TELEDYNE

Analytical Instruments

A Business Unit of Teledyne Instruments, Inc.

QUALITY SYSTEM MANUAL

Date: 2016-02-04

REVISION: 19

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OUR MISSION:

TELEDYNE ANALYTICAL INSTRUMENTS' Mission is to enhance our global market leadership position by meeting the unique needs and exceeding the expectations of each customer we serve. At the heart of this mission is the drive to be a profitable analytical instrumentation manufacturer most admired for our people, partnerships, products, performance, perseverance and ethical business practices. Everything we do reflects this mission and the values that make it possible.

QUALITY POLICY:

Our Policy is to continually improve the quality of our products and services. To achieve this, we have successfully built a solid foundation and infrastructure that encourage innovation, creativity and sustainable development in our relentless pursuit of customer satisfaction, compliance with applicable statutory and regulatory requirements, and of maintaining effectiveness of the quality management system. Our long-term strategies and short-term actions are molded in these core values, and are shared by everyone in the Company.

Each of us pledges to meet this commitment through a quality process based on our core values, conscientious attention to detail, proven product engineering, innovative design, and current good manufacturing practices, all geared to unlock our full potential towards delivering operational excellence in every facet of our business.

Tom Compas
Vice President and General Manager

Vasu Narasimhan
Vice President of Operations
(Manufacturing, SCM, QA, RA)

1.0 INTRODUCTION

This Manual documents our practices to meet the requirements of the Quality Management System of Teledyne Analytical Instruments (hereinafter called "company", "our", "organization", or "facility"), and demonstrates our ability to consistently provide products and services that meet customer and applicable statutory/regulatory requirements. This manual outlines the steps towards effective application of the Quality Management System, en route to enhancing customer satisfaction.

Company's principal business is the manufacture of process gas and liquid analytical instruments, and medical devices categorized as sensors, analyzers, and custom-engineered systems. Reference is made to our web pages at www.teledyne-ai.com for a comprehensive list of our technologies and products, and various industries that we market our products to.

2.0 SCOPE

This Manual forms the framework of our Quality Management System. This practice defines the quality system implemented at our facility, and complies with the requirements of various Standards, Directives and Regulations such as ISO 9001:2008, ISO 13485:2003, ISO 80079-34, ATEX Directive 94/9/EC, MDD 93-42/EEC/ as Amended by Directive 2007/47/EC, 21CFR820, and Canadian Medical Device Regulation.

3.0 PURPOSE

- The purpose of this Quality Manual is to describe and document the Quality System implemented within our company.
- This manual is the central source of general practices and procedures that authorize and govern creation of subsidiary quality systems related documentation and activities.
- This manual provides comprehensive evidence to customers, suppliers, and employees that the company is committed to establishing and maintaining acceptable levels of Quality in its products and services.

4.0 CONTROL OF MANUAL

Control and revision of the Quality Manual is conducted in accordance with the document control procedures described in Clause 4.2.3 - Control of Documents. Quality Manuals that are issued to customers and to others outside the facility are marked as UNCONTROLLED. Changes to the Quality Manual may be initiated by any employee when it is determined that change is necessary to improve the Quality Management System towards achieving quality objectives. Implementation of any suggested changes to the Quality Manual will need approval of the Configuration Control Board (CCB), the Management Representative and the VP/General Manager. Any significant changes that would cause a noncompliance to the Quality System will require notification to the affected regulatory or registration agency.

QUALITY SYSTEM CROSS-REFERENCE MATRIX

ISO 9001:2008 Clauses & CP100 Addendums	Reference Documents	ISO 13485:2003 Clauses	Medical Devices FDA 21CFR820	EU MDD 93-42/EEC, as Amended by Directive 2007/47/EC
4.1	CP230	4.1	820.20	Annex II-3.4
4.2	CP202,204,218,230; DC403,415,417,423,424,616	4.2	820.20, 820.40, 820.180, 820.186	Annex II-3.2, Annex II-3.4
5.1	CP100	5.1	820.5, 820.20	
5.2	SA400	5.2		
5.3	CP100	5.3	820.5, 820.20	
5.4	CP100,230	5.4	820.5, 820.20	Annex II-3.4
5.5	CP100	5.5	820.5, 820.20	
5.6	CP100	5.6	820.5, 820.20	
6.1	CP100	6.1	820.5, 820.20	
6.2	CP100,200	6.2	820.5, 820.20, 820.25	
6.3	MS400,401,402; PD400,401,402; SD400,401	6.3	820.70	
6.4	MS400,401,402; PD400,401,402; SD400,401	6.4	820.70	
7.1	CP230; QA401,402,404,405,406,413; TD402	7.1	820.20, 820.80	Annex II-3.4
7.2	ED400; SA400; SR401	7.2	820.30	
7.3	ED400; SR401	7.3	820.30	Annex II-3.4
7.4	PU400,402; QA401,402,404,405,406,413; TD402	7.4	820.50	
7.5	CP228,229,231; CS400,402; MS400,401,402; PD400,401,402; QA401,402,404,405,406,413; SD400,401; TD402,403; WH400,401,402,405,406,411	7.5	820.60, 820.65, 820.70, 820.86	Annex IV-6.4,
7.6	QA411,412	7.6	820.72	
8.1	CP219; QA401,402,404,405,406,413; TD402	8.1	820.80, 820.250	
8.2	CP219; QA401,402,404,405,406,413,417; TD402	8.2	820.80	
8.3	CP223; QA414,415	8.3	820.90	
8.4	CP219	8.4	820.250	
8.5	CP100; QA421	8.5	820.5, 820.20, 820.100	Annex II-3.1
Addendum A	Medical Devices-CP 207, 223	8.1, 8.2, 8.4	820.198	
Addendum B	COSO Framework (Finance)-CP 250			
Addendum C	Contact Information			
Addendum D	Obligation to Inform			
	CP251 - CMDR			

CLAUSE 4

QUALITY MANAGEMENT SYSTEM

4.1 GENERAL

This Quality Manual describes the quality system implemented and maintained at our facility that, amongst others, complies with the requirements of various standards mentioned elsewhere in this document.

