) of the submission folder. This information is considered essential for the application.
2005	♦ If the LRP is also an importer of the device, the box shall be checked.
2006	♦ If, to the knowledge of the LRP, the device has already been listed (albeit with another LRP), the box shall be checked with the known existing Listing Number of the device given.
3001	♦ One application shall be made for either a single device or a family of devices. If it is for a family of devices, the devices shall be of the same series and have the same intended use, design, construction and performance e.g. catheters of different diameters and lengths. Separate applications for each device shall be made if they do not meet the criteria of a family of devices. ♦ The appropriate box shall be checked to indicate whether the application is for a single device or a family of devices. In the latter case, for each member of the family, please provide its identifier(s) (e.g. product number), a brief account of its characteristics that distinguish it from other members (e.g. dimensions of its various parts), and, if any, its Universal Product Number. When needed, such details could be provided on a separate sheet enclosed under index (C1) of the submission folder.
3002	♦ The make and model of the device or the device family shall be specified. They shall be the same as the device under Note 0001.
3003	♦ If the device has other identifiers (including any Universal Product Number), these shall be specified.
3004	♦ The Global Medical Device Nomenclature (GMDN) (ISO/TS 20225:2001 or its latest version) description of the device together with the corresponding GMDN code shall be specified. If there is no applicable GMDN description, a short description of the device shall be entered. A copy of the GMDN is available at the MDCO for reference by applicants. Due to contract restrictions, no lending or photocopying service of the GMDN is available.
3005	♦ If there is any commonly used description of the device, it shall also be provided.
3006	♦ The intended use of the device shall be specified in English and Chinese and it shall be in agreement with the information provided in the labelling and the marketing approvals obtained from the GHTF founding members.
3007	♦ All accessories for the device shall be specified. ♦ When needed, the details of all the accessories of a device including their identifier(s) (e.g. part number), descriptions and, if any, Universal Product Numbers could be provided on a separate sheet enclosed under index (C1) of the submission folder.
3008	♦ Universal Product Numbers of the accessories, if any, shall be provided.
3009	♦ The reasons for classifying the device as a Class IV medical device shall be provided. The applicant shall refer to Appendix 1 under the Guidance Notes GN-01 for the Classification Rules for Medical Devices.
3010	♦ All the manufacturing sites for the medical device under this application shall be specified. Those manufacturing sites of the same manufacturer but not used for the production of the device to be marketed in Hong Kong need not be quoted.
3011	♦ If there is any history of the device related to recalls, reportable adverse incidents, banning of the device in other countries or post-market surveillance studies, the details of the events shall be provided under index (C2) of the

	submission folder. ♦ Where there are any recalls in progress or completed, details and current status of the recalls shall be provided. ♦ Where there are any reportable adverse incidents involving the same device or a design so close to the device, the following information shall be provided: i. Dates of the incidents; ii. To which regulatory agencies, and when, the incidents were reported; iii. Causes of the incidents; iv. Number of deaths and the serious injuries in these incidents; and v. Corrective actions taken (including those taken to prevent recurrence of similar incidents). ♦ Where there is any banning of the device, the dates, causes and related regulatory agents shall be provided. ♦ Where there are any proactive post-market surveillance studies conducted, details and results of those studies shall be provided.
3012	♦ If the device is for single use, supplied as sterile product, or requires special precautions for disposal, the appropriate boxes shall be checked. The information shall be identical to the specifications in the labelling.
3013	♦ If the device is non-repairable, the appropriate box shall be checked. ♦ If the device requires regular servicing, testing, checking or calibration, the appropriate box shall be checked. ♦ Where there is no repair or servicing provided, the appropriate box shall be checked. ♦ Where repairs and servicing are provided by the LRP or other parties appointed, please specify whether all or only some of the services are performed in Hong Kong. ♦ If technical support from the manufacturer is provided, the appropriate box shall be checked. ♦ This information is considered essential for the application.
3014	♦ If the instructions for use are available in either English, Chinese, or both languages, the appropriate boxes shall be checked. ♦ All labelling samples including instructions and manuals as specified under Appendix 3 of Guidance Notes GN-01 shall be submitted under index (C3) of the submission folder. Where the labelling is provided on the packaging and there is no separate instruction manual, the packaging or a photograph showing all the labelling information is acceptable as an alternative. ♦ The locations in the labelling samples where the Indications for use; Contraindications against use; Cleansing, disinfection and/or sterilization; User precautions; and Disposal precautions shall be quoted in the appropriate space.
3015	♦ If the device complies with any international or national standards, the standards shall be specified in the space provided. ♦ Where there are any type tests performed by the manufacturer or any other party, the test reports and certificates shall be provided under index (C4) of the submission folder. ♦ There shall be a risk analysis conducted and the report or the summary shall be provided under index (C4) of the submission folder. This information is essential for the application.
3016	♦ Clinical evaluation is the review of relevant scientific literature and/or the review and assessment of data collected through clinical investigation. It is a process to establish conformity of the device with the pertinent Essential Principles and to demonstrate that the device performs as intended by the manufacturer. It establishes the acceptability of risks and side effects when weighed against the intended benefits of the device. ♦ If clinical data/studies **not** directly referring to the medical device are used in

