1.0 Design of New Products or re-design of existing products

1.1 Final responsibility for product design or modification lies with the Managing Director; and no new design or modification of an existing design may be released to production without authority from him, or from his designated representative. .

1.2 All new products must carry the CE mark and comply with all relevant requirements, including EMC testing where appropriate.

1.3 Design of all medical products must comply with BS EN60601 (BS5724), IEC 601/1 (to include pt.II where existing) and shall be in accord with any current and relevant Council Directive (MDD Essential Requirements & CMD extra requirements).

1.4 Classification of products will follow the rules and principles of MDD Annex 9. & CMD extra requirements

2.0 General Requirements:

2.1 Products must be designed and manufactured in such a way as to ensure that they cannot compromise the clinical condition or safety of patients, or the safety and health of their operators.

2.2 Products must conform to current □ tate-of-the artsafety principles and legislation, including the provision of alarms when deemed necessary.

2.3 User operated controls shall be adequate, accessible and clearly identified.

2.4 Products must, throughout their design lifetime, under any reasonable environmental and climatic condition, and under the stress of normal use, always achieve the performance intended and specified. Components, materials, assembly methods and test procedures should be specified with this intention.

2.5 Product characteristics and performances must not be adversely affected by transport or storage.

2.6 Any undesirable side-effect must constitute an acceptable risk when measured against product performance and benefit to the patient. Acceptability will be determined on the basis of both clinical and legal advice. Where any residual risk to either patient or operator is identified, it will be clearly notified to the user.

2.7 Risk assessments to be carried out at important stages in accordance with ISO 14971 Annexe A & B using format used in CE files

3.0 Medical Design and Construction Requirements

3.1 The choice of design materials will be determined by environmental and ergonomic considerations; and must, where appropriate, be compatible with any biological tissue, cells, body-fluids and other materials with which they will come into contact.

3.2 Products will be designed in such a way that any risk of infection or microbial contamination is minimal. Any tissue of animal origin must derive from animals that have been subject to vetinary controls and safe-guarded from viral contamination.

3.3 Devices which must be used sterile must be manufactured and sterilised by a validated method and packed in a non re-usable pack. Those devices which are not sterile must be packaged in such a way that they are kept at a stipulated level of cleanliness. For identical products sold in both sterile and non-sterile states, the packaging and/or label of the device must distinguish between these. Packaging must keep the device in the appropriate condition until use or opening.

3.4 Devices must be designed to minimise or eliminate risks associated with physical features pressure, weight, environmental conditions magnetic fields, temperature, reciprocal interference with other devices, deterioration, fire and explosion.

3.5 Combination of devices to be used together must be safe and not impair each others performance.

3.6 Devices that have a measuring function should be ergonomically designed and manufactured so as to provide satisfactory accuracy and stability, the limits of which will be specified by the manufacturer The units of the measurements must conform to the provisions of Directive 80/181/EEC. or any later applicable EEC directive.

3.7 Any device intended to emit radiation shall be designed and manufactured to minimise exposure to patients and users consistent with its function. The level of output must be controllable with adequate warnings and instructions for use.

3.8 Information provided with the device will be clear and in the form of a label and instructions for use, if possible on the device itself and/or the packaging. In order to standardise the instructions, they should, if possible, be in the form of harmonised symbols or colours (e.g. EN 980, EN 1041

4.0 Labelling.

4.1 The label must show information in accordance with the requirements of the current MDD.& CMD extra requirements

5.0 Instructions.

5.1 Instructions must contain information in accordance with the requirements of the current MDD.& CMD extra requirements And be marked with the CE symbol

6.0 Technical Documentation.

Technical documentation is required in a special format for CE marking as follows:-

6.1 EC Declaration of Conformance

An EC Declaration of Conformance will be provided for every new or redesigned product.

6.2 Technical File Summary

This is a summary of the main files for submission to EU notified bodies on request:-
EC Declaration of Conformance
Checklist of the MDD Essential Requirements & CMD extra requirements and how these are met.
Reference to specific documents and/or where they are to be found (DOCREF).
Full description of the device with an outline/general assembly drawing if appropriate.
Copy of Notified Body Certification.
Copy of labels and instructions for use**.**

6.3 Full Technical File

Material Specifications and Formulations
Component, sub assembly or circuit drawings
Purchase specifications - including certificates of conformity where appropriate.
Work Instructions and Test Methods
Manufacturing route
Risk Analysis.
Packaging Trials and validation.
Packaging and handling specification
Labelling and Instructions for use (in all languages)
Sterilisation methods and validation report

MCA Product Licences, Pharmacopoeia References.
Quality Plan
Analysis of complaints/user feedback.
Maintenance Manual.

6.4 Design File

Test Reports and Design calculations
Analysis of complaints/user feedback
Clinical Trial Reports
Biocompatiblity and Toxicity Evaluation
Literature Reviews
Compatibility Trials
Qualification Test Reports

7.0 Design Control.

The Design Control procedure will be as follows:-

7.1 General Statement

The purpose of this section of the manuals is to establish and maintain procedures to control and verify the design of the product in order to ensure that the specified requirements are met. A portfolio will be created to maintain the documentation for each design and the Generic Design Plan shall be as follows

7.1.1 Reference Documents.

Generic Design Plan

Job Description and Specification Form	**QC22**
Design project Time scale estimates.	**QC23**
Design & Development Job Progress Form	**QC25**
Design Process Documentation Check list	**QC29**
Design Review	**QC24**
Design changes	**QC28**
Purchases	**QC27**
Work Logs	**QC26**
Project Validation	**QC30**

7.1.2. Specifications.

The initial stage for all design projects will be the completion of a Job Description & Specification Form. The form will provide a description of the requirements and may include sketches. Any trial requirements will also be documented on the form. (QC22) V17

7.2 Design & Development planning

7.2.1. The Managing Director or a Design supervisor delegated by the Managing Director is responsible for allocating work to specific staff .(QC23) ; and for monitoring the quality of their performance

7.2.2. The job number, date and description of the job are also entered into a Job Progress form which is also used to document preliminary drawings and design compliance.(QC25)

7.2.3. A design portfolio will be produced and all documentation for the project kept within the portfolio and up to date.