Key processes determined for incorporation into our Quality Management System and their interactions are outlined below. These processes are monitored, and where applicable, measured, and analyzed.

- Management System
    - Administered by the Executive Management, this process defines the Quality Policy and sets Quality Objectives, and is responsible for communicating these to all ranks within the company. This process is also responsible to ensure general availability of resources and information necessary to support the company operations.
    - Executive Management, with assistance from the Departmental Management, has the overall responsibility to implement actions necessary to achieve planned results and maintain effectiveness of the company processes.
- Sales/Contract Review
    - Input to this process is in the form of inquiries, requests for quotation or purchase orders/contracts from the customers. Each inquiry or contract received is reviewed to ensure that the customer requirements, both technical and commercial, are adequately defined and documented. The results from this process will be the inputs to either the Engineering or Operations functions.
- Operations
    - This process encompasses the Production Control, Purchasing, Warehousing, Manufacturing, Test & Calibration and Shipping functions of the company. This complex process has inputs typically coming from either the Sales or Engineering functions into the Production Control function, which then forms the feeder to the remainder of the Operations process. The typical final output from the Operations

process is the manufactured Product. The Product will be verified by the Quality process to ensure compliance to the customer/regulatory/notified body requirements prior to forwarding the Product to the Shipping function for shipment.

- Control of the products/processes outsourced will be administered as outlined in the Purchasing Department procedures.

- Engineering

  - This process involves all research and sustaining engineering activities. Sales and Marketing driven inputs to this process result in products engineered to specific customer needs or designed to fulfill discovered market opportunities.

- Quality Assurance

  - This process is responsible to ensure continued compliance of company's Quality System to various standards adopted by the company.

  - This process has the responsibility to ensure that the requirements of the customers, regulatory bodies, notified/registrar bodies and of company's internal procedures are in harmony and are reflected in our products, and in the event of any nonconformance, take necessary steps, including Corrective & Preventive actions, to correct such nonconformance.

  - This process is responsible to maintain continued compliance to company's Quality System through periodic internal audits.

- Human Resources

  - This process is responsible to ensure that the personnel performing work affecting product quality and related supporting functions are competent, based on appropriate education, training, skills and experience.

- Customer Service

  - This process is responsible for all product related field issues. This process also maintains metrics to measure company's performance related to post-sales customer feedback and vigilance en route to maintaining continual customer satisfaction.

4.2 DOCUMENTATION REQUIREMENTS

4.2.1 GENERAL

This section incorporates by reference our Mission, our Quality Policy and Quality Objective as illustrated elsewhere in this Quality Manual document.

The Quality System is structured into three levels of documentation:

1. Level One is documented in the form of a Quality Manual, which contains the Practices of the company.
2. Level Two documents are the departmental procedures that are referenced in the Quality Manual, which implement the quality system and quality policy.
3. Level Three documents are specific departmental work instructions utilized in most cases to carry out a specific task.

For each type of Medical Device, the company will maintain a device master record (technical file) containing all technical information about the device. Where applicable, the technical file will also include copies of manufacturing processes and installation/maintenance guidelines.

Records in support of the Quality System are maintained as outlined in section 4.2.4.

4.2.2 QUALITY MANUAL

This entire document forms the framework of our Quality Management System, and is hereby incorporated as our Quality Manual. As described elsewhere, this Manual establishes the Scope of our Quality Management System, and outlines various procedures as Reference Documents in support of our Quality Management System.

4.2.3 CONTROL OF DOCUMENTS

- Documents applicable to the Quality System defined in this Quality Manual are subject to review for adequacy, update and approval by authorized personnel prior to issue.

- Documentation will be controlled to ensure availability of current, pertinent and relevant information to all functioning organizations at the points of use.

- Documentation changes are reviewed by the Configuration Control Board (CCB). CCB representatives have access to pertinent information needed to approve/reject changes.

- A Master List of all documents applicable to this Quality System has been established and is maintained and readily available to preclude the use of invalid and/or obsolete documents.

- Documents of external origin necessary to comply with the Quality Management System, such as Standards documents, are under document control.

- Obsolete documents are removed to prevent inadvertent use. Documents that are retained for legal or historic purposes are labeled "obsolete" to ensure they are not mistakenly used. For critical equipment such as nuclear containment monitors and medical devices, the obsolete documents will be maintained for at least the lifetime of the equipment.

4.2.4 CONTROL OF RECORDS

- Documented procedures have been implemented for identification, collection, indexing, access, filing, storage, maintenance and disposition of quality records.

- Records demonstrating conformance to specified requirements and the effective implementation of this quality management system are maintained.

- Records will be legible, retrievable, stored and maintained in a safe, secure environment to prevent damage, deterioration and loss.

- Quality Records retention times are incorporated into the Quality Manual through reference to the Control of Quality Records Procedure CP204.

CLAUSE 5

MANAGEMENT RESPONSIBILITY

5.1 MANAGEMENT COMMITMENT

In our quest for continually improve the quality of our products and to achieve the goals of Customer Satisfaction and applicable statutory and regulatory compliance, the Executive Management of the company is committed to the summary implementation of the Quality Management System in accordance with the framework presented in this Quality Manual.