	clinical evaluation, equivalence of the concerned device to the device(s) to which clinical data/studies relate must be demonstrated and the applicability of the clinical data/studies must be shown in the clinical evaluation report. The appropriate box shall be checked. The make(s), model(s) and description(s) of the device(s) for which equivalence is claimed shall be provided and the bibliography of relevant references from Index Medicus shall be submitted under index (C5) of the submission folder. The clinical evaluation report shall be provided upon request. ♦ If clinical data/studies that refer directly to the medical device are used in clinical evaluation, the appropriate box shall be checked, and the bibliography of relevant references from Index Medicus shall be provided under index (C5) of the submission folder. The clinical evaluation report shall be provided upon request. However, if the clinical evaluation is not based on any published scientific/clinical literature (e.g. solely on the results of clinical investigations), the clinical evaluation report shall be provided.
4001	♦ If there are approvals for the device to be marketed in any of the GHTF founding members namely Australia, Canada, the European Union, Japan and the USA, the appropriate boxes shall be checked and the approval documents shall be provided under index (D1) of the submission folder. ♦ Where any of these approvals have been obtained on or before 31 December 2004, submission of the Essential Principles Conformity Checklist (Form MD-CCL) is not required. ♦ Where all the approvals are obtained on or after 1 January 2005, the duly completed Essential Principles Conformity Checklist (Form MD-CCL) shall also be provided under index (D1) of the submission folder. ♦ Where no such approval has been obtained, the application will not be processed until a list of acceptable Conformity Assessment Bodies (CAB) for the MDACS has been promulgated by the Department of Health.

7. Enquiries

Enquiries concerning this booklet and the Medical Device Administrative Control System 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

8. References

[1] Department of Health. Overview of the Medical Device Administrative Control System. Guidance Notes GN-01 (2004 Edition).

Medical Device Control Office
Department of Health

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

For official use only

Date Received: _____ *Application No.:* _____ *Officer:* _____
Date Approved/Rejected: _____ *Listing No.:* _____
Tracking Required: ____Y / N____ *PMS Report Required:* ____Y / N____
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 Medical Devices if this application is approved. They include (i) the make and model of the device (0001), (ii) the manufacturer's name, address of its head office and its website (1001), (iii) the LRP's name, address in Hong Kong, and contact telephone number for public enquiries (2001), and (iv) the intended use of the device (3006). The details will normally appear on The List of Medical Devices 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 Medical Devices 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	Application for the Listing of the following Class IV Medical Device:			Encl.
0001	Make*	*in English*	*ABC Medical*	
		in Chinese	*N.A.*	
	Model*	*in English*	*HeartAid*	
		in Chinese	*N.A.*	

