exsurco® medical

QUALITY SYSTEM MANUAL

ISO 13485 U.S. QSR (21 CFR 820)

RELEASED

Name/Date: [illegible] 07-01-22

EXSURCO MEDICAL
10804 GREEN ROAD WAKEMAN OH. 44889

INTRODUCTION

Exsurco Medical, Inc. developed and implemented a Quality Management System to document the company's best business practices, better satisfy the requirements and expectations of its customers and improve the overall management and performance of the company.

The Quality Management System of Exsurco meets the requirements of the international standards ISO 13485 and U.S.QSR (21 CFR 820). This system addresses the design, development, production, distribution and servicing of the company's product(s).

The manual is divided into eight sections that correlate to the Quality Management System sections of ISO 13485 and U.S.QSR (21 CFR 820). Each section begins with a statement outlining Exsurco's commitment to implement the basic requirements of the referenced Quality Management System section. Each statement is followed by specific information pertaining to the procedures that describe the methods used to implement the necessary requirements. In Appendix B a list of all procedures is referenced.

This manual describes the Quality Management System, delineates authorities, inter-relationships, and responsibilities of the personnel responsible for performing within the system. The manual also provides procedures or references for all activities comprising the Quality Management System to ensure compliance to the necessary requirements of the standard.

This manual is used internally to guide the company's employees through the various requirements of the ISO and US QSR standards that must be met and maintained in order to ensure customer satisfaction, continuous improvement and provide the necessary instructions that create an empowered work force.

This manual is used externally to introduce our Quality Management System to our customers and other external organizations or individuals. The manual is used to familiarize them with the controls that have been implemented and to assure them that the integrity of the Quality Management System is maintained and focused on customer satisfaction and continuous improvement.

Sara Ann MacKinlay, President — Date: 07-01-2021

Swasita Saigal, Vice President of Technical Operations & Compliance — Date: 07-01-2021

Kayli Camp, Technical Operations & Quality Manager — Date: 07-01-2021

COMPANY PROFILE

Exsurco Medical is a leading-edge equipment manufacturer for tissue bank and manufacturer and distributor of surgical applications committed to improving grafting and excision results by providing devices and instruments for tissue recovery and processing. Its products have been designed to meet the applicable regulatory requirements and the requirements of its customers, but are propriety in design, not designed to customer specifications. Exsurco Medical is located at 10804 Green Road Wakeman, OH 44889 (corporate location).

QUALITY POLICY

As a responsible company, Exsurco Medical will conduct business with integrity and our commitment is based on "Quality without Compromise". Our policy is as follows:

QUALITY POLICY

EXSURCO MEDICAL is committed to a policy of "**QUALITY WITHOUT COMPROMISE**"

We are committed to exceeding our customers' expectations by developing and delivering safe and effective medical devices. Through vigilant implementation and maintenance of our quality management system, we are committed to the highest quality standards for the patients we serve.

We will achieve this by:

- **Complying with applicable quality, safety, legal, and regulatory requirements**
- **Monitoring our customers' total experience**
- **Continuously developing and improving medical devices that redefine excision science**
- **Conducting ourselves with integrity and striving for excellence in all we do**

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4.0 SCOPE

1.1 GENERAL

1.1.1 The Quality System defined in this manual is designed to meet the needs of Exsurco Medical in the operation of its business and has been developed from the business principles expressed in the Mission Statement, and the Quality Policy.

1.2 APPLICATION

1.2.1 The Quality Management System of Exsurco meets the requirements of the international standards ISO 13485 and U.S.QSR (21 CFR 820). This system addresses the design, development, production, distribution and servicing of the company's product(s).

1.3 NON-APPLICATION

1.3.1 The following applications do not apply to Exsurco Medical based on the intended use and indications for use of products:

- ISO 13485, 7.5.1.2.2- Installation activities for medical device
- ISO 13485, 7.5.3.2.2- Requirements for active implantable medical devices and implantable medical devices
- ISO 13485, 8.2.4.2- Requirements for active implantable medical devices and implantable medical devices

2.0 REFERENCES

2.1 GENERAL

2.1.1 The Exsurco Medical Quality Management System has been developed to be in compliance with the applicable requirements and most recent revision of the ISO 13485 and U.S. QSR (21 CFR 820). Exsurco's Quality Management System is ISO 13485certified for the scope of design, manufacture, distribution and servicing of power-operated excision equipment, air operated excision and grafting and mechanical instruments and replacement blades used in Cadaveric and Surgical settings.

3.0 TERMS AND DEFINITIONS

3.1 GENERAL

3.1.1 For the purposes of this document, the terms and definitions given in ISO 13485 and U.S. QSR (21 CFR 820) apply.

4.0 QUALITY MANAGEMENT SYSTEM

4.1 GENERAL

4.1.1 Exsurco Medical has established, documented, implemented and maintained a Quality Management System (QMS) in accordance with the requirements of ISO 13485 and U.S.QSR (21 CFR 820). The effectiveness of the QMS is maintained and the system continually improved with the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action, event review team meetings and management review. To design and implement the QMS Exsurco Medical has:

- Identified the processes needed for the QMS and their application throughout the organization.
- Ensure risk-based approach is applied to appropriate processes needed for the quality management system.
- Determined the sequence and interaction of these processes.
- Determined criteria and methods needed to ensure that the operation and control of the processes are effective and documented them in quality plans and work instructions.
- Ensured the continuing availability of resources and information necessary to achieve planned results and continual improvement of these processes.
- Ensured that Exsurco employees are trained to understand our Quality procedures and their application.
- Established systems to monitor, measure and analyze these processes.
- Established processes to identify and implement actions necessary to achieve planned results and continual improvement of these processes.
- Ensure software validation of eQMS as required.
- Ensured that applicable regulatory requirements are identified and met.

4.2 DOCUMENTATION REQUIREMENTS

4.2.1 The QMS documentation includes:

- A documented Quality Policy
- Quality Objectives
- This Quality Manual
- Documented Procedures, Work Instructions and Forms.
- Documents identified as needed for the effective planning, operation and control of our processes.
- Quality Records
- Any other documentation specified by national or regional regulations.
- Each procedure, activity or special arrangement that has been documented is also implemented and maintained.

