VIAMED Ltd

QUALITY MANUAL

BS EN ISO 9000:2000
ISO 13485:2003
MDD / 93 / 42 EEC
CMDCAS

JSL v.1.6 18 August 2006

Issue 3

				AMENDMENT	
SECTION	PAGE	**ISSUE**	**DATE**	**DETAILS OF CHANGE**	**INT**
1.3.6	1	1 Rev 1	21.4.94	Copy nos 2 & 3 removed	
1.3.6	1	1 Rev 1	10.94	Copy 4 removed	
1.3.5	1	1Rev 2	10.94	Copy to accreditation body removed	
Manual	All	2	1.08.95	Upgraded to ISO9001/EN4601	
2.2.2	1	2 Rev1	24/7/96	Addition of master File Location	
0	1	2 Rev 1	24/7/96	Addition of Service to process Control	
4.4	1	2 Rev1	24/7/96	Section 4.4 added	
1.2	1	2	20/1/98	Ref MDD added	
4.2	5	2 rev 3	22/09/02	International stds	
4.2	5	2 rev 3	22/09/02	Technical file	
4.3	28	2 rev 3	22/09/02	Risk analysis	
4.3	29	2 rev 3	22/09/02	Clinical investigation	
4.8	15	2 rev 3	22/09/02	Implantable records	
4.9	10	2 rev 3	22/09/02	Temporary secondment	
4.14	23	2 rev 3	22/09/02	Complaints	
4.1.2	15	2 rev 3	06/11/02	Traceability extended back to supplier	
4.1.3	15	2 rev 3	06/11/02	Section added extending to end user	
1.3.1		2 rec 3	06/11/02	Health & Safety added	
6.4.3		2 rev 3	06/11/02	Reference to CMDCAS & international requirements	
Appendix A			06/11/02	New procedures added	

QUALITY MANUAL

CONTENTS OF MANUAL

1 Company Policy Statement and Objectives

Viamed Ltd is totally committed to achieving the highest levels of Quality in all the products we supply and the services we provide. Therefore if we are to succeed, all our employees must share this objective too.

Our Customers judge us by our products and services, therefore we must be totally committed in our outlook with regards to Quality

One of our Business objectives is to continually meet the requirements of the various international systems to which we have been assessed and approved. Conformance to the Processes and Systems recorded in this Quality Manual is mandatory, and will enable us to meet that objective

In addition to strict adherence to these processes we need to continually develop and maintain the right Attitude towards high Quality achievement throughout the company

Only in this way will we reach our Quality Policy of complete customer satisfaction

Signed:…… Date:……

J.S. Lamb Managing
-Director

2 Scope

This Quality manual details the requirements of Viamed Ltd Quality management systems, which are structured to operate in accordance with all relevant international standards

The manual acts as a reference as to how the management systems are implemented, maintained and continually improved

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The product range and services provided by Viamed, under the Quality management systems described in this manual are:

The design, manufacture, warehousing and distribution of Medical electronic equipment and accessories to hospitals, and the service and maintenance of such equipment.

Technical and Design files of all relevant information for the above products and services are maintained and continually reviewed for adequacy

3 Company Quality Manual

This Company Quality Manual will be used to describe the Quality Policies, basic Quality Systems, & Health & Safety policies operating in the Company

The policies and systems recorded in this Manual will be supported where necessary with Job Specifications, Quality plans, Detailed Procedures./Work

Instructions which will record the activities required of employees in meeting the company's quality policies and systems.

Procedures are set out in the Company Operating Procedures Manual, and are listed in Appendix A. to be checked/

A summary of amendments to the manual will be recorded on the Quality Manual Amendments List (Section 1.3.7)

A modification to any page for a Section in the manual will require the number of all pages of that Section to be raised.
The index pages will be modified at the same time

A Master Copy of the Manual will be maintained and the Managing Director will be responsible for this Master Copy. Any subsequent modifications will be provided to the accreditation organisation for consideration. On acceptance, modified pages will be filed in the master copy of the Manual.

Controlled copies of this Manual will be restricted to:-
Copy No. 1 - Managing Director Technical Library
Other copies - Intrastats:. Library Directory

4.0. Quality Management System

4.1. The organization has established, documented, implemented, and maintains aquality management system and maintains its effectiveness in accordance with the requirements of this International Standard and the requirements of The MDD and CMDCAS.

4.1.a Processes needed for the quality system have been identified and applied throughout the organization

4.1.b The sequence and interaction of these processes have been determined

4.1.c The criteria and methods needed to ensure that both the operation and control of these processes are effective has been determined Process 01 VM3/COP 30+ Products

4.1.d The availability of resources and information necessary to support the operation and monitoring of these processes has been assured .

4.1.e These processes are monitored, measured, and analysed.

4.1.f The actions necessary to achieve planned results and to maintain the effectiveness of these processes have been implemented Management & Stock meetings need a new procedure Intrastats

These processes are managed by the organization in accordance with the requirements of this International Standard.

Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system (see 8.5.1).

4.2 **Documentation Requirements**

4.2.1 The quality manual system documentation includes

4.2.1a Documented statements of a quality policy and quality objectives

4.2.1b This Quality Manual. Quality Process Manual V1.5

4.2.1c All procedures relevant to the control of quality are documented Process 01 VM3/COP 30+ Products

The Manual details a set of sub-tier documents, forms, procedures, diagrams and charts which describe in more detail the essential controls, which are used to enable the various processes to be carried out.