	Part A: Particulars of Manufacturer			
1001	Manufacturer's name*	*in English*	*ABC Medical Ltd.*	
		in Chinese	*N.A.*	
	Address of Head Office*:	*in English*	*1324N. Derby Road, Arlington VA, USA*	
		in Chinese	*N.A.*	
	Post Code: *VA 12345-6789*		Country: *USA*	
	Contact person: *John Smith*		Telephone: *800.332.2354*	
	Fax: *703.276.0314*		E-mail: *jsmith@abcmed.com*	
	Website*: *http://www.abcmedical.com*			
1002	☐ Registered place of business in Hong Kong:			(A1) ☐
	☐ Copy of business registration certificate (with business registration number _____) is enclosed			
	Contact person:		Telephone:	
	Fax:		E-mail:	
1003	Established Quality Management System ☒ Full quality management system covering device design, production, and post-production processes ☐ Partial quality management system covering processes: _____ Standards with which the system complies: ☐ ISO9001:2000 ☐ ISO13485:1996 ☒ ISO13485:2003 ☒ GMP ☐ Others _____ (please specify) ☒ System certified by *CAB Systems Ltd* (certification body), and a copy of the certificate is enclosed			(A2) ☒
1004	Established Recall & Tracking System ☒ Distribution records ☒ Complaint handling ☒ Tracking of specific medical devices (procedures to be provided if applicable) ☒ Recalls (procedures to be provided) ☒ Alerts and modifications ☒ Reportable adverse incidents in Hong Kong			(A3) ☒
1005	Has the manufacturer designated any Local Responsible Person (LRP)? *(N.B. If the manufacturer has no registered place of business in Hong Kong, it must designate a legal person incorporated in Hong Kong or a natural or legal person with a registered place of business in Hong Kong as the LRP.)* ☒ Yes ☐ No, manufacturer itself acts as the LRP			

	Part B: Particulars of Local Responsible Person (LRP)			
2001	LRP's name*	*in English*	*CARDIO SUPPLIES LTD.*	(B1) ☒
		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*	
		in Chinese	*香港銅鑼灣喜樂街123號都市中心32樓*	
	Contact person: *CHAN TAI-MAN*		Telephone: *2800 0000*	
	Fax: *2900 0000*		E-mail: tchan@cardio.com.hk	
	Contact telephone for public enquiries (if different from the number given above)*: *2000 0000*			
	Contact telephone after office hours: *9000 0000*			
	☒ Copy of business registration certificate (with business registration number: *BR123467*) is enclosed			
2002	Date designated as LRP by the manufacturer: *31 December 2004* ☒ Manufacturer's designation letter is enclosed			(B2) ☒
2003	Established Quality Management System ☒ ISO9001:2000 ☐ ISO13485:1996 ☐ ISO13485:2003 ☐ none ☐ Others _____ ☒ System certified by *ABC Agency* (certification body), and a copy of the certificate is enclosed			(B3) ☒
2004	Documented Procedures Established ☒ Distribution records ☒ Complaint handling ☒ Maintenance and service arrangements ☒ Tracking of specific medical devices (procedures to be provided if applicable) ☒ Recalls (procedures to be provided) ☒ Alerts and modifications ☒ Reportable adverse incidents in Hong Kong			(B4) ☒
2005	☒ The LRP is also an importer of the device named in Part C			
2006	☐ The device named in Part C is currently a listed device (under another LRP), with Listing No._____.			