7.2.4. A Design Documentation check list will be used to ensure each stage of the design process is considered.(QC29)

7.3. Organisational and Technical Interface

When other outside organisations or technical groups are required to contribute to the design function, these should be identified so far as is possible in the preliminary stage of design, and their input identified and retained on the project master file. Where the need for outside advice or assistance arises in the course of the development of a project, this input will also be retained on the project master file, adjacent to any modification or response made as a result of it.(QC24/28) V17 / 4.3

7.4 Design Input

7.4.1. The Technical & Commercial Review shall consist of the completion of a Design Compliance form showing compliance with the MDD, and any necessary preliminary drawings. This ensures the translation of the brief for a product that provides customer satisfaction at an acceptable price and a satisfactory return on investment for the enterprise. It should be ensured that the product will be producible the design controllable, and the performance of the design verifiable.

7.4.2. The Design Compliance form will be used to document the necessary considerations given before commencement of the project. Consideration will be given to the intended use of the device, the environment of its operation, the materials needed and the estimated labour costs for Viamed and any necessary sub-contractor.(QC22)

7.4.3. Intervals for project progress meetings/reports and estimated time for final inspection and test and for project validation**.** These time estimates are not to be legally binding unless made f the essencein a customer original specification.(QC23)

7.4.4. Any standards and statutory requirements appropriate to the design and the requirements to be met . (MDD) Essential Requirements)

7.4.5. The tests to be carried out on the final product and the criteria to be met for acceptance of the product.(QC22)

7.4.6. Where necessary, copies of any preliminary drawings will be placed on file.

7.4.7. Construction of the project will not commence until any incomplete, ambiguous or conflicting requirements have been resolved. At this stage the Job Progress form (QC25) will be updated to show the new start date and the schedule re-timed accordingly. (Issue new QC23). Staff will be allocated the tasks of purchasing, producing working drawings and construction.(QC26/27). Dates for progress meetings/reports will be allocated on the progress plan.(QC25)

7.4.8. All documents, manuals and specifications should be maintained in accordance with the Viamed QualityManual.

7.4.9. All materials or parts used in design shall be from an Approved Supplier and supplied with Certificates of Conformity where deemed necessary. If an Approved Supplier is not available the permission to use non-approved suppliers must be obtained from the Quality Manager, using a Concession Note.

7.4.10. Customer supplied parts will comply with the requirements of the Viamed Quality Manual. Where,for any reason, this is not possible, the Customer must sign a waiver accepting responsibility for any degradation of performance or other unforeseen circumstances arising from the incorporation of the non-compliant parts.

7.4.11. Any design being processed by Viamed shall have its current status identified

7.5. Design Review.(QC24)

7.5.1. Reviews will take place to verify the progress and performance of all group identified in the design process. Records will be kept indicating who attended these reviews and any action agreed on the Job Progress form..

7.5.2. Any amendments to a design will be documented on the Job Progress form (QC25)

7.6. Design Output

Where appropriate, design output will be verified against the design input throughout the construction of a project to ensure that the finished product will be able to meet the requirements set out in the design compliance form .This will be done, where possible, by both circuit block emulation and by construction, test and verification of circuit/device stages in prototype as agreed at progress meetings. Test parameters will be derived from the brief and from relevant legislation. Record of the verification will be made on the Job Progress form. Any required changes revealed by the verification will be recorded .

7.7. Design Verification

Completed designs will be verified to ensure that:

7.7.1. The criteria required by the brief have been met.

7.7.2. The acceptance criteria for the final tests proposed has been met.

7.7.3. The criteria for any standards and statutory requirements has been met.

7.7.4. The results of any tests carried out will be attached to the Job Progress Form. A brief **r**esume of the results will be entered upon the Job progress Form (QC25)

7.7.5. Where the required testing can only be performed by the customer, or clinical trials are required, a statement indicating this will be made on the Service Request form.

7.8. Customer Acceptance

On completion of the project the customer will be given:

7.8.1. The completed device

7.8.2. The user Information specified upon the Design Compliance form

7.8.3. A copy of the Test Schedule indicating the device has met the acceptance criteria for testing.

7.8.4. The customer will signify his acceptance of the product in writing.

7.9 Field Trials

7.9.1. During trials the advantage of minor modifications to improve a design or to overcome minor problems may become apparent. In such cases a new Job Progress form will be added to the design portfolio and the design supervisor will allocate staff for the modification work.

7.9.2. Where more extensive modifications are required the design will be processed as a new job request.

7.10. Product Validation

After a period of use, specified upon the quotation, designed products will be validated by the Quality Manager using the Validation form. (QC30)

8 Design Changes

IF any changes to Design which may

1
2 in the case of a Class III or IV medical device any significatant change
3 a change that would affect the class of the device;
4 a change in the name of the manufacturer,
5 a change in the name of the device
6 a change in the identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family
7 in the case of calss II medical device, a change in the medical conditions, purpose, or uses for which the device is manufactured, sold or represtented.
8 The Device has been registered / Licenced with CMDCAS.

Then CMDCAS / Healh Canada Minister needs to be informed using the Current Licence Amendment Form found on the CMDCAS website.