4.2.1d The company operates a system for the registration, issue, revision and control of all significant documents, including this manual.

The company operates a system for the control and issue of manufacturers manuals, technical data, international standards and regulatory requirements ISO Databases Live Idmanual 2006

This data is stored in the company's library and electronically,

A record of ISO and other Standards in use in the Company is and regularly updated ISO Databases Live. Standards Database BSindex 2006 Approach files

Specification changes/product updates and document changes are controlled in accordance with Company Operating Procedure

4.2.1e Quality records demonstrate achievement of the required quality and are used as a source of data for investigation and analysis purpose. Records are maintained as objective evidence that the documented procedures are operational in practice. Library, Electronic

4.2.1.f Documents specified in addition by national or regional regulations are recorded and subsequently archived Library, Electronic PDF's in S;/

For each type or model of medical device, the organization has established and maintains a file either containing or identifying documents defining product specifications and quality management

system requirements (see 4.23). These documents shall define the complete manufacturing process and, if applicable, installation and servicing.

4.2.2.a Quality manual

4.2.2a_ The organization shall established and maintains a quality manual that includes the scope of the quality management system, including details of and justification for any exclusion and/or non-application (see 1.2),

4.2.2b . the documented procedures established for the quality management system, or reference to them, and description of the interaction between the processes of the quality management system.

4.2.2c . The quality manual shall outline the structure of the documentation used in the quality management system.

4.2.3 **Control of documents**

Documents required by the quality management system are controlled
Records are controlled according to the requirements of 4.2.4
Document procedures are established to define the controls needed

4.2.3a Documents either paper or electronic will be reviewed prior to use

4.2.3b All changes to documents are reviewed and approved by the same authority that controlled the original, unless designated otherwise.

4.2.3c The nature of change(s) to documents are identified, recorded, signed and dated.
All documentation, records and forms used in the Quality Assurance Programme are subject to methodical issue and modification.
Issues are restricted to Major changes in documentation
Minor changes will be identified by revision date.

4.2.3d Copies of catalogues, specifications, Master Device Files for Technical products and technical standards are retained in the Library /Intrastas/and/or Electronically and are available for consultation by persons needing them. Drive L and/or Paperport/Intrastats

4.2.3e Hard copy documents (including records) are assessed regularly for legibility; illegible documents are withdrawn and replaced with new. Needs to be in Audit

4.2.3f The control of all Manufacturers/Suppliers catalogues, specifications and technical standards ie the responsibility of the Managing Director/Technical Director

4.2.3g All obsolete documents are removed from points of issue and use. They are archived . Minimum retention periods are specified for all documents and records

4.2.4 Control of records

Records are established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records remain legible, readily identifiable and retrievable. A documented procedure is established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.
The organization retains the records for a period of time at least equivalent to the lifetime of the medical device as defined by the organization,legal advice received and the MDD but not less than two years from the date of product release by the organization or as specified by relevant regulatory requirements

5.0 **Management Responsibilities**

5.1 The responsibility for the direct management is in accordance with the policies and strategies as determined by the Board of Directors, and is vested in the management team. management meetings

5.1.a The management team is responsible for ensuring that all personnel are aware of the need to meet all the customer, statutory and regulatory requirements

5.1.b They will also ensure that the Quality Policy is understood Company meetings. Induction

5.1.c its objectives are established and implemented

5.1.d The management team is also responsible for the annual review of the company's Quality system.

5.1.e The authority for the implementation and maintenance of the management system is invested in the . Technical Director who is the management representative for these activities.

All personnel employed by the company, up to and including senior management are responsible for the activities assigned to them.

Their reporting and communication channels are described on the organization chart

5.2 **Customer focus**

Top management ensures that customer requirements are determined and met (man meetings)

5.3 Quality Policy

5.3a Top management ensures that the quality policy is appropriate for the purpose; Policy page 4

5.3b It includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system.

5.3c It also provides a framework for establishing and reviewing quality objectives.

5.3d The quality policy is communicated and understood within the organization

5.3e It is reviewed for continuing suitability

5.4 **Planning**

5.4.1 **Quality Objectives**

Management assures that the quality objectives including those that meet requirements for product (7.1) are established at relevant functions and levels within the organization. The quality objectives are measurable and consistent with the quality policy management meetings

5.4.2 Quality management system planning

5.4.2a Management ensures that the planning of the quality management system is carried out in order to meet the requirements given in 4.1 as well as the quality objectives and

5.42b ensures the integrity of the quality system is maintained when changes to the quality management system are planned and implemented.