4.3 CONTROL OF PROCEDURES AND RECORDS

4.3.1 Procedures to control the development, release and revision of documents have been established (See Appendix B for reference).

5.0 MANAGEMENT RESPONSIBILITY

5.1 MANAGEMENT COMMITMENT

5.1.1 Executive management has been actively involved in implementing the quality management system (QMS). It has provided the vision and strategic direction for the growth of the QMS, and established quality objectives and the quality policy.

5.1.2 The procedure covering Management Responsibility (See Appendix B for reference) is established and maintained. Executive management provides evidence of its commitment to meeting requirements for the design, manufacture, distribution, and support of safe and effective medical devices through the quality management system and maintaining its effectiveness by:

- Communicating the importance of meeting customer, statutory, and regulatory requirements throughout the organization.
- Establishing quality objectives.
- Establishing the quality policy.
- Conducting at a minimum annual Management Reviews. Reporting of quality data occurs quarterly at Event Review Team Meetings and annually at Management Review or more frequently as needed.
- Reviewing the quality system during Management Reviews.
- Ensuring that the resources necessary to maintain and continually improve the QMS are available, including a quality assurance unit.

5.2 CUSTOMER FOCUS

5.2.1 Exsurco's Executive Management ensures that current and future customer requirements and regulatory requirements are determined and are met.

5.2.2 Executive management ensures that customer requirements are understood and met, by requiring compliance with documented customer communication procedures. Customer requirements are determined, converted into internal requirements, and communicated to the appropriate employees in our organization.

5.3 QUALITY POLICY

5.3.1 The Quality Policy has been established to provide the framework for the development and implementation of a QMS that will assure design, product, and customer service quality. The policy clearly states our commitment to regulatory compliance and meeting customer requirements and provides the framework for establishing quality objectives. It is annually reviewed for suitability during the company's annual Strategic Planning process and is communicated throughout the organization annual via email with an update on Management Review. In addition, it is posted throughout the organization (i.e. offices and manufacturing floor) to ensure employees understanding and awareness.

5.0 MANAGEMENT RESPONSIBILITY CONTINUED

5.4 PLANNING

5.4.1 Quality objectives

5.4.1.1 Executive Management ensures that quality objectives, including those needed to meet product or service requirements, are established at relevant functions and levels at Exsurco Medical. These objectives define the relevant quality practices, resources, and activities. Quality objectives are measurable and consistent with the quality policy.

5.4.2 Quality Management System Planning

5.4.2.1 QMS planning consists of the implementation, updating and maintenance of the Quality Manual and the supporting processes and procedures. Quality planning also includes maintaining the integrity of the QMS when changes are planned and implemented.

5.5 RESPONSIBILITY, AUTHORITY AND COMMUNICATION

5.5.1 Responsibility and authority

5.5.1.1 Exsurco Medical defines and documents responsibilities and authorities in job descriptions and organizational charts and procedures. Responsibilities and authorities are communicated within the organization.

5.5.2 Management representative

5.5.2.1 The President, Exsurco Group, who is appointed by the CEO of Red Barn Holdings has been assigned the role of Management Representative. The Management Representative has the authority and responsibility to ensure that the QMS requirements are established, implemented and maintained and that the system complies with the requirements of the regulations and standards listed in section 2.1. The organizational structure provides the Management Representative with unobtrusive access to the quality conduct of the organization.

5.5.2.2 The role of management representative includes the reporting to Executive Management on the effectiveness of the QMS through the management review process and creating awareness throughout the organization of statutory, regulatory, and customer requirements.

5.5 RESPONSIBILITY, AUTHORITY AND COMMUNICATION CONTINUED

5.5.3 Internal communication

5.5.3.1 Executive Management ensures that the appropriate communication processes are established, and that communication takes place regarding the effectiveness of the QMS.

5.5.3.2 Communication is achieved through internal auditing, training, meetings, nonconformance, corrective actions, preventive actions, complaint feedback, investigations, event review team meetings and management reviews and any other tool that may be developed and implemented to monitor the effectiveness of the QMS or to continually improve the system.

5.6 MANAGEMENT REVIEW

5.6.1 Executive Management and the Management Representative review the QMS at planned intervals (at a minimum annually). The purpose of the review is to assess the adequacy, effectiveness, and continuing suitability of the QMS. The review includes assessing opportunities for improvement and the need for changes to the QMS, including the quality policy and quality objectives. Records from the management review meetings are maintained.

6.0 RESOURCE MANAGEMENT

6. 3 INFRASTRUCTURE

6.3.1 Exsurco maintains an infrastructure necessary to achieve product and service quality standards and QMS compliance.

6.3.1.1 Buildings, workspaces and associated utilities are suitably designed and configured to facilitate cleaning, maintenance and orderly process flow.

6.3.1.2 Process equipment and supporting services are provided and maintained as needed for conformity to product/service requirements.

6.3.1.3 The layout of workspaces ensures that appropriate separation of activities is maintained to prevent adverse occurrences, such as contamination or mix-ups.

6.3.1.6 Sewage, trash and other refuse is removed from buildings and premises in a safe and sanitary manner.

6.3.1.7 Exsurco Medical maintains buildings in a good state of repair.

6.3.1.8 Documented procedures are established for maintenance activities, including their frequency, when such activities or lack thereof can affect product/test quality. Records of maintenance are maintained.

6.4 WORK ENVIRONMENT

6.4.1 Exsurco Medical ensures that the work environment necessary to achieve conformity to product/service requirements is achieved through the following activities:

6.4.1.1 Exsurco Medical establishes documents outlining the health, cleanliness and clothing of personnel if contact between an employee and the product or work environment could adversely affect the product.

6.4.1.2 Exsurco Medical provides personnel appropriate clothing and personal protective equipment for the duties they perform as needed.

6.4.1.3 Exsurco Medical ensures that adequate clean toilet facilities and washing facilities are provided, including hot and cold water, soap and single-service towels that are accessible to work areas.

