A Sample of the Completed Essential Principles Conformity Checklist MD-CCL

For a medical device to be listed, the Local Responsible Person, with support from the manufacturer, is responsible for demonstrating that the device conforms to the *Essential Principles of Safety and Performance of Medical Devices*, as well as the *Medical Device Labelling Requirements* (please refer to the corresponding articles).

Please take note that in your application for listing of Class IV Medical Devices, 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, while all of these approvals are obtained on or after 1 January 2005, the duly completed Essential Principles Conformity Checklist (Form MD-CCL, a sample of which is shown below) should be provided in your application submission folder. If any of these approvals have been obtained on or before 31 December 2004, submission of the Form MD-CCL is not required.

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*

Reference:

Department of Health. Overview of the Medical Device Administrative Control System. Guidance Notes GN-01 (2004 Edition), Section 3.4.

Department of Health. Guidance Notes for Listing Class IV Medical Devices. Guidance Notes GN-02 (2004 Edition), Section 6 and Appendix 2.

For more information

For more information regarding application for listing of Class IV medical devices, please do not hesitate to contact the Medical Device Control Office with the following contact information:

Medical Device Control Office, Department of Health,
Government of the Hong Kong Special Administrative Region,
18/F, Wu Chung House,
213 Queen's Road East,
Wan Chai, Hong Kong.
Tel: 2961 8788
Fax: 3157 1286
Email: mdco@dh.gov.hk
Website address: http://www.mdco.gov.hk/

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