5.5. **Responsibility authority & communication**

5.5.1 Top management ensures that responsibilities and authorities are defined, documented, and communicated within the organization. They have established the interrelation of all personnel who manage, perform and verify work affecting quality, and ensure the independence and authority to perform these tasks

5.5.2 Management representative

Management have appointed a management representative

5.5.2a Ensuring that processes needed for the quality management system are established, implemented and maintained

5.5.2b They report to top management on the performance of the Quality management system and any requirements for improvement

5.5.2c They ensure the awareness of regulatory and customer requirements throughout the organization This also includes liaison with external parties

5.5.3 **Internal communication**

. Top management ensures that appropriate communication processes are established within the . organization and that communication takes place regarding the effectiveness of the quality .

management system management meetings

5.6 **Management review**

5.6.1 Top management reviews the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews shall be maintained (see 4.2.4). Management Reviews

5.6.2 **Review input**

The input to management review includes information on

5,6,2a results of audits

5.6.2b customer feedback, Positive as well as complaints Complaints file

5.6.2c process performance and product conformity,

5.6.2d status of preventive and corrective actions, management meeting minutes

5.6.2e follow-up actions from previous management reviews,

5.6.2f changes that could affect the quality management system,

5.6.2g recommendations for improvement, and

5.6.2h new or revised regulatory requirements

5.6.3 **Review output**

The output from the management review includes any decisions and actions related to

5.6.3a improvements needed to maintain the effectiveness of the quality management system and its processes

5.6.3b improvement of product related to customer requirements, and

5.6.3c resource needs

6.0 Resource Management

6.1 The organization determines and provides the resources needed

6.1.a To implement the quality management system and to maintain its effectiveness

6.1.b To meet regulatory and customer requirements

6.2 **Human resources**

6.2.1 General

Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

6.2.2 Competence awareness and training

Training needs are identified by the specific requirements of current practices in producing the company's products and services, and re-training will be given as a consequence of change.

6.2.2a. Trained / experienced / skilled personnel are assigned to all verification activities that are identified as such. All personnel whose activities could affect Quality will be suitably qualified and have had appropriate experience and/or training.

6.2.2b Training ensures that personnel develop the appropriate knowledge and skills required to enhance their contribution to the development of the Quality System. Where there is any shortfall on the part of any of the personnel in meeting the requirements of their job function, or temporary secondment to tasks under special conditions, the Managing Director will arrange for the necessary training to be provided.

6.2.2c Adequate and appropriate in-house verification of requirements are identified and provide to ensure that contract requirements can be met, and that appropriately qualified personnel are assigned to activities commensurate with their abilities.

6.2.2d All employees will be made aware, during their induction, of their contribution to, and the importance of, their activities within the company's system. Induction

6.2.2e A Training Record will be raised for each employee, which details the training, which has been provided and will be signed on satisfactory completion.
Training will be planned, carried out and recorded in accordance with company operating Procedure, National and international requirements will be taken into account .

6.3.1 Infrastructure

The organization determines, provides and maintains the infrastructure needed to achieve conformity to product requirements. Infrastructure includes,

6.3.a Buildings,workspace, and associated utilities

6.3b process equipment hardware and software

6.3c supporting services

Records of such maintenance are maintained (see 4.2.4). PAT

6.4 **Work environment** The organization has determined and manages the work environment needed to achieve conformity to product requirements.

6.4a The organization has established documented requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or worn environment could adversely affect the quality of the product (see 7.5.1.2. I).

6.4b Where work environment conditions can have an adverse effect on product quality, the organization has established documented requirements for the work environment conditions and documented procedures or work instructions to monitor and control these work environment conditions (see 7.5.1.2.1).

6.4c The organization ensures that all personnel who are required to work temporarily under special environmental conditions within the work environment are appropriately trained or supervised by a trained person [see 6.2.2 b)

6.4d Special arrangements have been established and documented for the control of contaminated or potentially contaminated product in order to prevent contamination of other product, the work environment or personnel (see 7.5. a 1).

7.0 **Product Realisation**

7.1 Planning of product realization

The organization has planned and developed the processes it needs for product realization. Planning of product realization is consistent with the requirements of the other processes of the quality management system (see 4.1).
the following, are also considered as appropriate:

7.1a quality objectives and requirements for the product

7.1b the need to establish processes, documents, and provide resources specific to the product Process 01; VM3/COP30 + Products

7.1c required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; QA procedures; Process 01 VM3/COP30 + Products

7.1d records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).The output of this planning is in a form suitable for the organization's method of operations .The organization has established documented requirements for risk management throughout product realization. Records arising from risk management shall be maintained (see 4.24 in the Technical or CE files

7.2 Customer related processes

7.2.1 **Determination of requirements related to the product**

7.2.1a Where enquiries are turned into orders then cognizance is taken of such factors as delivery activities, and post delivery, Viamed-online.com

7.2.1b additional requirements (not specified by the customer) as deemed necessary to individual product.

7.2.1c Statutory and regulatory requirements are observed

7.2.1d Where deemed necessary additional requirements will be determined by the organization

7.2.2. **Review of requirements related to the product**

The organization reviews the requirements related to the product. This review is conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and ensures that

7.2.2a product requirements are defined and documented

7.2.2b contract or order requirements differing from those previously expressed are resolved, and

7.2.2c the organization has the ability to meet the defined requirements

Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed before acceptance.