6.4.1.4 Exsurco Medical maintains all buildings in a clean and sanitary condition free of infestation by rodents, birds, insects or other vermin.

6.4.1.5 Exsurco Medical establishes and maintains documented procedures for sanitation describing methods and responsibility. Use of cleaning and sanitizing agents, as well as the use of insecticides is detailed to ensure the prevention of contamination or harm to product or testing activities.

6.4.1.6 Exsurco Medical establishes documents outlining the work environment requirements, such as humidity, temperature or lighting, if the work environment could adversely affect the product quality. Procedures for monitoring work environment conditions are also established and records of monitoring are maintained.

6.4.1.9 Exsurco Medical ensures personnel who must work temporarily under special environmental conditions are appropriately trained or supervised by a trained Associate.

6.4.1.10 Exsurco Medical establishes documents outlining the procedure to follow in the event products are contaminated in order to prevent contamination of other products, the work environment or personnel.

7.0 PRODUCT REALIZATION

7.1 PLANNING OF PRODUCT REALIZATION

7.1.1 Exsurco Medical uses a product development process that utilizes a series of Gates and Stages for product realization (Stage Gate Process ®) and is consistent with other processes of the QMS. The following are considerations for the planning of product realization;

- Determination of product performance requirements
- Determination of product and process specifications
- Determination of purchasing requirements
- Determination of information requirements
- Determination of compliance requirements
- Other requirements that may not be specified but may be necessary for intend use.

7.1.2 Risk management is an integral part of the product realization process at established stages in the product life cycle.

7.2 CUSTOMER RELATED PROCESSES

7.2.1 Determination of requirements related to the product.

7.2.1.1 Exsurco Medical only produces products to its own product specifications and does not produce custom products based upon customer specifications.

7.2.1.2 Product requirements for Exsurco-designed products are identified as part of the Exsurco implementation of the Stage Gate process and are recorded in the Integrated Product Definition.

7.2.1.3 Exsurco Medical determines the following:

- User Requirements specified by the customer, including requirements for delivery.
- Requirements not stated by the customer, but necessary for specified or known intended use.
- Statutory and regulatory requirements.

7.2.2 Review of requirements related to the product

7.2.2.1 Exsurco Medical conducts contract review to ensure customer requirements are defined and documented in order to identify and resolve any differences between the customer's expectations and Exsurco's ability to meet the requirements.

7.2.2.2 Contract review is conducted prior to committing to supply a product or service to a customer and to ensure:

- Product/service requirements, including special requirements, are defined and accepted.

- Any contract or order requirements differing from those previously expressed are resolved.
- Exsurco Medical has the ability to meet the defined requirements.
- Special training of personnel, equipment or materials have been identified.

7.2.2.3 Where the customer provides no documented statement of requirement, Exsurco Medical confirms the customer requirements prior to acceptance.

7.2.3 Customer Communication

7.2.3.1 Exsurco Medical determines and implements arrangements for communicating with customers. This communication involves product/service information, inquiries, contracts or order handling, customer feedback including complaints and advisory notices.

7.3 DESIGN AND DEVELOPMENT

7.3.1 Design and development planning

7.3.1.1 Established and documented procedures identify the sequence and interrelationship of design and development activities. These activities will be planned and executed using a process that uses a series of Gates and Stages to meet the needs of Exsurco Medical.

7.3.1.2 The Project Manager is responsible for managing the development and execution of design and development plans and the execution of the process. This responsibility will include interfacing with different functional areas to assure effective communication and clear execution of responsibilities in line with each design and development plan.

7.2.1.3 Design and development plans are reviewed for adequacy and approved before moving through each gate to the next stage. Records of the review and approval are maintained in a Design History File. The Design History File (DHF) also serves as the Medical Device File to comply with ISO requirements.

7.3.2 Design and development inputs

7.3.2.1 Design inputs will be identified and documented within the design and development process, and will include;

- Functional, performance and safety requirements according to intended use
- Product performance requirements;
- Applicable statutory and regulatory requirements;
- Customer-specified requirements where applicable.
- Outputs of risk management

7.3.2.2 Design inputs are reviewed for adequacy and approved before moving through each gate to the next stage. Records of the review and approval are maintained in a Design History File (DHF).

7.3 DESIGN AND DEVELOPMENT CONTINUED

7.3.3 Design and Development Outputs

7.3.3.1 Design and development outputs will be documented and maintained in a Design History File (DHF) for each type of finished component produced by Exsurco Medical. At planned intervals in the design and development process, design outputs will be verified against design inputs, and the results of those verifications will be approved and recorded.

7.3.3.2 Design and development outputs will;

- meet applicable statutory and regulatory requirements
- meet the approved design input requirements
- provide the information necessary for purchasing, production, and service provision proportionate to the risk associated with the component
- define the acceptance requirements for the device, and
- define the essential requirements for safe and proper use of the device

7.3.3.3 For devices that complete the design and development process, design and development outputs will be recorded and maintained in a Device Master Record (DMR). The DMR will be reviewed and approved prior to release of the device.

7.3.4 Design and development review

7.3.4.1 Design reviews are conducted at planned intervals during the design and development process. Design reviews will be used to assure that the design process continues to align with design and development plans, or to assure that the design outputs match design input requirements. If it is determined that changes to either plans, designs, or design input requirements need to be made, that the changes to the plan, the product, or the requirements are documented and approved.

7.3.4.2 Design Engineering is responsible for assuring that design reviews are conducted and for assuring that records of those reviews are maintained.

7.3.4.3 Participants in the design review process include representatives of functions concerned with the design and development stage(s) being reviewed as well as other subject matter experts (SME) as appropriate.

7.3.4.4 Records of design reviews will be recorded and maintained in the Design History File (DHF).

7.3.5 Design and Development Verification

7.3.5.1 Design and development verification is conducted in accordance with design and development plans during the design and development stage of the development process and is the responsibility of Design Engineering. Results of verification activities and any resulting actions necessary will be recorded and maintained in the DHF. Design verification will be conducted using units under actual or simulated production conditions.