This objective is achieved through:

- Clear and periodic communications with the management team and the employees regarding the importance of meeting the requirements of the customers, standards, regulatory agencies, registrar and notified bodies and of our Quality Management System. Partial list of forums used for such communications are:
  - Management Review Meetings
  - Staff Meetings
  - Company All-hands Meetings
- Establishment of the Quality Policy and execution of the Quality Objectives.
- Ensuring that requisite resources - qualified personnel, equipment and facility - are in place.

5.2 CUSTOMER FOCUS

Each contract or order that is received is reviewed to ensure that the customer requirements, both technical and commercial, are adequately defined and documented. Our capabilities are assessed in relation to the customer requirements to determine our ability to accept the order. The review will also include any statutory and regulatory requirements related to the product or order.

If the customer's requirements are different from our capabilities, then those differences are communicated to the customer and any issues resolved prior to our accepting the order.

The Customer Service function will address the post-sales product related field issues along with maintaining relevant metrics to measure/monitor company's performance related to post-sales customer feedback and vigilance en route to maintaining continual customer satisfaction.

5.3 QUALITY POLICY

The Top Management of the company is committed to continual improvement of the quality of our products, satisfaction of our customers and compliance with applicable statutory/regulatory requirements. Management is also committed to comply with the requirements and maintain the effectiveness of our Quality Management System.

This Policy is communicated to all ranks within the organization, and is periodically reviewed for its continued suitability.

5.4 PLANNING

5.4.1 QUALITY OBJECTIVES

We assess the success of our Quality Objectives through frequently collected measurable data that are discussed during our periodic Management Review sessions. The specific and measurable Quality Objectives are:

- First Pass Yield
  - Instruments
  - Spares
- Sensor Production Yield
- Price of Nonconformance
  - Cost of Scrap
  - Cost of Rework
  - Cost of Warranty
- On-Time Delivery
  - To our Customers
  - From our Suppliers
- Linear Shipment

5.4.2 QUALITY MANAGEMENT SYSTEM PLANNING

Through the provisions and processes mentioned under the Clause 4.1 of this document, augmented by the company/departmental procedures and work Instructions, the top management of the company ensures that the quality management system complies with the meets the quality policy and strives to achieve the goals set for quality objectives.

Configuration Control Board authorization will be required before implementing any changes to the quality system. Changes to this quality manual will require approval by the top management.

5.5 RESPONSIBILITY, AUTHORITY AND COMMUNICATION

5.5.1 RESPONSIBILITY AND AUTHORITY

This practice defines the company's responsibility, authority, and the interrelationship of all personnel.

The organization is structured functionally with all the department heads reporting directly to the VP/General Manager. The Human Resources and the Finance functions have an indirect reporting responsibility to the General Manager.

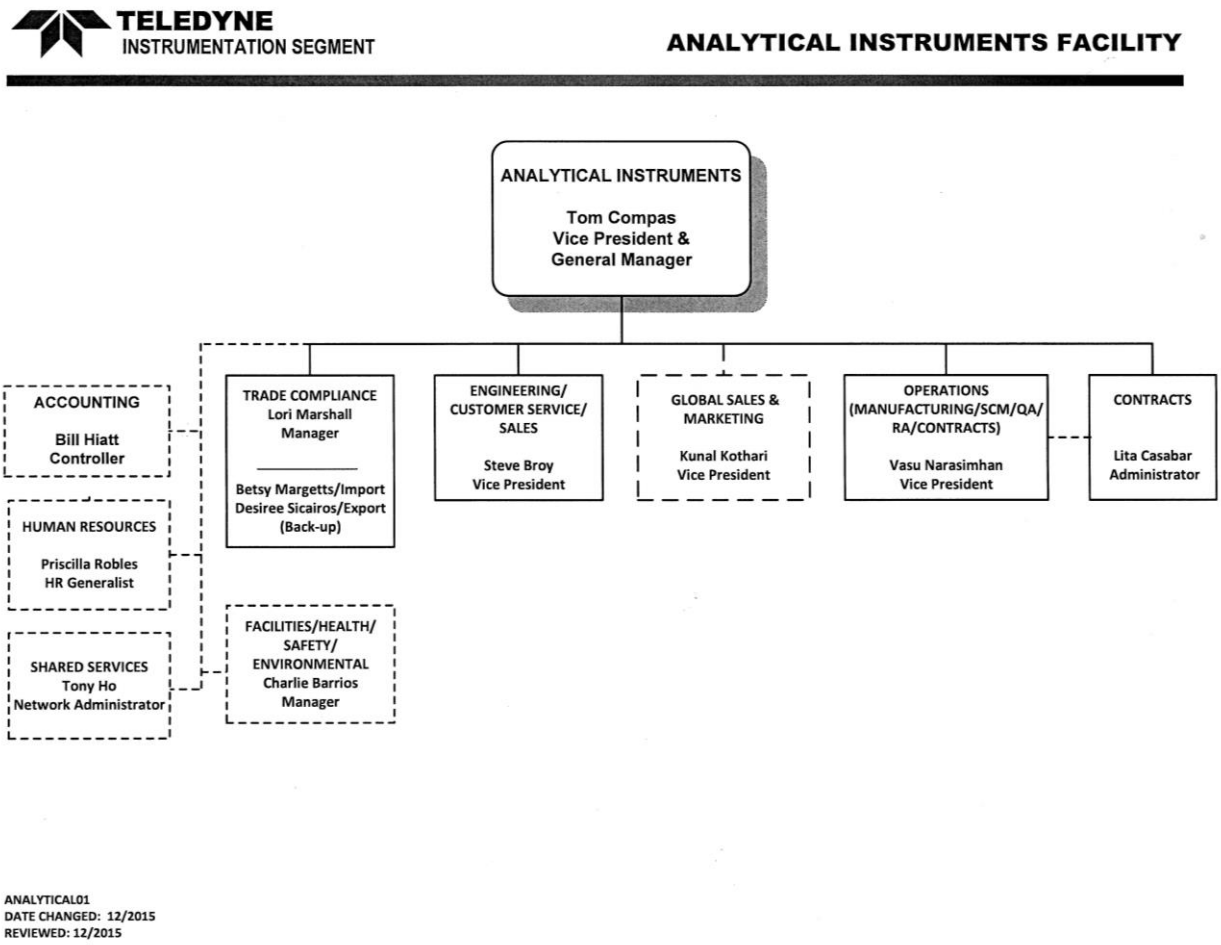
Independent of his/her position, any individual in the company has the authority to stop the product that he/she feels does not meet quality requirements.