Where product requirements are changed, the organization ensures that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

As in Internet sales, a formal review is impractical for each order. The review will cover relevant product information such as catalogues, advertising material and web content Sales & Marketing meeting

7.2 .3 Customer communication

The organization determines and implement effective arrangements for communicating with customers. Communication with customers is paramount to the company's operations, as such all communications are recorded in "Goldmine", verbal enquires are recorded with all relevant information. Effective arrangements are in place for communicating with the customers in relation to

7.2.3a Product information,

7.2.3 enquiries,contracts,order handling,and amendments

7.2.3c customer feedback, including customer complaints , will be dealt with immediately to ensure the customer's complete satisfaction

7.2.3d and advisory notices (see a 5.1). Competent Authority form

7.3 Design and Development

7.3.1 Design & Development planning.

Documented procedures are established and maintained to control and verify the design of product in order to ensure that the specified requirements are met. Throughout the design process, organization determines

7.3.1.a the design & development stages

7.3.1.b reviews , verifies, and validates design transfer activities that are appropriate at each design stage.

7.3.1.c Responsibility and authority for design & development

Organisational and technical interfaces between different groups, which input into the design process are defined, and the necessary information documented, transmitted and regularly reviewed

Risk analysis is performed at all relevant stages of design, as dictated by design evolution CMDCAS requirement

7.3.2 **Design & Development Inputs** **CE Files Y**

Design input requirements relating to the product, including applicable statutory and regulatory requirements will be identified, documented, and recorded Inputs will include

7.3.2a functional, performance and safety requirements, according to the intended use 7.3.2b applicable statutory and regulatory requirements MDD 93/42/EEC & 98/79/EEC

7.3.2c where applicable, information derived from previous similar designs

7.3.2d other requirements essential for design and development, and) output(s) of risk management (see 7.1). These inputs will be reviewed for adequacy and approved. Design Files & CE Files

Requirements shall be complete, unambiguous and not in conflict with each other.

7.3.3 **Design & Development outputs** **CE Files Z**

Design output will be documented and expressed in terms that can be verified and validated against design input requirements.

Design and development outputs will nsure that the design

7.3.3a meets the input requirements for design and development

7.3.3b provides appropriate information for purchasing, production and for service provision

7.3.3c contains or references product acceptance criteria, and

7.3.3d specifies the characteristics of the product that are essential for its safe and proper use. Records of the design and development outputs shall be maintained (see 4.24). NOTE Records of design and development outputs can include specifications, manufacturing procedures, engineering drawings, and engineering or research logbooks Not in Intrastats

7.3.4 **Design & Development Reviews**

At appropriate stages of design, formal documented reviews of the design results are planned and conducted. To

7.3.4a evaluate the ability of the results of design and development to meet requirements,

7.3.4b to identify any problems and propose necessary action

Participants at each design review shall include representatives of all functions concerned with the design stage being reviewed, as well as other specialist personnel, as required. see 5.5.1 and 6.2. 1) Records of such reviews shall be maintained

7.3.5 **Design & Development Verification;**

At appropriate stages of design, design verification shall be performed to ensure that the design stage output meets the design stage input requirements. The design verification measures will be recorded. Design verification may include activities such as performing alternative calculations; comparing the new design with a similar proven design, if available; undertaking tests, demonstrations and reviewing the design stage documents before release.

7.3.6 **Design & Development Validation**

Design validation shall be performed to ensure that product conforms to defined user needs and/or requirements. Design validation follows successful design verification. Validation will normally be performed under defined operating conditions Validation will normally performed on the final product. but may be necessary in earlier stages prior to product completion. Multiple validations may

be performed if there are different intended uses. Clinical investigation or trials will be undertaken to ensure intended product performance

Records of the results of validation and any necessary actions will be retained

7.3.7 **Design & Development Design Changes.**

All design changes and modifications shall be identified,. Documented, reviewed, recorded and approved by authorised personnel before their implementation. All design changes and modifications are identified, documented recorded reviewed and approved by authorized personnel before their implementation. The review of design and development changes will include evaluation of the effect of the changes on constituent parts and product already delivered.

Records of the results of the review of changes and any necessary actions will be maintained

7.4 **Purchasing**

Purchase process

The organization has documented procedures to ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product is dependent upon the effect of the purchased product on subsequent product realization or the final product.

The organization evaluates and selects suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).

7.4.2 **Purchasing information**

Purchasing information shall describe the product to be purchased, including where appropriate

Type, brand, identification and/or specification, and

7.4.2a requirements for approval of product, procedures, processes and equipment Any test certificate, certificates of conformity

7.4.2b requirements for qualification of personnel,

7.4.2c quality management system requirements

The organization ensures the adequacy of specified purchase requirements prior to their communication to the supplier to the extent required for traceability given in 7.5.3.2, the organization shall maintain relevant purchasing information, i.e. documents (see 4.2.3) and records (see 4.24).

Barcoding

7.4.3 **Verification of purchased product**

The organization has established and implements the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where the organization or its customer intends to perform verification at the supplier's premises, the organization will state the intended verification arrangements and method of product release in the purchasing information Records of verification will be maintained

Purchasing documents contain, where applicable, the number and issue of any quality standard or regulatory requirement applicable to the product.

All purchasing documents are reviewed and approved by a Director prior to issue.

Records of the verification shall be maintained (see 4.2.4).

Purchaser Supplied Product Free-issue material is not a part of the company's normal business activities except for repairs. Where required by contract, the customer will be allowed reasonable access to verify purchased product either at source or at the company's premises. Where verification is at source, then the supplier is informed on the purchase order.

In this situation the company accepts full responsibility for the effective storage, handling, identification, etc., of customer-supplied product.
All products provided by Viamed Ltd under cover of its Registration, will be procured from a "Quality Assured Source" where possible.