7.3.6 Design and Development validation

7.3.6.1 Design and development validation is conducted in accordance with design and development plans during the testing and validation stage of the development process to ensure the resulting product is capable of meeting requirements for intended use. This validation must be completed prior to delivery or implementation of the product. Results of validation activities will be recorded and maintained in the DHF.

7.3.6.2 Clinical and/or performance evaluations are performed as required by national or regional regulations and as appropriate for the nature and intended use of the device.

7.3.6.3 Design validation will be conducted using units under actual or simulated production conditions.

7.3.7 Control of design and development changes

7.3.7.1 Exsurco Medical has established documented procedures for design changes.

7.3.7.2 Design and Development changes are identified, and records are maintained.

7.3.7.3 Changes are reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes include an evaluation of the effect of the changes on component parts and product already delivered or testing previously conducted.

7.3.7.4 Records of the results of the review of changes and any necessary actions are maintained.

7.3.8 Device Master Record (DMR)

7.3.8.1 A DMR is maintained for each type of finished component and includes or refers to the location of the following information:

- Device specifications including appropriate drawings, composition, formulation, component specifications and software specifications.
- Production process specifications including the appropriate equipment specifications, production methods, production procedures and production environment specifications.
- Quality assurance procedures and specifications including acceptance criteria and the quality assurance equipment to be used.
- Packaging and labeling specifications including methods and processes used.

7.3.9 Design transfer

7.3.9.1 Exsurco Medical has established documented procedures for design transfer. Design transfer is provided in a manner that ensures that the design is correctly translated into production specifications.

7.3.10 Design History File (DHF)

7.3.10.1 Exsurco Medical establishes and maintains a DHF for each type of device in which Exsurco Medical is responsible for the design control. The records contain information that demonstrates that the design was developed in accordance with the approved design plan.

7.3.10.2 The DHR includes at a minimum, the dates of manufacture, the quantity manufactured, the quantity released for distribution, acceptance records, the primary identification label and labeling used, any device identification and control number(s) used.

7.4 PURCHASING

7.4.1 Purchasing process

7.4.1.1 Exsurco Medical has established documented procedures to ensure purchased product conforms to specified purchase requirements.

7.4.1.2 Exsurco Medical has established documented procedures for supplier assessment that includes criteria for selection, evaluation, and re-evaluation. The evaluation includes the supplier's ability to supply product in accordance with Exsurco Medical's requirements. The evaluations are documented. The type and extent of control applied to the supplier and the purchased product is dependent upon the effect of the purchased product on the final product realization. Documentation of approval is maintained.

7.4.1.2 Exsurco has established a risk-based approach proportionate to the risk associated with the components that are being purchased per Appendix I of Supplier Quality and Purchasing SOP. Documentation is collected based on this guidance.

7.4.1.2 Records of supplier evaluations and any actions arising from those evaluations will be maintained.

7.4.2 Purchasing information

7.4.2.1 Purchasing information will define or describe the requirements for the product or service to be purchased. This information will be provided to the supplier as part of the conditions of purchase of those products or services.

7.4.2.2 Where appropriate or necessary, purchasing information will include;

- Exsurco engineering design specifications and/or drawings,
- Exsurco quality requirements that differ from or are not specified in engineering specifications and/or drawings,
- Requirements necessary for adherence to statutory or regulatory requirements,
- Special requirements for the provision of information to accompany product delivery,
- Special requirements for personnel, processes, or quality systems,
- Requirements that the supplier notify Exsurco Medical about any changes to the product and/or service so that Exsurco can determine whether those changes would affect the quality of a finished device, and
- Requirements for traceability where applicable.

7.4.2.3 Purchase requirements and specifications will be reviewed for adequacy prior to issue to the supplier.

7.4.3 Verification of purchased product

7.4.3.1 Purchased products and/or services will be verified for compliance with specified requirements prior to acceptance by Exsurco Medical. The type and extent of verification performed is determined by the nature of the product and/or service, the impact of that product or service on subsequent or finished products, and the historical performance of the supplier.

7.4.3.2 Where verifications are to be performed at the supplier's premises, the arrangements for verification and release of verified products will be agreed upon between Exsurco Medical and the supplier prior to those verifications being performed.

7.4.3.3 Records of product verifications will be maintained.

7.5 PRODUCTION AND SERVICE PROVISION

7.5.1 Control of production and service provision

7.5.1.1 Production of devices by Exsurco Medical will be carried out under controlled conditions, which include the following elements as part of a DMR and DHR:

Product requirements and/or specifications, which will be defined by;

- design specifications, and/or
- purchasing requirements, and/or
- manufacturing and/or process specifications, and/or
- quality plans,

Production processes, which will be defined by;

- standard operating procedures, and/or
- work instructions, and/or
- manufacturing process drawings, and/or
- production routings,
- Suitable facilities, equipment, training, and tools,

Monitoring and measuring of products and/or processes, which will be defined by;

- suitable monitoring and measuring devices, and/or
- suitable measurement procedures, and/or
- reference materials or standards, where required, and/or
- defined workmanship criteria or samples when acceptance criteria cannot otherwise be specified,
- Defined requirements and procedures for product labeling and packaging, including application of unique device identification, as appropriate, and
- Procedures for product release, delivery and post-delivery activities where applicable,
- A DHR for each batch of medical components produced by Exsurco Medical will be created and maintained, even if that batch only consists of one device. That DHR will provide traceability to the device master record and will identify the number of devices produced and the number of devices approved for distribution.

7.5 PRODUCTION AND SERVICE PROVISION CONTINUED

7.5.2 Control of production and service provision—specific requirements

7.5.2.1 Cleanliness of product and cleanliness control

7.5.2.1.1 Requirements for product cleanliness will be determined prior to placing the product on the market, and those requirements will be documented.

7.5.2.2.1 Control of work environments will be considered as part of the evaluation of cleanliness requirements, as described in section 6.4.

7.5.2.3.1 Products that are to be provided to the customer as sterile, or products that are to be provided as non-sterile and for which cleanliness is of significance during use will be cleaned according to documented requirements.

7.5.2.4.1 Products that are to be provided to the customer and which must be subjected to a cleaning process and/or sterilization by the customer prior to use will have manufacturing materials or process agents removed according to documented requirements prior to distribution.