	Part C: Particulars of the Device			
3001	☒ A single device or ☐ A family of devices. For each member of the family, please provide its identifier(s) (e.g. product number), a brief account of its characteristics that distinguish it from other members (e.g. dimensions of its various parts), and, if any, its Universal Product Number (use separate sheet if required): _____ _____			(C1) ☐
3002	Make: *ABC Medical*		Model: *HeartAid*	
3003	Universal Product Number (if any): *4898118900000*			
	Other identifiers (if any) of the device: *PN: PL3000*			
3004	Description of the device: *(Please enter the appropriate GMDN description. If none of the descriptions in GMDN appear appropriate, enter a short description of the device.)* *PACEMAKER, CARDIAC, IMPLANTABLE*			
	GMDN Code: *(Please enter if known)* *12913*			
3005	Other common descriptions of the device: *IMPLANTABLE PACEMAKER*			
3006	Intended use of the device*	*in English*	*A single chamber pacemaker intended to treat bradyarrhythmias. It monitors the electrical impulses in the heart and, when needed, delivers electrical stimuli to make the heart beat in a normal rhythm.*	
		in Chinese	*擬用以治療過緩性心律失常的單心室起博器。此儀器監察心臟的電脈動，並在有需要時施加電刺激，以令心跳的節律正常。*	
3007	Accessories *(For each accessory, please provide its identifier(s) (e.g. part number), description and, if any, Universal Product Number. Use separate sheet if required)*: *(1) Unipolar pacing leads – PN: PL3024* *(2) Unipolar pacing leads – PN: PL3025*			(C1) ☐
3008	Universal Product Numbers (if any) of the accessories: *Nil*			
3009	Reasons for classifying the device as Class IV device: *It is an active implantable device (Rule 8)*			
3010	Manufacturing sites: *(1) 1324N, Derby Road, Arlington, VA 12345-6789, USA* *(2) 1000 Butler Road, Plymouth Place, PA 12486-1248, USA*			

3011	History ☐ No previous recalls, reportable adverse incidents, banning in other countries or post-market surveillance studies ☒ Yes (Please tick the appropriate boxes and provide details): ☐ Recalls completed or in progress ☐ Any reportable adverse incidents bearing implications to the device ☐ The device banned previously in other countries ☒ Proactive post-market surveillance studies	(C2) ☒
3012	Usage ☒ The device is for single use ☒ The device is supplied as sterile product ☐ Disposal of used device or any part thereof (including any used accessories or consumables) requires special precautions.	
3013	Repair & Servicing ☒ The device is non-repairable ☒ The device requires regular servicing/testing/checking/calibration ☐ Repairs and servicing not provided ☒ Repairs and servicing provided by the LRP or appointed party in Hong Kong ☐ All repairs and servicing performed in Hong Kong ☒ Part of the repairs and servicing performed in Hong Kong ☒ Technical support provided by the manufacturer	
3014	Labelling Requirements Instructions for use are available: ☒ in English ☒ in Chinese ☒ Labelling samples are enclosed. Please indicate where in the samples the following information is given: (1) Indications for use of the device: *Pages 4 – 8 of the instructions for use* (2) Contraindications against use of the device: *Pages 9 – 11 of the instructions for use* (3) Cleaning, disinfection and/or sterilization procedures: *N. A* (4) User precautions: *Pages 24 – 28 of the instructions for use* (5) Disposal precautions: *Page 29 of the instructions for use*	(C3) ☒
3015	Performance and Safety International or national standards with which the device complies: *(1) ISO 5841-1:1989; (2) ANSI/AAMI PC69:2000; and (3) IEC 60601-1:1998+ A1:1991+A2:1995* ☒ Type test performed: report or test certificate is enclosed ☒ Risk analysis conducted: report or summary is enclosed	(C4) ☒
3016	Clinical Evaluation ☒ Clinical evaluation of the device is based on clinical data/studies on the following device(s) to which equivalence of the device is claimed, and the bibliography of references from the Index Medicus is attached (clinical evaluation report shall be submitted upon request): *"PM Technology / PM II" pacemaker, cardiac, implantable* ☐ Clinical evaluation of the device is based on clinical data/studies that refer directly to the device ☐ The bibliography of references relevant to the device from the Index Medicus is attached; OR ☐ The clinical evaluation report is attached	(C5) ☒

	Part D: Marketing Approvals and Essential Principles	
4001	Marketing Approvals in Foreign Countries ☒ Approval obtained for the medical device to be placed on the market of the following countries: ☐ Australia (The Therapeutic Goods Administration) ☐ Canada (Health Canada) ☒ Member countries of European Union that have implemented the European Council Directives 90/385/EEC and 93/42/EEC ☐ Japan (Ministry of Health, Labour and Welfare) ☒ United States of America (U.S. Food and Drug Administration) ☐ Earliest approval obtained on or before 31 December 2004 ☒ Earliest approval obtained on or after 1 January 2005 ☒ Essential Principles Conformity Checklist MD-CCL is attached	(D1) ☒