7.5 **Production and service provision**

7.5.1 The processes required for production are identified, planned and carried out under controlled conditions, which may include
7.5.1.1a Information that describes the characteristics of the product
7.5.1.1b the issue of work instructions, manufacturing specifications and test instructions.
7.5.1.1c the use of suitable equipment
7.5.1.1d the use of monitoring and measuring devices
7.5.1.1f The implementation of release, delivery, and post delivery activities
7.5.1.1g The implementation of defined operations for labeling and packaging
7.5.1.2 **Control of product and service provision –Specific requirements.**
7.5.1.2.1 Cleanliness of product and contamination control Documented requirements will be established if
7.5.1.2.1a product is cleaned by the organization prior to sterilization and/or its use, or
7.5.1.2.1b product is supplied non-sterile to be subjected to a cleaning process prior to sterilization and/or its use, or
7.5.1.2.1c product is supplied to be used non-sterile and its cleanliness is of significance in use, or
7.5.1.2.1d process agents are to be removed from product during manufacture
If product is cleaned in accordance with a) or b) above, the requirements contained in 6.4 a) and 6.4 b) do not apply prior to the cleaning process.
Where appropriate, the organization WILL establish documented requirements which contain acceptance criteria for installing and verifying the installation of the medical device.
If the agreed customer requirements allow installation to be performed other than by the organization or its authorized agent, the organization will provide documented requirements for installation and verification.
Records of installation and verification performed by the organization or its authorized agent shall be maintained (see 4.2.4).
7.5.1.2.2 **Installation**
7.5.1.2.3 **Servicing Repair and Maintenance**
The procedures for ensuring that purchaser owned equipment accepted for repair by Viamed Ltd is repaired to the quality standard are contained in Company Procedures
Repair and maintenance of purchaser owned equipment and sub assemblies must where possible be carried out to original specifications (including where applicable authorised modification) in accordance with any other documents necessary to affect a repair
On completion of repair and test the engineer will complete the Service Repair Note and Test Certificate. Records
In coming products for repair should be cleaned by the customer prior to shipment under DoH documentation (Mac part 1-4 (L Drive Sterility)
A Viamed Safety Test Certificate following repair/servicing will be issued to the customer where appropriate

7.5.1.3 Sterility

Products requiring sterility will be subject to current regulations regarding sterility. These will be documented and controlled Special Processes when required will be located in the Master Technical File

7.5.2 Validation of processes for production and service provision

7.5.2.1 General Requirements

The organisation will validate any process for production and service where the resulting output cannot be verified by subsequent monitoring or measurement

This includes any process where deficiencies become apparent only after the product is in use or the service has been delivered.

Validation will demonstrate the ability of these processes to achieve planned results. The organisation will establish arrangements for these processes including as applicable

7.5.2.1a defined criteria for review and approval of the process

7.5.2.1b approval of equipment and qualified personnel

7.5.2.1c use of specific methods and procedures

7.5.2.1d requirements for records (4.2.4) and

7.5.2.1 revalidation

The organisation will establish documented procedures for the validation of application of computer software (and changes to such software and/or its application) for production and service provision that effects the ability of the product to conform to specified requirements. Such software applications will be validated prior to initial use.

Records of validation shall be maintained

7.5.2.2 When required documented procedures will be established for the validation of sterilization processes. These processes will be validated before use.

7.5.3 Indentification and Traceability

7.5.3.1 Identification

The organization identifies the product throughout product realization and has documented procedures for such product identification Bar codes

The organization has documented procedures to ensure that medical devices returned are identified and distinguished from conforming product

Labeling is as stated in the MDD requirements or covered by an ISO standard and associated instructions.

All products are traceable to the manufacturer or supplier by part number and/or description.

Barcodes

Instruments and key components are identified by individual serial numbers, and/or barcodes which give full traceability to office records which fully document specifications for these products The Office Manager will be responsible for ensuring that products in the warehouse are adequately identified at all times.

All finished product is traceable through records/barcodes to the end user.

7.5.3.2. **Traceability**

7.5.3.2.1. **General**

The organization has established documented procedures for traceability. Such procedures define the extent of product traceability and the records required (see 4.2.4, & 3 and 8.5).

Where traceability is a requirement, the organization controls and records the unique identification of the product (see 4.2.4).

7.5.3.2.2 **Implantable medical devices**

A particular set of requirements will be created if implantable devices are offered.. These will include Records of components, materials, environmental conditions.
Distributors and agents will be required to maintain records of distribution
In defining the records required for traceability, the organization shall include records of all components, materials and work environment conditions, if these could cause the medical device not to satisfy its specified requirements.
The organization requires that its agents or distributors maintain records of the distribution of medical devices to allow traceability and that such records are available for inspection.
Records of the name and address of the shipping package consignee shall be maintained (see 4. a 4).
Records of shipping will be recorded

7.5.3.3 **Status identification**

The organization identifies the product status with respect to monitoring and measurement requirements.
The identification of product status is maintained throughout production, storage, installation and servicing of the product to ensure that only product that has passed the required inspections and tests (or released under an authorized concession) is dispatched, used or installed.