7.5.3 Servicing activities

7.5.3.1 Where servicing is a specified requirement, procedures for the performance, verification, and recording of those activities are governed by Product servicing procedure.

7.5.3.2 Servicing activities that are related to remediation or correction of a deficiency will be treated as complaints and processed according to documented procedure.

7.5.3.3 A service report that represents an event which must be reported to the FDA will automatically consider the report a complaint and will process it in accordance with the requirements of 21 CFR 820.198.

7.5.4 Particular requirements for sterile medical devices

7.5.4.1 For products that are to be sold as sterile, Exsurco Medical will maintain records of the sterilization process that was used for each sterilization batch. Sterilization records will be traceable to each production batch of devices.

7.5.5 Validation of processes for production and service provision

7.5.5.1 General Requirements

7.5.5.1.1 Exsurco validates any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. Validation demonstrates the ability of these processes to achieve planned results Exsurco Medical has established arrangements for these processes including, as applicable:

- Defined criteria for review and approval of the processes
- Approval of equipment and qualification of personnel
- Use of specific methods and procedures
- Requirements for records

7.5.5.1.2 In those instances where software is a component of the final Exsurco device, and that software affects the ability of the device to conform to specified requirements, that software that is part of production and servicing, along with the product will be validated prior to its initial use and for each revision of that software according to the documented procedure. Exsurco has established a risk-based approach proportionate to the risk associated with the software. Records of those software validations will be maintained.

7.5.5.2 Particular requirements for sterile medical devices

7.5.5.2.1 For products that are to be sold as sterile, the sterilization process that is to be used will be validated prior to first distribution of those products per the documented procedure. Records of the validations of sterilization processes will be maintained in the Design History File (DHF) for the device.

7.5.5.2.2 Process parameters used for each sterilization process will be established during the validation process and will be specified as a purchase specification when sterilization activities are performed by an outside facility.

7.5.5.2.3 Process parameters used for each batch of sterilized products will be maintained as part of the Device History Record (DHR) for that batch, and sterilization records will be traceable for each batch of products.

7.5.6 Identification and traceability

7.5.6.1 Identification

7.5.6.1.1 Product will be suitably identified throughout all stages of product realization, including through distribution and until receipt by the customer.

7.5.6.1.2 A system for assigning unique identification to devices will be developed and maintained to meet applicable regulatory requirements.

7.5.6.1.3 Devices that are returned from customers will be clearly identified to assure that they are not mixed with new products, as per documented procedure.

7.5.6.2 Traceability

7.5.6.2.1 Product traceability requirements will be defined early in the design and development process. When traceability is an identified requirement, the procedures used for traceability will be defined per the documented procedure, and will include the extent of traceability requirements, the methods for executing traceability, and the records required for that traceability.

7.5.6.2.2 Where traceability is a requirement, each device will be assigned a unique identification, and records of that identification will be maintained.

7.5.6.3 Status Identification

7.5.6.3.1 The acceptance status of products will be identified by suitable means throughout all stages of manufacturing, packaging and labeling, storage, dispatch or delivery and post-delivery activities, as required.

7.5 PRODUCTION AND SERVICE PROVISION CONTINUED

7.5.7 Customer property

7.5.7.1 Customer property will be identified, verified, and protected while under the possession or control of Exsurco Medical. Where there is damage to or loss of customer property, or if it is found to unsuitable for use, the customer will be notified of this, and records maintained.

7.5.7.2 Customer property that is returned to Exsurco Medical for servicing will be tracked and controlled until final disposition and/or return of that property to the customer. The customer will be notified of the suitability of the product for service and the status of that service.

7.5.8 Preservation of product

7.5.8.1 Product will be suitably packaged, handled, stored and shipped to protect the quality and ensure conformity of the products throughout processing, assembly, storage, and delivery, according to documented procedure. When special package or handling requirements are required, they will be identified on the work order or in packaging specifications.

7.5.8.2 Products that have limited shelf-life or that require special storage conditions will be identified, handled, and stored as per the documented procedure.

7.6 CONTROL OF MONITORING AND MEASURING EQUIPMENT

7.6.1 Exsurco Medical will develop quality plans to define and document the methods and equipment to be used for the monitoring and measurement of products to ensure compliance to product requirements.

7.6.2 Monitoring and measuring equipment will be calibrated or verified at specified intervals to reference standards which are traceable to national standards (NIST) where possible, as defined in the documented procedure. The calibration status of equipment will be suitably identified. Records of calibration will be maintained.

7.6.3 Monitoring and measuring equipment will be stored, handled, and protected to assure that accuracy and fitness for use are maintained, and to prevent unauthorized adjustment.

8.0 MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 GENERAL

8.1.1 Exsurco Medical plans and implements the monitoring, measurement, analysis and improvement processes needed to:

8.1.1.1 Demonstrate the conformity of the product/service.

8.1.1.2 Ensure conformity of the QMS.

8.1.1.3 Maintain the effectiveness of the QMS.

8.1.2 The planning and implementation includes a determination of applicable methods, including statistical techniques, and the extent of their use (See Appendix B for reference).

8.2 INTERNAL AUDITS

8.2.1 Internal audits are conducted at planned intervals to determine whether the QMS conforms to the planned arrangements, to applicable external standards and regulations and to internal QMS requirements. The audits also are used to determine if the QMS is effectively implemented and maintained.

8.2.2 The audit program is planned taking into consideration the status and importance of the processes and areas to be audited, in addition to the results of previous audits. The audit criteria, scope, frequency and methods are defined. The selection of auditors and conduct of audits ensure objectivity and impartiality of the audit process. Auditors do not audit their own work.

8.2.3 A documented procedure is in place that defines the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (See Appendix B for reference).

8.2.4 Management responsible for the area being audited reviews the results and is responsible for ensuring that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results.