DECLARATION

1. To the maximum extent permitted by law and in consideration of the Department of Health of the Government of the Hong Kong Special Administrative Region ("the Government") processing our application under the MDACS, we, *CARDIO SUPPLIES LTD., 32/F., METROPOLITAN CENTRE, 123 MERRY STREET, CAUSEWAY BAY* *[name and address of the Applicant]*, 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 our part or on the part of our employees or agents;
   b. any defect in the design, material, workmanship or installation of our device or devices;
   c. any use of any of the information supplied by us or our employees or agents in relation to our device or devices whether or not such information has materially contributed to the inclusion of the device or devices on the List of Medical Devices and whether or not such information is misleading, wrong or inaccurate.
2. We also agree and accept that:
   a. the Government, its employees or agents shall not be liable to 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 our application, the inclusion or non-inclusion of any of our information and/or device or devices on 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 the devices (including any spares or replacement parts) listed or considered for listing under the MDACS, whether or not they are included in the List of Medical Devices, are of merchantable quality or are fit for the purposes for which they are commonly bought and that the spares or replacement parts are readily available.
3. We confirm that the information contained in our application is true and correct and that our device or devices (including any spares or replacement parts) are of merchantable quality and are fit for the purposes for which they are commonly bought.
4. We fully understand and agree that any future changes or additions to the requirements of the Medical Device Administrative Control System (MDACS) can be imposed by the Department of Health without prior notice. We hereby undertake to comply with the latest requirements of the MDACS that are in force. It is one of the current requirements of the MDACS that the LRP will, within two weeks after receiving the request from the Department of Health, produce the originals or certified copies of the documents that, according to the claims in this submission, are within the possession of the LRP or the manufacturer.
5. We confirm that 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.

Signature: _____
Name: *CHAN TAI-MAN*
Position: *GENERAL MANAGER*
Contact telephone number: *2800 0000*
The Applicant (Local Responsible Person): *CARDIO SUPPLIES LTD*
Date: *3 January 2005*

Personal Data (Privacy) Ordinance

Statement of Purposes

1. Purpose of Collection

The personal data that are provided by you with whom the Department of Health (DH) interacts in connection with the Medical Device Administrative Control System (MDACS) will be used by the DH for the management and implementation of the MDACS.

2. Classes of Transferees

The personal data you provide are mainly for use within the DH but they may also be disclosed to other Government bureaux/departments or relevant parties for the purpose mentioned in para. 1 above, and related matters if required. 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 concerning the personal data provided, including the making of access and corrections, should be addressed to the Medical Device Control Office, Department of Health (18/F., Wu Chung House, 213 Queen's Road East, Wanchai, Hong Kong; fascimile number: 3157 1286; telephone number: 2961 8788). Please quote your application number when submitting the request.

Essential Principles Conformity Checklist

Medical Device Control Office
Department of Health
Medical Device Administrative Control System

Make: *ABC Medical*
Model: *HeartAid*

Clause	Essential Principle	Applicable	Method of Conformity	Identity of Specific Documents
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.	*Yes*	*1. The devices are designed and manufactured under a full quality management system in accordance with ISO 13485 and presently certified* *2. The implantable cardiac pacemaker is tested to comply with ISO 5841-1 standard.* *3. Risk analysis has been performed in accordance with ISO 14971. Together with the proactive surveillance studies, it shows that any risks which may be associated with the devices are acceptable when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.*	*1. ISO 13485 Certificate No. 012345* *2. Type Test Certificate No. 123456 compliant with ISO 5841-1 standard.* *3. Proactive Surveillance Report PSR-001* *4. Risk Analysis Report RAR-001*