All employees are responsible for fulfilling the quality system requirements for their respective areas. All employees have the authority to identify problems and to initiate, recommend or provide solution through their department supervisor, or manager.

Quality Assurance Department principally has the responsibility to identify and record non-conformances, and the authority to initiate action to prevent noncompliance issues to the product, process and quality system.

The Material Review Board (MRB) (consisting of representatives from Production, Engineering and Quality Assurance Departments) is responsible for recommending, providing and implementing solutions to correct and prevent non-conformances.

ORGANIZATIONAL CHART



5.5.2 MANAGEMENT REPRESENTATIVE

The Company's Management Representative reports to the top management, and is assigned with the responsibility and the requisite authority to ensure that the processes required to administer the quality management system are established and implemented.

Management Representative is also responsible for and has the appropriate authority to ensure compliance with the requirements of various Standards/Regulatory/Registrar/Notified bodies.

Management Representative will ensure the promotion of regulatory and customer requirements and is responsible for reporting to company's management on the performance of the Quality System and any recommended changes or improvement to the system.

Management Representative: As appointed by the Head of the Organization, VP of Operations/ QA

5.5.3 INTERNAL COMMUNICATION

The top management will periodically discuss with the company's management team and the employees of the importance of meeting the requirements of the customers, standards, regulatory agencies, registrar and notified bodies and of our Quality Management System.

5.6 MANAGEMENT REVIEW

5.6.1 GENERAL

Top Management will review the Quality System, Policy & Objectives with the company's management team on an annual basis, as a minimum and not to exceed 14 months, to ensure its continued adequacy, suitability and effectiveness, and to discuss opportunities for improving the quality system.

The certified product liaison under the ATEX directive, i.e., authorized person, must attend this review.

5.6.2 REVIEW INPUT

The review shall address the following as a minimum:

- Action items from the previous management review meetings.
- The audit program (internal/external) – Results of previous audits, schedule for the future ones and any quality system improvement opportunities resulting from the audits.
- Status of Corrective & Preventive Actions (internal/external)
- Status of the third party certified products.
- Product conformance profiles and cost of quality discussions.
- Internal (manufacturing) and external (supplier) operational performance – Opportunities and challenges.
- Internal and external (e.g. customer) feedback on product and market performance trends, and recommendations to process improvements.
- The quality system effectiveness with respect to the adopted standard(s).
- Any recommendations for improving the Quality Management System.
- Any new or revised statutory or regulatory requirements.

5.6.3 REVIEW OUTPUT

The Management Review is to facilitate the necessary actions and allocate the resources to improve the quality system, processes and products to comply with customer and statutory/regulatory body requirements.

CLAUSE 6

RESOURCE MANAGEMENT

6.1 PROVISION OF RESOURCES

Company's Management shall identify resource requirements and provide adequate resources to implement the Quality Management System and maintain its effectiveness, enhance customer satisfaction, and to meet regulatory and customer requirements. The term "resources" is used in this paragraph to include Human, Facility and Environmental resources.

6.2 HUMAN RESOURCES

6.2.1 GENERAL

As noted above, the company's Management shall identify the human resource requirements and provide adequate resources to enhance customer satisfaction and meet regulatory and customer requirements. This includes the assignment of trained personnel for management, performance of work and verification activities including internal quality audits.

6.2.2 COMPETENCE, TRAINING AND AWARENESS

This practice defines the provisions made within the company to ensure that all personnel are adequately trained for the tasks that they are required to undertake.

Documented procedures have been implemented to identify training needs and the training of all personnel performing activities affecting product quality and conformity. The objective is to ensure the employees are aware of the importance of, and how they contribute to, their activities.

Personnel performing specific assigned tasks are qualified based on education, experience and/or training.

Records of training are maintained.

6.3 INFRASTRUCTURE

The top management has allocated and maintained the necessary infrastructure in keeping with the strategic growth plans for the company. The infrastructure development includes the building management, workspace development, office/process equipment, communications equipment, information systems and utilities maintenance. The adequacy of company's infrastructure will be reviewed and changes are made as needed to meet the growth initiatives.

6.4 WORK ENVIRONMENT

The company has identified and planned the production and servicing processes that directly affect product quality and shall ensure that these processes are carried out under controlled environment which include:

- Documented procedures defining the method of production.
- Use of suitable production equipment, and a suitable working environment to achieve product conformity.
- Criteria for workmanship as defined in the written standards, representative samples, photos, and/or illustrations.
- Manufacturing equipment maintenance plans to ensure continuing process capability.
- Procedures for Electrostatic Discharge Protection and Personal Protection Equipment to help eliminate any adverse effects due to interaction amongst the personnel, product and the work environment.