8.3 MONITORING AND MEASUREMENT

8.3.1 Feedback

8.3.1.1 Internal data (data from audits, monitoring of established performance metrics, etc.), in addition to positive and negative customer generated data (complaints, surveys, etc.) are used as feedback to determine whether customer requirements are being met, to provide early warning of quality problems and for input into the corrective and preventive action processes. The information gathered in the feedback process shall serve as potential input into risk management for monitoring and maintaining the product requirements as well as the product realization or improvement

processes.8.3.1.2 Procedures are maintained for receiving, documenting, reviewing and evaluating complaints for products and service. These procedures and work instructions (See Appendix B for reference) ensure the following:

- All complaints are processed in a uniform and timely manner.
- Oral complaints are documented upon receipt.
- Complaints are evaluated to determine whether the complaint is a reportable event under Medical Device Reporting.
- All complaints are reviewed and evaluated to determine whether an investigation is necessary. When no investigation is necessary, a record is maintained that includes the reason no investigation was conducted and the name of the individual responsible for the decision to not investigate.
- Any complaint involving the possible failure of a device, labeling or packaging to meet any specifications is reviewed, evaluated and investigated unless an investigation for a similar complaint was performed.
- Any complaint that represents a reportable event under 21 CFR 803 is promptly reviewed, evaluated and investigated. These complaints are clearly identified. The investigation record includes a determination of whether the device failed to meet specifications, whether the device was being used for treatment and the relationship, if any, of the device to the reported incident or adverse event.

8.3 MONITORING AND MEASUREMENT CONTINUED

- Records of investigation are maintained and include the name of the device; the date the complaint was received; any device identification(s) and control number(s) used; the name, address and phone number of the complainant; the nature and details of the complaint; the dates and results of the investigation; any corrective action taken; any reply to the complainant.

8.3.3 Monitoring and measurement of process

8.3.3.1 Suitable methods are applied for monitoring and measurement of the QMS processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, corrective action is taken to ensure product conformity.

8.3.4 Monitoring and measurement of product

8.3.4.1 Documented procedures are implemented to monitor and measure the characteristics of the product to verify that product requirements are met. This is carried out at appropriate stages of the product realization process in accordance with the planned arrangements. Evidence of conformity with the acceptance criteria is maintained and records indicate the person(s) authorizing release of the product. Product release does not proceed until the planned arrangements are satisfactorily completed.

8.3.4.2 Documented procedures are established and maintained for identifying valid statistical techniques for establishing, controlling, and verifying the acceptability of process capability and product characteristics.

8.3.4.3 Quality plans will be developed for each finished component designed and/or manufactured by Exsurco Medical and based on valid statistical rationale. Documented procedures are established and maintained to ensure that sampling methods are adequate for their intended use and to ensure that when changes occur the Quality plans are reviewed. All such activities are documented.

8.3.4.4 The acceptance status of devices and components will be identified throughout the manufacturing, packaging, labeling, storage and distribution to ensure the only product that has met all of the criteria established in the quality plan have been met prior to distribution or use. The status of devices returned for servicing will be similarly identified until accepted and returned to the customer.

8.3.4.5 Records of monitoring and measurement activities will be maintained as part of the device history record and will include the activities performed, the date when the activity took place, the results of the activity, the signature of the person conducting the activities, the person(s) authorizing release of product, and, when appropriate, the equipment used for those activities.

8.4 CONTROL OF NONCONFORMING PRODUCT

8.4.1 Product

8.4.1.1 Documented procedures are implemented to ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use, release, or delivery. The procedures also address evaluation, segregation and disposition. The controls and related responsibilities for dealing with nonconforming product are defined.

8.4.1.2 The evaluation of nonconformance includes a determination of the need for an investigation and notification of the persons or organization responsible for the nonconformance.

8.4 CONTROL OF NONCONFORMING PRODUCT CONTINUED

8.4.1.3 Nonconforming product is processed in one of the following ways:

- Action is taken to eliminate the detected nonconformity.
- Authorization of use, release, or acceptance under concession is given only when regulatory requirements are met with records of the personnel authorizing the concession being maintained.
- Action is taken to preclude its original intended use or application.

8.4.1.4 Records of the nature of nonconformities and any subsequent actions taken, including evaluations, investigations, dispositions and concessions obtained, are maintained.

8.4.1.5 When nonconforming product is corrected, it is subjected to reverification to demonstrate conformity to the requirements.

8.4.1.6 When nonconforming product is detected after delivery or use has started, appropriate action is taken to the effects or potential effects of the nonconformity

8.4.1.7 If product is reworked one or more times, the rework process is documented and subject to the same approval and authorization as the original work instruction. Prior to authorization and approval, a determination of any adverse effects of the rework upon the product is made and documented.

8.5 ANALYSIS OF QMS DATA

8.5.1 Documented procedures are implemented to determine, collect and analyze appropriate data to demonstrate the suitability, adequacy and effectiveness of the QMS and to evaluate if improvement of the effectiveness of the QMS can be made. The data includes data; appropriate methods including statistical techniques and the extent of their use, which is generated as a result of monitoring and measurement and from other relevant sources. The following information will be collected and assessed, at a minimum;

- Customer feedback
- Service Reports
- Audits
- Conformity to product requirements
- Process performance and opportunities for improvement, and
- Supplier performance

8.5.2 Data is analyzed and, where found to be outside pre-defined criteria, planned action is taken to correct the problem and prevent any incorrect results from being reported.

8.5.3 Records of the results of analysis of data are maintained.

8.6 IMPROVEMENT

8.6.1 General

8.6.1.1 Exsurco Medical identifies and implements changes necessary to ensure and maintain the continued suitability and effectiveness of the QMS through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, event review team meetings and management review.

8.6.1.2 Documented procedures are established for the issue and implementation of advisory notices. These procedures are capable of being implemented at any time.

8.6.1.3 Records of customer complaint investigations are maintained. If an investigation determines that the activities outside the organization contributed to a customer complaint, relevant information is exchanged between the organizations involved.

8.6 IMPROVEMENT CONTINUED

8.6.1.4 If a customer complaint is not followed by corrective and/or preventive action, the reason is authorized and recorded.

8.6.1.5 Documented procedures are established to address notification to regulatory authorities where national and regional regulations require notification of adverse events that meet specified reporting criteria.