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 risks so that the residual risks 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.	*Yes*	*- Ditto -*	*- Ditto -*
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.	*Yes*	*- Ditto -*	*- Ditto -*
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.	*Yes*	*- Ditto -*	*- Ditto -*
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.	*Yes*	*- Ditto -*	*- Ditto -*
6.	The benefits must be determined to outweigh any undesirable side effects for the performances intended.	*Yes*	*- Ditto -*	*- Ditto -*

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.	*Yes*	*The materials used to manufacture the device have been subject to biological evaluation in accordance with ISO 10993 standards.*	*Biological Evaluation Test Report No. 012345*
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.	*Yes*	*1. The materials used to manufacture the device have been subject to biological evaluation in accordance with ISO 10993 standards.* *2. The devices are packaged in accordance with a system in compliance with ISO 11607.*	*Biological Evaluation Test Report No. 012345*
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.	*Yes*	*1. The materials used to manufacture the device have been subject to biological evaluation in accordance with ISO 10993 standards.* *2. Risk analysis has been performed in accordance with ISO 14971.*	*1. Biological Evaluation Test Report No. 012345* *2. Risk Analysis Report RAR-001*
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.	*No*	*Not applicable*	*Not applicable*
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.	*Yes*	*1. The materials used to manufacture the device have been subject to biological evaluation in accordance with ISO 10993 standards.* *2. Risk analysis has been performed in accordance with ISO 14971.*	*1. Biological Evaluation Test Report No. 012345* *2. Risk Analysis Report RAR-001*

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.	*Yes*	*Risk analysis has been performed in accordance with ISO 14971.*	*Risk Analysis Report RAR-001*
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.	*Yes*	*1. The devices are produced under strictly controlled conditions to minimize contamination. The devices are sterilized using EtO. The methods of sterilization and process control of sterilization are in conformance with ISO 11135.* *2. Risk analysis has been performed in accordance with ISO 14971.* 3. *The devices are packaged in accordance with a system in compliance with ISO 11607.*	*Risk Analysis Report RAR-001*
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.	*No*	*Not applicable*	*Not applicable*
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.	*No*	*Not applicable*	*Not applicable*
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.	*No*	*Not applicable*	*Not applicable*

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.	*Yes*	*1. The devices are produced under strictly controlled conditions to minimize contamination. The devices are sterilized using EtO. The methods of sterilization and process control of sterilization are in conformance with ISO 11135.* *2. Risk analysis has been performed in accordance with ISO 14971.* 3. *The devices are packaged in accordance with a system in compliance with ISO 11607.*	*Risk Analysis Report RAR-001*
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.	*Yes*	*-Ditto-*	*Risk Analysis Report RAR-001*
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.	*Yes*	*The devices are sterilized using EtO. The methods of sterilization and process control of sterilization are in conformance with ISO 11135.*	
8.8	Devices intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.	*Yes*	*The devices are sterilized in conditions tightly controlled under the Quality Management System that governs the entire manufacturing process. The environments are in compliance with ISO 14644 standard.*	*Clean Room Certificate No. 012345*
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.	*No*	*Not applicable*	*Not applicable*
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.	*No*	*Not applicable*	*Not applicable*
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.	*No*	*Not applicable*	*Not applicable*

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.	*Yes*	*1. The device is tested to comply with ISO 5841-1.* *2. Risk analysis has been performed in accordance with ISO 14971.*	*1. Type Test Certificate No. 123456 compliant with ISO 5841-1.* *2. Risk Analysis Report RAR-001*
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.	*Yes*	*- Ditto -*	*- Ditto -*
9.4	Devices must be designed and manufactured in such a way as to facilitate the safe disposal of any waste substances.	*No*	*Not applicable*	*Not applicable*
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.	*No*	*Not applicable*	*Not applicable*
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.	*No*	*Not applicable*	*Not applicable*
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.	*No*	*Not applicable*	*Not applicable*