CLAUSE 7

PRODUCT REALIZATION

7.1 PLANNING OF PRODUCT REALIZATION

In keeping with the quality management system, the company has adopted the following plan and developed processes and procedures needed to manufacture the product.

- Preparation of Quality Plans (Route Sheets).
- Identification and acquisition of controls, processes, equipment, fixtures, resources and training that may be required.
- Ensuring the compatibility of the design, processes, inspection and testing procedures and applicable documents.
- Ensuring that inspection and testing documents are updated as needed.
- Identification of verification, validation, monitoring and measurement requirements that meet the known state of the art to allow for the development of adequate techniques.
- Identification of required and/or necessary inspection and test operations in the product flow to achieve product acceptance.
- Inspection and test criteria shall be clarified, particularly those criteria that may be subjective.
- Identification and preparation of quality records (For medical devices this includes the device master file).
    - Files shall be maintained defining type and/or model of Medical Device, corresponding product specifications, manufacturing process methods, installation and service, as applicable.
- Any other documentation required by Domestic or International regulations.

Documented procedures have been implemented for inspection and testing activities in order to verify that specified requirements are satisfied. Records of the required inspection and testing are defined in the procedures.

The internal audit process verifies the effectiveness of the product realization plan.

7.2 CUSTOMER-RELATED PROCESSES
7.2.1 DETERMINATION OF REQUIREMENTS RELATED TO THE PRODUCT,
7.2.2 REVIEW OF REQUIREMENTS RELATED TO THE PRODUCT

7.2.3 CUSTOMER COMMUNICATION

Requests for proposal or contracts or orders are reviewed to ensure that the customer requirements, both technical and commercial, are adequately defined and documented. Our capabilities are assessed in relation to the customer requirements to determine our ability to accept the order. The review will also include any statutory and regulatory requirements related to the product or order.

If the customer's requirements are different from our capabilities, then those differences are communicated to the customer and any issues resolved prior to our accepting the order.

Amendments to contracts are identified and revised requirements are distributed to appropriate functions. When applicable, contract amendments will be evaluated to ensure compatibility with registrar/notified body certifications.

The proposal, product brochure or the order acknowledgement will serve as the document to confirm the requirement of the customer.

The records of the review will be maintained.

The Customer Service and Quality Assurance functions will perform the post-sales product related customer communications along with maintaining relevant metrics to measure/monitor company's performance related to post-sales customer feedback and vigilance, including handling customer complaints and issuance of any advisory notices.

7.3 DESIGN AND DEVELOPMENT

7.3.1 DESIGN AND DEVELOPMENT PLANNING

Plans are prepared for each design and development activity. The plans describe or reference these activities, including verification and/or validation actions deemed appropriate for each design and development stage. The plan also assigns responsibilities to qualified employees for completion of the activities, including the design transfer activities prior to production. The plans are updated as designs evolve.

Resource and Technical Interfaces between different departments of the company that provide input into the design process are documented, transmitted and reviewed.

7.3.2 DESIGN AND DEVELOPMENT INPUTS

All design requirements such as functional/performance, statutory/regulatory and safety requirements and statutes related to the product design and intended use are identified, documented, reviewed and approved. Incomplete, ambiguous and conflicting requirements are resolved with personnel imposing these requirements. When applicable, the design input process will take into consideration the results of any contract review activities, requirements of any statutory/regulatory bodies and the result of risk management study.

7.3.3 DESIGN AND DEVELOPMENT OUTPUTS

All design outputs are verified/validated, documented, maintained against the design input requirements. Design output requirements shall meet or exceed the input requirements, contain or reference acceptance criteria and identify those characteristics that are crucial to product safety and the safe and proper functioning of the product. Design output documents are reviewed for completeness prior to release to purchasing, production and service functions. Records of the activity are maintained.

7.3.4 DESIGN AND DEVELOPMENT REVIEW

At appropriate stages of design and before product release, formal design reviews are conducted in accordance with the Design and Development Planning. Representatives of all functions involved in that stage of the design, competent independent observer, and others as deemed necessary will participate in these reviews. Review records are maintained.

7.3.5 DESIGN AND DEVELOPMENT VERIFICATION

Verification of design is conducted at appropriate stages to ensure that the design stage output meets the design stage input requirements. These verification measures are recorded.

7.3.6 DESIGN AND DEVELOPMENT VALIDATION

Design validation is performed to ensure that the product conforms to defined user needs and/or requirements. Validation shall be completed prior to production activities. Where necessary, such validation shall entail off-site studies such as EMI/RFI studies, clinical trials, and the like. The validation records are maintained.

7.3.7 CONTROL OF DESIGN AND DEVELOPMENT CHANGES

Before implementation, design changes and modifications are identified, documented, reviewed and approved by authorized personnel.

7.4 PURCHASING

7.4.1 PURCHASING PROCESS

The suppliers are selected based on their ability to meet company's Quality System requirements.

Measures of evaluation, selection, and re-evaluation of sub-contractors are documented and shall include one or more of the following:

- Type of product
- Evaluation of the sub-contractor's previous inspection history.
- Sub-contractor's technical and quality capability as determined by an audit of the sub-contractor's facility and quality system.
- Sub-contractor's achievement of an internationally approved quality system.
- The impact of the supplied product in meeting the quality of the final product.

Records of approved suppliers are maintained.

7.4.2 PURCHASING INFORMATION

Purchase Orders and documents containing requirements for products being ordered shall include, as applicable:

- Type, class, grade or other precise identification.
- Positive identification, including titles, numbers, revision levels, special requirements and instructions, including approval or qualification of product, procedures, traceability (critical components and materials), process equipment and personnel.
- Applicable Quality System standards.

Procurement documents are reviewed and approved for adequacy of the specified requirements prior to release. Copies of the purchase orders are maintained.