8.6.2 Corrective action

8.6.2.1 Documented procedures have been established and implemented to ensure that appropriate actions to eliminate the cause of nonconformities is taken in order to prevent recurrence.

8.6.2.2 The documented procedures define the requirements for:

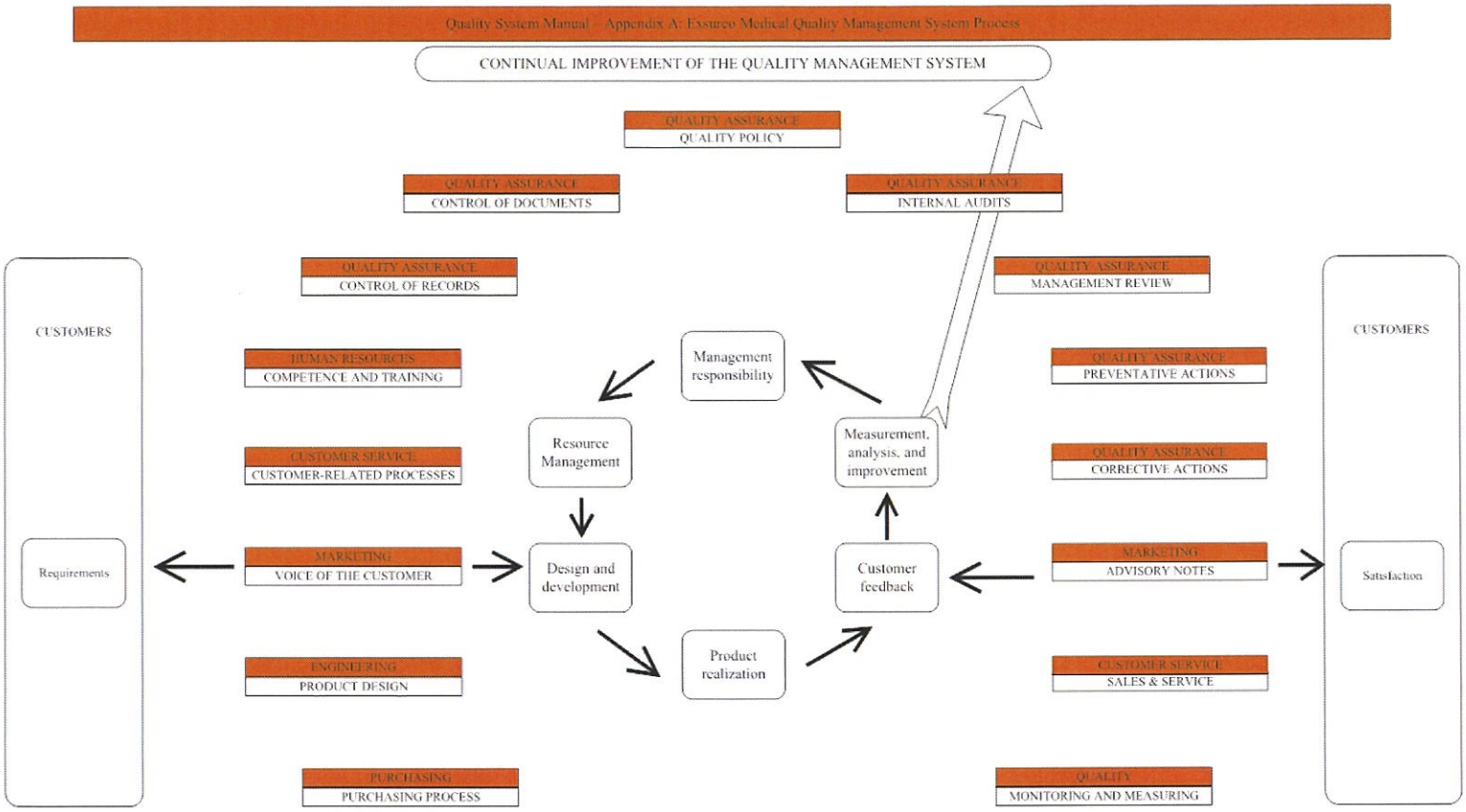
- Reviewing nonconformities, including all complaints and quality audit findings.
- Conducting internal audits, to ensure departments are in compliance with internal procedures, standards or regulations.
- Determining the causes of nonconformities.
- Evaluating the need for action to ensure that nonconformities do not recur.
- Determining and implementing actions needed, including, if appropriate, updating documentation.
- Recording all activities and the results of any investigation and action taken.
- Reviewing corrective action taken and its effectiveness. If necessary, internal audits are conducted to confirm effectiveness.
- Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of the product or the prevention of the problems.
- Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for event review team meetings and management review.

8.6.3 Preventive Action

8.6.3.1 Exsurco Medical determines actions to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems. A documented procedure has been established and implemented to define the requirements for:

- Determining potential nonconformities and their causes.
- Evaluating the need for action to prevent occurrence of nonconformities or opportunities for improvement.
- Determining and implementing actions needed.
- Recording the results of any investigation and action taken.
- Reviewing preventive action taken and its effectiveness

APPENDIX A: QUALITY MANGEMENT SYSTEM PROCESS



APPENDIX B: LIST OF PROCEDURES FOR REFERENCE

DOCUMENT ID	DOCUMENT NAME
MNT-7_00001	Equipment Calibration and Preventative Maintenance
MNT-7_00002	Pest Control Program
MNT-7_00003	Equipment Relocation
EOP-4_00001	Wash Tank Set-Up and Tear Down
EOP-4_00002	Accu-Seal 5506
MVP-8_00001	Master Validation Plan (MVP)
ORG-1_00001	Organizational chart
QP-1_00001	Quality Policy
SAFETY-1_00001	General Safety
SAFETY-1_00002	Bloodborne Pathogens Exposure Control Plan
SAFETY-1_00003	Hazard Communication Program
SAFETY-1_00004	Lockout Tagout Policy
SOP-1_00001	External Audits
SOP-1_00002	Good Documentation Practices
SOP-1_00003	Management of Quality System Documents
SOP-1_00004	Job Descriptions
SOP-1_00005	Access and Distribution of Controlled Document Copies
SOP-1_00006	Statistical Techniques and Quality Data Trending
SOP-1_00008	Employee Training
SOP-1-00009	Control of External Documents and References
SOP-1_00010	Management Review
SOP-1_00012	Internal Audits
SOP-1_00041	Risk Management
SOP-2_00014	Design & Development Plan
SOP-2_00015	Design Review
SOP-2_00016	Design Control
SOP-2_00017	Design Inputs
SOP-2_00018	Design Verification
SOP-2_00019	Design Validation
SOP-2_00020	Design Outputs
SOP-2_00035	Design Changes
SOP-2_00036	Design Transfer