7.5.4 **Customer property** Process 01 VM3/COP30.02

The organization exercises care with customer property while it is under the organization's control or being used by the organization. The organization identifies, verifies, protects and safeguards customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained (see 4.2.4).
NOTE Customer property can include intellectual property or confidential health information

7.5.5 Preservation of product Handling Storage ,Packing and delivery VM3/COP08

Product Handling

The organization has documented procedures or documented work instructions for preserving the conformity of product during internal processing and delivery to the intended destination.
This preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.
The organization has documented procedures or documented work instructions for the control of product with a limited shelf life or requiring special storage conditions. Such special storage conditions are controlled and recorded (see 4.2.4). Process 1 sub processes VOP07
Products will be stored in an adequate, secure and appropriately controlled environment Methods of handling and adequate handling facilities will be provided to prevent abuse, misuse, damage or deterioration during all phases of handling/storage/packing.
It will be the responsibility of the Warehouse Manager to ensure that adequate facilities are available.
Items in the main store will be identified by labeling Each product will be identified in the warehouse by the supplier part number and/or description
Incorrect incoming products will be identified and Procedure followed

Packaging, Delivery and Installation

All products will be appropriately packaged and protected on despatch to ensure their safe arrival and ready identification when received at the customer's premises.
If the customer has any specific requirements these will be considered at the time of the Contract Review.
Products awaiting despatch will be boxed and labelled as appropriate and stored in the 'despatch' area.
Installation will be carried out to original manufacturers instructions and current safety regulations and customer specific instructions.
Packing, delivery and installation is carried out in accordance with procedure
As necessary HOLD labels will be used to indicate the inspection status of non-conforming product in quarantine.
All Corrective Action will be recorded.
Correction Action will be taken in the warehouse when incorrect product is found.
Corrective Action will be taken when non-conforming product is discovered on picking or assembling for despatch.
Marked gangways will be kept clear.
Stock rotation on a first-in-first-out basis will be applied for shelf life products and wherever necessary.
Stock levels are held on computer and/or manual records and are controlled by office staff in accordance with Company Operating Procedure.
Suspect Product in stock shall be withdrawn and investigated and the non-conformance procedure followed.
Stock subject to deterioration will be monitored at regular intervals set be the manufacturer Rotation of stock (where applicable) is systemized in order to prevent deterioration.
Sterile stock will be stored in sterile conditions in accordance with documented procedures
Free issue material is not a part of the company's normal business activities, except for repairs. In this situation the company accepts full responsibility for the effective storage, handling, identification, security etc., of customer-supplied property.
Preservation and delivery of product is controlled to prevent damage, deterioration or loss, according to procedures. Storage areas are identified and adequate methods are in use to ensure authorized receipt and dispatch.
Packaging, cleanliness, preservation and marking processes are controlled in accordance with specific requirements
Delivery is controlled after inspection and test in order that protection is given to product during transit to its location.
Adequate resources are identified and made available to ensure conformity to the above statements. These resources may include such as machinery and equipment, monitoring and measuring items and suitability of delivery controls

Certificates of Conformity/Test QC

Where requested by a customer a Certificate of Conformance will be provided.

7.6 Control of Monitoring & Measuring Devices

The organization determines the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1).The organization has established documented procedures to ensure that

monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment shall

7.6a be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded

7.6b be adjusted or re-adjusted as necessary

7.6c be identified to enable the calibration status to be determined

7.6d be safeguarded from adjustments that would invalidate the measurement result;

7.6e. be safeguarded from adjustments that would invalidate the measurement result;

In addition, the organization assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification are maintained (see 4.2.4).

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application will be confirmed. This willl be undertaken prior to initial use and reconfirmed as necessary.

NOTE See ISO 10012 for guidance related to measurement management systems.

All equipment prior to dispatch will be tested in accordance with the relevant Process 01 VM3/COP Appendix B

All inspection measuring and test equipment is identified with a unique identification number and calibration status

The Technical Manager will be responsible for the effective operation for the calibration procedure, in accordance with Process 01 VM3/COP/11 ; Process 01 VM/COP/09.

It will be possible at all times for the Inspection Status of products to be known by reference to the appropriate documentation

Inspection Status of incoming products will be identified by signature and delivery documentation.

These records are assessed when a piece of equipment is found to be inaccurate, in order to enable corrective action to be taken in relation to the non-conforming equipment and any product measured on it.

8. Measurement, Analysis and Improvement

8.1 General

The organization plans and implement the monitoring, measurement, analysis and improvement processes needed

8.1.a to demonstrate conformity of the product Process 01 VM3/COP's

8.1b to ensure conformity of the quality management system, and

8.1.c to maintain the effectiveness of the quality management system

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

NOTE National or regional regulations might require documented procedures for implementation and control of the application of statistical techniques.

8.2 **Monitoring and measurement**

8.2.1 **Feedback** VOP04

IN order to measure the performance of the quality management system, the organization monitors information relating to whether the organization has met customer requirements.
The methods for obtaining and using this information shall be determined.
The organization has established a documented procedure for a feedback system [see 7.2.3 c)J to provide early warning of quality problems and for input into the corrective and preventive action processes (see 8.5.2 and &5.3).

8.2.2. Internal audit Process 1 sub processes VOP13 ; Process 01 VM3/COP13 ;Process 0 Forms QC45 GCD01

A plan for internal audits is established, documented and implemented in order to determine the effectiveness of the management system and that it

8.2.2.a. conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and

8.2.2.b is effectively implemented and maintained.