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.	*No*	*Not applicable*	*Not applicable*
10.5	Wherever possible values expressed numerically should be in commonly accepted, standardised units, and understood by the users of the device.	*No*	*Not applicable*	*Not applicable*
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.	*No*	*Not applicable*	*Not applicable*
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.	*No*	*Not applicable*	*Not applicable*
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.	*No*	*Not applicable*	*Not applicable*
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.	*No*	*Not applicable*	*Not applicable*
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.	*No*	*Not applicable*	*Not applicable*
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.	*No*	*Not applicable*	*Not applicable*
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.	*No*	*Not applicable*	*Not applicable*

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.\	*No*	*Not applicable*	*Not applicable*
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.	*Yes*	*1. The devices are designed and manufactured under a full quality management system in accordance with ISO 13485 and presently certified* *2. The device is tested to comply with ISO 5841-1 standard.* 3. *Risk analysis has been performed in accordance with ISO 14971.*	*1. ISO 13485 Certificate No. 012345* *2. Type Test Certificate No. 123456 compliant with ISO 5841-1 standard.* 3. *Risk Analysis Report RAR-001*
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.	*Yes*	*The device is tested to comply with ISO 5841-1 standard.*	*Type Test Certificate No. 123456 compliant with ISO 5841-1 standard*
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.	*No*	*Not applicable*	*Not applicable*
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.	*No*	*Not applicable*	*Not applicable*
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.	*Yes*	*1. The device is tested to comply with ISO 5841-1 standard.* 2. *The device is tested to comply with ANSI/AAMI PC69:2000 standard.*	*1. Type Test Certificate No. 123456 compliant with ISO 5841-1 standard.* 2. *Type Test Certificate No. 123457 compliant with ANSI/AAMI PC69:2000 standard.*
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.	*Yes*	*- Ditto -*	*- Ditto -*
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.	*Yes*	*The device is tested to comply with ISO 5841-1 and IEC 60601-1 standards.*	*1. Type Test Certificate No. 123456 compliant with ISO 5841-1 standard.* *2. Type Test Certificate No. 123458 compliant with IEC 60601-1 standard.*

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.	*No*	*Not applicable*	*Not applicable*
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.	*No*	*Not applicable*	*Not applicable*
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.	*No*	*Not applicable*	*Not applicable*
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.	*No*	*Not applicable*	*Not applicable*
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.	*No*	*Not applicable*	*Not applicable*
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.	*Yes*	*1. The devices are designed and manufactured under a full quality management system in accordance with ISO 13485 and presently certified* *2. The device is tested to comply with ISO 5841-1 standard.* 3. *Risk analysis has been performed in accordance with ISO 14971.*	*1. 13485 Certificate No. 012345* *2. Type Test Certificate No. 123456 compliant with ISO 5841-1 standard.* 3. *Risk Analysis Report RAR-001*
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.	*Yes*	*1. The devices are designed and manufactured under a full quality management system in accordance with ISO 13485 and presently certified* *2. The device is tested to comply with ISO 5841-1 standard.* 3. *Risk analysis has been performed in accordance with ISO 14971.*	*1. 13485 Certificate No. 012345* *2. Type Test Certificate No. 123456 compliant with ISO 5841-1 standard.* 3. *Risk Analysis Report RAR-001*

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.	*No*	*Not applicable*	*Not applicable*
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.	*No*	*Not applicable*	*Not applicable*
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.	*No*	*Not applicable*	*Not applicable*
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.	*No*	*Not applicable*	*Not applicable*
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.	*Yes*	*The information supplied with the device complies with the labelling requirements specified under Appendix 3 of Guidance Notes GN-01.*	*Labels and instructions for use enclosed under index (C3) of the submission folder*
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.	*No*	*Not applicable*	*Not applicable*
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.	*No*	*Not applicable*	*Not applicable*

I confirm that I have neither amended the wording in this form, nor otherwise altered the form in any material manner, apart from filling in the blanks.

I declare that the information provided in this form is accurate and correct and the device conforms to all the applicable requirements stipulated above.

Signature: _____
Name: *CHAN TAI-MAN*
Position: *GENERAL MANAGER*
The Applicant (Local Responsible Person): *CARDIO SUPPLIES LTD*
Date: *3 January 2005*