DOCUMENT ID	DOCUMENT NAME
SOP-2_00037	Design History File
SOP-3_00013	Supplier Quality and Purchasing Controls
SOP-4_00011	Re-Work Procedure
SOP-4_00021	Manufacturing Environmental Controls
SOP-4_00022	General Warehouse Cleaning Procedures
SOP-4_00023	Cleanroom Guidelines
SOP-4_00024	Cleanroom Cleaning Procedure
SOP-4_00025	Non-Viable and Viable Particulate and Environmental Management
SOP-4_00026	In Process Production
SOP-4_00027	Identification and Traceability of Product
SOP-4_00028	Limited Shelf Life Products
SOP-4_00029	Labeling, Packaging, Handling, Storage, and, Distribution Controls
SOP-4_00045	Creating a Device History Record (DHR)
SOP-4_00046	Creating a Device Master Record (DMR)
SOP-4_00050	Process Qualification and Validation
SOP-4_00051	Bioburden and Dose Audit Program
SOP-4_00052	Gamma Product Family Adoption Process
SOP-5_00007	Non-Conforming Event (NCE)
SOP-5_00030	Complaint Handling
SOP-5_00031	Corrective and Preventive Action (CAPA)
SOP-5_00032	Health Hazard Evaluations
SOP-5_00034	Product, Corrections, Removals, Withdrawals and Stock Recoveries
SOP-5_00038	Regulatory Affairs Activities
SOP-5_00053	Unique Device Identification
SOP-6_00042	Service Repair Procedure
SOP-6_00042_POLICY-G01	Exsurco Service Policy
SOP-9_00040	Electronic Records, Electronic Signatures and Computerized Systems
SOP-9_00044	Computerized Systems Software Validation
SOP-10_00047_ POLICY-G01	Customer Service and Sales Policy
SOP-10_00048	Contract Review of Standard Product(s)

Revision History

REVISION	DCR #	DESCRIPTION	EFFECTIVE DATE	AUTHOR
-	N/A	Initial Release	5-8-2013	Geoff Rapp
A	N/A	D0000653 –On File	7-15-2013	Geoff Rapp
B	N/A	D0000653 –On File	5-13-2014	Geoff Rapp
C	N/A	D0000653 –On File	5-28-2014	Geoff Rapp
D	N/A	D0000653 –On File	6-10-2014	Geoff Rapp
E	N/A	D0000653 –On File	6-26-2014	Geoff Rapp
F	N/A	D0000653 –On File	7-29-2014	Geoff Rapp
G	N/A	D0000653 –On File	4-3-2015	Ed Hawkins
01	00291	Complete re-write of Quality Manual to include U.S. QSR (21 CFR 820) requirements and removed ISO 9001 requirements. This includes new nomenclature and revision method based on current system.	11-15-2016	Swasita Saigal
02	00479	Updated the address from Birmingham to Wakeman. Updated quality policy. Updated the organization chart to Rev. 05. Updated title on page 1. In section 2.0 updated scope from ISO certificate. Clarified company profile on page 2. Corrected section 5.1.2 bullet 4 from bi-annual to annual as per procedure. Updated title Statistical Techniques and Quality Data Trending (SOP-1_00006) on page 25. Updated title Management of Quality System Documents (SOP-1_00003) on page 25. Added SOP-4_00050 Process Qualification and Validation to Appendix C.	2/20/2018	Swasita Saigal
03	00533	Updated Quality Manual with Organizational Chart, Rev. 06. Removed 2016 in section 2.1.1.	10-03-2018	Swasita Saigal
04	00557	Updated Sara Ann Mackinlay's title. Updated Kayli Camp's title. Removed Appendix B Organizational Chart from the Quality Manual. Made Appendix C List of Procedures for Reference New Appendix B. Removed and traveler from Section 7.5.5.2.3, and 7.5.1.1 updated to align with SOP (DHR) updates made under CCR_00518. Updated Appendix C references throughout to Appendix B. Updated section 5.5.2.1 with new titles for Sara Ann MacKinlay and Don Esch. Removed organizational chart.	11-21-2019	Kayli Camp

05	00624	The following updates were part of OFIs through an Internal Audit, BSI Audit feedback and UDI update. The following changes were made: Updated titles on page 1 of this document to reflect current Organization. Updated Scope clarified applications and non-applications per ISO requirement. Updated section 4.1 with general language on software validation as during this review, it was observed to be missing. Added in section 4.1 and 5.1.2 the reference of Event Review Team Meetings (ERT) to reflect our current process of reviewing QMS data quarterly. In section 5.3.1, added clarification on how we communicate the Quality Policy. In section, 5.5.2.2 replaced "performance" with effectiveness per language update in new ISO standard. In section 5.5.3.2 added ERT per current practice. In section 7.2.1.3 added Medical Device File to satisfy ISO requirement as equivalent to Design History File that is compliant to 21 CFR 820. In section 7.3.3.2 added clarification on how risk is determined on purchased parts. Added language around risk-based approach based on our current practice in Section 7.4.1.2, Added section 7.5.1.1 referencing UDI as applicable. Updated 7.5.5.12 with language to clarify when software validation is required for both product and quality data. Added section 7.5.6.1.2 referencing UDI as applicable. Added UDI SOP and Software Validation SOP references. Added language on current practice in section 8.3.1 and 8.6.1. Updated language per ISO standard in section 8.5.1.	07-01-2021	Swasita Saigal