7.4.3 VERIFICATION OF PURCHASED PRODUCT

Right to verify materials at source, when necessary, will be specified in the purchase document.

Where required by contract, right of access to company's and sub-contractor facilities/records for product verification will be made available.

Verification of product by the customer shall not be used by the company as evidence of effective control of quality by the sub-contractor.

Verification of product by the customer does not absolve the company of the responsibility to provide acceptable product, nor does it preclude subsequent rejection by the customer.

No purchased product shall be used until it has been inspected, or otherwise verified as conforming to specified requirements, or considered dock-to-stock based on vendors' history. Activity records are maintained.

7.5 PRODUCTION AND SERVICE PROVISION

7.5.1 CONTROL OF PRODUCTION AND SERVICE PROVISION AND
7.5.2 VALIDATION OF PROCESSES FOR PRODUCTION AND SERVICE PROVISION

These practices define the way in which the manufacturing and servicing processes will be controlled, and where required, validated.

Company has identified and planned the production and servicing processes that directly affect product release, product quality, delivery and post-sales activities, and shall ensure that these processes are carried out under controlled infrastructure which include:

- Documented procedures and work instructions defining the method of production.
- Use of suitable production, monitoring and measuring equipment and a suitable working environment to achieve product conformity.
- Monitoring and control of suitable process and production parameters.
- The approval of processes and equipment, as appropriate.
- Criteria for workmanship as defined in written standards, representative samples, photos, and/or illustrations.
- Manufacturing equipment with maintenance plans to ensure continuing process capability.

- Protection of products after final inspection and test. Where required, this protection will be extended to the delivery to destination.
- Servicing process control, utilizing post-production activities or customer feedback. Records of any factory service performed shall be maintained.
- Validation of any software.

Any process that cannot be verified by subsequent inspection and testing will be carried out by qualified operators and/or the process parameters will be controlled and monitored continuously and revalidated, as necessary, to ensure specified requirements are met. The requirement for qualification of any operation or operator will be documented and records maintained.

EXCEPTIONS TO ISO 13485:2003 STANDARDS:

7.5.1.2.1

Medical devices supplied by the company are not sterile devices nor or they designed to be sterilized in use. Their cleanliness is not significant in use. Hence, the referenced clause of the standard is not applicable to the company.

7.5.1.2.2:

Devices supplied are oxygen analyzers, monitors and sensors, requiring no factory assisted installation.

7.5.1.3:

Not applicable as the devices supplied are not sterile devices.

7.5.2.2:

Not applicable as the devices supplied are not sterile devices.

7.5.3 IDENTIFICATION AND TRACEABILITY

This practice defines how product identification and traceability will be maintained.

Product shall be identified through all stages of production to delivery. Identification will be provided through physical identification (marking or tags) wherever practical. When physical identification is impractical, appropriate means of identification will be used.

When traceability is a specified requirement, the company maintains procedures that define the method used for the identification of the individual product or lot to specific documentation such as purchase order, work order and/or sales order number. This identification will be recorded.

The inspection and test status of product are identified by suitable means (e.g. monitoring, measurement), which indicate the conformance or nonconformance of product with regard to inspections and tests performed. Records of inspection and test are maintained.

EXCEPTIONS TO ISO 13485:2003 STANDARD:

7.5.3.2.2:

Not applicable as supplied devices are not implantable devices.

7.5.4 CUSTOMER PROPERTY

The company ensures that any customer supplied product or information for incorporation into the final product is identified, verified, stored, and maintained. If such a property is inadvertently lost, damaged, or otherwise found unsuitable for use, this shall be reported to the customer and records shall be maintained.

7.5.5 PRESERVATION OF PRODUCT

Documented procedures have been implemented for identification, handling, storage, packing, preservation and delivery of the product.

Product is handled in such a way as not to damage the product.

Designated storage areas are used to prevent damage to the product pending use or delivery.

Product will be packaged and marked to insure product quality and identification requirements are maintained.

Product is preserved through appropriate methods to ensure ongoing fitness for use. Product subject to deterioration with age or with a specified shelf life will be controlled.

7.6 CONTROL OF MONITORING AND MEASURING EQUIPMENT

Documented procedures have been implemented to control, calibrate and maintain inspection, measuring and test equipment used to demonstrate conformance of product to specified requirements.

The inspection, measuring and test equipment will be used in a way that is consistent with the measurements it is required to make.

Inspection, measuring and test equipment are identified, calibrated and adjusted at prescribed intervals against certified equipment having known relationships to national or international standards. Where no such standards exist, the basis for calibration shall be documented.

Steps are taken to ensure that the environmental conditions are suitable when calibration of inspection, measurement and test equipment is performed.

Inspection, measuring and test equipment are tracked by equipment type, unique identification, location, frequency of checks, check method, acceptance criteria, and action to be taken when the results are unsatisfactory.

Test software and hardware are tested on a regular basis to ensure continuing suitability. Records or such checks are maintained.

Where required by customers, technical data on inspection, measuring and test equipment shall be available.

Inspection, measuring and test equipment have their calibration status clearly identified and verifiable by the operator/inspector.

When inspection, measuring and test equipment are found to be out of calibration, an evaluation shall be made and documented to address product tested on the suspect inspection, measuring and test equipment.

Records for calibration of inspection, measuring and test equipment are maintained.

Inspection, measuring and test equipment are stored in such a way that fitness for use is maintained, and are safeguarded against adjustments that would invalidate calibration.

CLAUSE 8

MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 GENERAL

As discussed elsewhere, through the provisions and processes mentioned under the Clause 4.1 of this document and augmented by the company/departmental procedures and work Instructions, the company ensures that proper monitoring, measurement, analysis and improvement processes are established to ensure conformity to and maintain/improve the effectiveness of the quality management system.