An audit programme has been planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.
The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) are defined in a documented procedure.
The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).
NOTE See ISO 19011 for guidance related to quality auditing.

8.3 Systems Audits and Reviews

Appropriately trained and / or experienced personnel (who are not involved in the function or area being audited) carry out the audit program, and the results of the audit are brought to the attention of the person responsible for the area audited.
Internal audits are scheduled so that all departments, procedures, processes are covered within a twelve month period.
The results of these audits will be recorded.
Additional audits are undertaken should a serious problem occur, or should preventive measures need to be addressed.
The results of audits are notified to the relevant Director who satisfies himself that the corrective actions taken have corrected any deficiencies.
The management team undertakes a full management review annually to assess compliance to the requirements and achievement of policies and objectives is still being met.
This review is to a set agenda and minutes are taken to form the basis of a required program of work.
Audits and reviews are carried out in accordance with Company Operating Procedure Process 01 VM3 /COP/13.
Where a Systems Audit indicates a deviation from the written procedures, corrective action will be taken either by amending the procedure when the actions are more effective in achieving the desired result or by reverting the actions back in accordance with the written procedure.

Each quarter records of non-compliance/customer complaints, will be collated and analyzed by the Managing Director for consideration of any consistent problems or deteriorating trends.
Each quarter Repair records will be analysed by the Managing Director to establish possible preventative action.
In-Process Inspection and Testing
All those in-process checks, or measurements which need to be carried out to confirm that products are to technical requirements will be prescribed.
Special processes when encountered will have detailed procedures written and recorded.

8.2.3 **Monitoring and measurement of processes** Process 1 sub processes VOP15
The organization applies suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action can be taken, as appropriate, to ensure conformity of the product

8.2.4 Monitoring and measurement of product

8.2.4.1 **General requirements**

The organization monitors and measures the characteristics of the product to verify that product requirements have been met. This is carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1) and documented procedures (see 7.5.1.1).
Evidence of conformity with the acceptance criteria is maintained. Records indicate the person(s) authorizing release of product (see 4.2.4). VOP06
Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed. Particular requirement for active implantable medical devices and implantable medical devices
The organization shall record (see 4.2.4) the identity of personnel performing any inspection or testing.

8.2.4.2 **Particular requirement for active implantable medical devices** and implantable medical devices
The organization l records (see 4.2.4) the identity of personnel performing any inspection or testing

8.3 **Control of Non-Conforming Products**

The organization ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure the organization shall deal with nonconforming product by one or more of the following ways

8.3.a by taking action to eliminate the detected nonconformity
8.3.b by authorizing its use, release or acceptance under concession;
8.3.c by taking action to preclude its original intended use or application

The organization ensures that nonconforming product is accepted by concession only if regulatory requirements are met Records of the identity of the person(s) authorizing the concession shall be maintained (see 4.24).
Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).
When nonconforming product is corrected it shall be subject to re-verification to demonstrate

conformity to the requirements.
When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.
If product needs to be reworked (one or more times), the organization shall document the rework process in a work instruction that has undergone the same authorization and approval procedure as the original work instruction. Prior to authorization and approval of the worn instruction, a determination of any adverse effect of the rework upon product shall be made and documented (see 4.2.3 and
All products which are non-conforming to technical requirements or specification will be clearly designated as such, and segregated, in accordance with Procedure.
A HOLD Label will indicate that there is some uncertainty regarding the future use or disposition of the products involved.. The label will indicate the reason why the products are being held in quarantine and who is responsible for dealing with the matter.

8.4 . Analysis of Data

The organization shall establish documented procedures to determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate if improvement of the effectiveness of the quality management system can be made.This shall include data generated as a result of monitoring and measurement and from other relevant sources. The analysis of data shall provide information relating to

8.4a feedback (see 8.2.1),
8.4b conformity to product requirements (see 7.2.1),
8.4c characteristics and trends of processes and products including opportunities for preventive action, and suppliers.

Records of the results of the analysis of data shall be maintained (see 4.24).

8.5 **Improvement**

8.5.1 **General**

The organization shall identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.
The organization shall establish documented procedures for the issue and implementation of advisory notices. These procedures shall be capable of being implemented at any time.
Records of all customer complaint investigations shall be maintained (see 4.2.4). If investigation determines that the activities outside the organization contributed to the customer complaint, relevant information shall be exchanged between the organizations involved (see 4.1).
If any customer complaint is not followed by corrective and/or preventive action, the reason shall be authorized (see 5.5.1) and recorded (see 4.24).

If national or regional regulations require notification of adverse events that meet specified reporting criteria, the organization shall establish documented procedures to such notification to regulatory authorities.
Process 01 VM3/COP/10. **Initial Incident Report IIRMDD**

8.5.2 Corrective action

The organization takes action to eliminate the causes of nonconformities in order to prevent recurrence. Documented procedures are in place to ensure that timely and effective action is taken to ensure that Non-conformities are regularly reviewed to determine their root cause.
Where these are found, then corrective actions are undertaken to bring product back to specificationCorrective actions shall be appropriate to the effects of the nonconformities encountered.
A documented procedure shall be established to define requirements for

8.5.2.a reviewing nonconformities (including customer complaints), **meeting**
8.5.2.b determining the causes of nonconformities **meeting**
8.5.2.c evaluating the need for action to ensure that nonconformities do not recur **meeting meeting**
8.5.2.d determining and implementing action needed, including, if appropriate, updating documentation (see 4.2), **meeting**
8.5.2.e recording of the results of any investigation and of action taken (see 4.2.4), and
8.5.2.f reviewing the corrective action taken and its effectiveness **meeting**

Recall of Suspect Product
In the event that it is discovered that suspect product has been delivered to a customer, the Managing Director will be responsible for informing the customer and making the necessary arrangements for the return, replacement, etc, of the products in question Process 01 VM3/COP/10).
On return to the warehouse the material will be treated in accordance with the non-conformance procedure.
Product recall and reporting of incidents Initial Incident Report IIRMDD
Product recall and reporting of incidents will be in accordance with the MHRA requirements, CMDCAS , and any other International body in countries to which goods are exported

8.5.3 **Preventive action** Process 1 sub processes VOP15 ; Process 01 VM3/COP10
The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.
A documented procedure shall be established to define requirements for

8.5.3.a Determining potential nonconformities and their causes,
8.5.3.b evaluating the need for action to prevent occurrence of nonconformities
8.5.3.c determining and implementing action needed
8.5.3.d recording of the results of any investigations and of action taken (see 4.2.4), and)reviewing preventive action taken and its effectiveness

Appendix – A

Procedure No	Title	Owner
VOP/01	Documentation	Quality
VOP/02	Responsibilities	Directors
VOP/03	Office Procedures	Sales
VOP/04	U.K. & Export Sales	Sales
VOP/05	Purchasing	Directors
VOP/06	Inspection & Test	Production
VOP/07	Handling, Storage etc.	Production
VOP/08	Production	Production
VOP/09	Repairs	Production
VOP/10	Non-conforming Product	Quality
VOP/11	Calibration	Technical
VOP/12	Training	Directors
VOP/13	Internal Audits	Quality
VOP/14	Servicing	Sales
VOP/15	Data & Information Analysis	Quality
VOP/16	Health & Safety	Quality
VOP/17	Design & Development	Technical
VOP/18	Maintenance & Environment	Directors
VOP/19	Repairs Testing	Production
VOP/20	Goods-in	Production
VOP/21	Customer Complaints	Directors
VOP/22	Picking & Packing	Production
VOP/99	VOP master Blank	
Appendix – B		
VM3COP00.xx	Master Blank	
VM3/COP/30	$Sp0_2$ Probe Criteria Procedures	Production
VM3/COP/31	Probe Repair Procedures	Production
VM3/COP/32	Probe Assembly Procedures	Production
VM3/COP/33	Extension Cable Procedures	Production
VM3/COP/34	Temperature Probe Procedures	Production
VM3/COP/35	"Y" Probe Procedures	Production
VM3/COP/36	Microstim Procedures	Technical
VM3/COP/37	Oxygen Sensors Procedures	Production
VM3/COP/38	Oxygen Analysers Procedures	Technical
VM3/COP/39	Oxygen Sensor Holder Procedures	Production
VM3/COP/40	Vandagraph Procedures	Vandagraph
VM3/COP/43	ECG Monitors Procedures	Technical
VM3/COP/45	DL3000 Procedures	Technical

VM3/COP/46	Pippa Procedures	Production
VM3/COP/47	Apgar Timer Procedures	Production
VM3/COP/48	NIBP Calibration Procedures	Technical
VM3/COP/49	Defibrillators Procedures	Technical
VM3/COP/50	Tom Thumb Procedures	Production
VM3/COP/51	Resuscitation Cabinet Procedures	Production
VM3/COP/52	Headbox Procedures	Production
VM3/COP/53	Nufer Procedures	Production
VM3/COP/54	Mixcheq Procedures	Technical
VM3COP/56.xx	Foetal Heart Simulator	Technical
VM3COP58.xx	Infant Resuscitation	Technical

Appendix – C

QC 01	Duplicate Order Book	QC 21	Non-conformance Report
QC 02	Stock Record	QC 22	Job Description & Spec
QC 03	Invoice	QC 23	Estimated Timescales
QC 04	Purchase Order	QC 24	Design Review
QC 05	Investigation Report	QC 25	Progress Plan
QC 06	Supplier Questionnaire	QC 26	Work Log
QC 07	Training Requirements	QC 27	Purchases
QC 08	G.R.N.	QC 28	Design Changes
QC 09	S.R.N.	QC 29	Document Checklist
QC 10	Electrical Safety Test	QC 30	Project Validation
QC 11	Customer Complaints Index	QC 31	Daily Repair Log
QC 12	Customer Complaints Form	QC 32	Daily Production Log
QC 13	C. of C.	QC 33	Tom Thumb Test Sheets
QC 14	Calibration Register		
QC 15	Calibration Record		
QC 16	Training Record		
QC 17	Internal Audit Checklist		
QC 18	Internal Audit Report		
QC 19	Stock Transfer Note		
QC 20	Document Update		

Purchase Order (specials)
Supplier Register
Advice Note
Customer Orders
CE Technical Files
Design Files
MDA Correspondence
CMDCAS Correspondence
Competent Authority Correspondence
Notified Body Correspondence

Induction procedures