Documented procedures have been implemented for inspection and testing activities in order to verify that specified requirements for the product are satisfied. Records of the required inspection and testing are defined in the procedures.

Statistical techniques are employed where applicable for establishing, controlling and verifying process capability and product characteristics. The key performance indicator (KPI) data are collected and analyzed for trends and identification of improvement opportunities. The data will be distributed for management and factory personnel knowledge and awareness.

8.2 MONITORING AND MEASUREMENT

8.2.1 CUSTOMER SATISFACTION AND FEEDBACK

As part of the KPI data, the company will gather post-sales product performance and customer feedback data for analysis and possible implementation of improvements to ensure that the company has met the customer requirements and has achieved continued customer satisfaction. The aspects of customer perception on our performance and customer satisfaction are crucial to the survival of the company. These performance indicators are verified and validated during the pre-sales and post-sales customer visits undertaken by various personnel of the company.

8.2.2 INTERNAL AUDIT

This practice defines the conduct of internal quality audits. The intent is to monitor and measure quality system processes and demonstrate ability of the system to achieve planned results.

Documented procedures have been implemented for the performance of regularly scheduled internal quality audits to verify that activities and related results comply with planned arrangements and to determine the effectiveness of the quality system.

Audits are planned and scheduled based on the status and importance of the activity being audited. Individuals who do not have direct responsibility for the activities being audited perform these audits.

Audit results will be recorded and reported to personnel responsible for the activity being audited. The management personnel responsible for the area will take timely corrective action on deficiencies noted during the audit.

Should a nonconformity discovered during the internal audit be significant as to affect the product quality or safety if not immediately corrected, the management of the area being audited shall ensure that immediate and necessary corrections are implemented, and then determine the cause for such a nonconformity and take corrective actions to prevent occurrence.

Follow-up audit activities will be utilized to verify and record the implementation and effectiveness of any corrective action taken.

Results of internal audits shall comprise part of the management review.

8.2.3 MONITORING AND MEASUREMENT OF PROCESSES

As discussed elsewhere, through the provisions and processes mentioned under the Clause 4.1 of this document, the company ensures that proper monitoring, measurement, analysis and improvement processes are established to ensure conformity to and improve the effectiveness of the quality management system.

When the inspection, statistical data (KPI) or the internal audit processes discover that the planned results are not achieved, correction through an ECO or corrective action, as appropriate, will be taken to ensure conformity to the plan.

8.2.4 MONITORING AND MEASUREMENT OF PRODUCT

No product shall be used until it has been inspected, or otherwise verified as conforming to specified requirements. Verification of the specified requirements is performed to the Quality Plan and/or documented procedures.

In-process inspection and test steps are defined in the Quality Plan and/or procedures.

All Final Inspection and Testing will be completed in accordance with the Quality Plan and/or documented procedures to complete the evidence of conformance of the finished product to the specified requirements.

In addition to the inspection of finished product characteristics, checks will be made to establish that all previous inspections and tests have been carried out with satisfactory results.

Product will not be released until all required inspections and tests determine product has conformed to requirements or deviations have been approved by the customer or relevant authority.

Records of inspection and test are maintained. These records clearly show whether the product has passed or failed the inspections and/or tests defined in documented criteria. Products that fail any inspection and/or test will be handled in accordance with the procedure for control of nonconforming products.

Records are also maintained of the individuals having authority and responsibility to release product.

EXCEPTIONS TO ISO 13485:2003 STANDARD:

8.2.4.2: Not applicable as the devices supplied are not implantable devices.

8.3 CONTROL OF NONCONFORMING PRODUCT

Documented procedures have been implemented to ensure that product that does not conform to specified requirements is prevented from unintended use, installation or delivery.

The system for the control of nonconforming product provides for the identification, documentation, evaluation, segregation, disposition of nonconforming product and notification to the functions concerned.

The responsibility for review and authority for disposition of nonconforming product is defined in documented procedures. The review and disposition of Nonconforming product such as use as is, reject, repair or rework is performed in accordance with documented procedures. Where required, any statutory/regulatory guidance shall be considered.

When required by contract, product that does not conform to the customer's specification will only be used or supplied with the customer's prior knowledge and written consent. A

description of the actual condition that has been accepted, with possible concessions or deviations, shall be recorded.

Any product that is repaired or reworked shall be reinspected according to a Quality Plan and/or documented procedure.

8.4 ANALYSIS OF DATA

Statistical techniques are applied to gather and analyze the KPI data to demonstrate the effectiveness of the quality management system and evaluate steps towards continual improvement of the system, and helps gauge customer satisfaction. Results of the analysis will be discussed at the management review meetings.

8.5 IMPROVEMENT

8.5.1 CONTINUAL IMPROVEMENT

As mentioned elsewhere, through the provisions and processes mentioned under the Clause 4.1 of this document, augmented by the company/departmental procedures and work Instructions, the company ensures that the quality management system meets the quality objective and policy guidance.

In the quest for continually improving the quality of our products and achieving the ultimate goal of Customer Satisfaction, the company is committed to the summary implementation of the Quality Management System, including using the avenues of audit results, analysis of data, corrective & preventive actions and continual customer communication.

The effectiveness of the quality management system will be discussed during the management review meetings.

Organization has established “Medical Product Complaint Handling” and “Product Recall” procedures that act as vehicles to the issuance of customer advisory notices when required.

Customer Complaint Reports generated per Complaint Handling procedure shall be maintained. When the investigation reveals factors outside of the company may have contributed to the complaint, such information will be shared with the customer and other relevant organizations.

The Customer Complaint Report (CCR) discusses the disposition of customer complaints, and identifies the need for any failure analysis that may lead to corrective/preventive actions. The

CCR also identifies the need for any reporting to the Regulatory authorities based on the Medical Product Complaint Handling procedure.

8.5.2 CORRECTIVE ACTION

Documented procedures are in place for implementing corrective and preventive action.

The company ensures that conditions adverse to quality such as customer complaints, returns, product nonconformities and supplier issues, including on the degree of magnitude and risk of the nonconformity, are identified and corrected.

When processes are changed as the result of corrective actions, these changes shall be institutionalized and appropriate procedures updated.

Company ensures customer complaints and reports of nonconformities are handled in a timely, effective manner.

The corrective action will include investigation of the cause of the nonconformities relating to product, process and quality system, and recording the results of the investigation.

The investigation includes the corrective action necessary to prevent recurrence.

Controls include follow-ups to ensure that the corrective actions are completed and effective.

8.5.3 PREVENTIVE ACTION

Preventive action shall be taken as necessary pursuant to the

- Audit results.
- Assembly, Test, Inspection and Process yield trends.
- Customer complaints/data.

These measures are analyzed in order to detect and eliminate potential causes of nonconformities.

The preventive action system includes the determination of steps needed to deal with any problem requiring preventive action. Preventive action system includes the initiation of preventive actions and checks to ensure that the preventive actions are effective.

Such action will be documented and discussed during the management review.

ADDENDUM A

MEDICAL DEVICE REGULATORY COMPLIANCE

A. PURPOSE

This practice defines company's methods of complying with United States Food and Drug Administration (Code of Federal Regulations 21CFR Part 820), European Medical Devices Directive, Canadian Medical Device Regulation, and other applicable statutory and regulatory requirements.

B. PRACTICE

Documented procedures have been implemented to review, evaluate and file all complaints; to determine if an investigation is necessary; to record the reason if no investigation is made; assign responsibility for deciding when not to investigate; and, designate the personnel to perform these activities.

ADDENDUM B

SARBANES-OXLEY 404 - INTERNAL CONTROLS COSO FRAMEWORK

This document is under the control of the Plant Controller or designee, and is not a part of company's Quality Management System, hence, not auditable under ISO 9001:2xxx, ISO 13485:2xxx or other Company-adopted quality standards.

This document will form the guiding document for our internal financial controls, and will be the framework for any Corporate Internal and External audits.

ADDENDUM C

CONTACT INFORMATION

This addendum lists various regulatory, registrar and notified bodies that are relevant to our business.

Standards, Directives, Regulations	Regulatory/Notified Body/Registrar Contact Information
ISO 9001:2xxx	Registrar: Intertek Testing Services 70 Codman Hill Road, Boxborough, MA 01719 T: 978-929-2100; F: 978-635-8595 Intertek-sc@intertek.com
ISO 13485:2xxx and Canadian Medical Device Regulations	Registrar: BSI Management Systems, Inc., 12110 Sunset Hills, Ste. 200, Reston, VA 20190 T: 703-437-9000; F: 703-437-9001 Inquiry.msamericas@bsigroup.com
European Medical Devices Directive	Notified Body: BSI Product Services Kitemark House, Maryland Avenue Hemel Hempstead, HP2 4SQ, UK T: 011-44-1442 278 625; F: 011-44-1442 278 575 Product.Services@BSIGroup.com Competent Authorities: For a current list, refer to http://ec.europa.eu/enterprise/medical_devices/ca/list_ca.htm Master Distributor: Viamed Limited 15 Station Road, Cross Hills, Keighley, West Yorkshire BD20 7DT, UK T: 011-44-1535 634542; F: 011-44-1535 635582 enquiries@viamed.co.uk
US FDA QSR (21CFR820) 510(k) inquiries	Food and Drug Administration Center for Devices and Radiological Health Office of Device Evaluation (HFZ-401) 9200 Corporate Boulevard Rockville, MD 20850

ADDENDUM E

OBLIGATION TO INFORM (THIS SECTION WILL BE UPDATED AS NEEDED)

Send/Report What?	To Whom?	By Who?	By When?
ISO 9001:2xxx Certificate (Number 96-653x)	Customers and others, as needed	Sales and others, as requested (Either send a copy or refer to our web pages)	As required
ISO 13485:2xxx Certificate (Number FM 75659)	Customers and others, as needed	Sales and others, as requested (Either send a copy or refer to our web pages)	As required
ISO 13485:2xxx Certificate (Number FM 75659)	Health Canada, Medical Devices Bureau	Quality Assurance (With HC form to submit QMS certificate via fax 613-957-6345)	Within 30 days of issuance of new or revised certificate
Medical Device License Renewal Form (License # 8339, 66350 & 66351)	Health Canada, Device Licensing Services	Quality Assurance	Every year, before November 1
Device Manufacturing License Renewal Form (License # 60335)	State of California, Dept of Public Health Food & Drug Branch	Quality Assurance	Before July 1 of the year the license expires
Medical Device – Adverse Event, Significant Change to Product, Process or Quality System	Regulatory Bodies (FDA, MDD, HC, TGA, and others as applicable); EU Competent Authorities; Notified Bodies;	Quality Assurance (Refer to Adverse Event Notification guidelines on the web pages of various regulatory bodies in countries where we market our products to)	As indicated on CP207 – Medical Product Complaint Handling
Defect or failure to comply (Nuclear Containment Monitors and spare parts thereof)	The Regional NRC and the Utilities	Quality Assurance (Refer to CP205 and to the current version of 10CFR21 regarding reporting requirements)	As indicated on CP205.