S.S. WHITE Technologies®

World Leader In Flexible Shaft Technology

SHUKLA MEDICAL®

Universal Orthopedic Extraction Technologies

QUALITY POLICY MANUAL FOR MEDICAL PRODUCTS DIVISION

Welcome to the Quality Manual:

S.S. White has a rich history in providing quality flexible shaft assemblies and casings since 1844. It is with great pride that we make our Quality Policy Manual available to you.

If you need additional information, including procedures, work instructions or marketing material, please contact your salesperson or one of our Quality Staff members. We would be happy to supply you with whatever quality information you need.

You can also visit our website at www.sswhite.net and www.shuklamedical.com.

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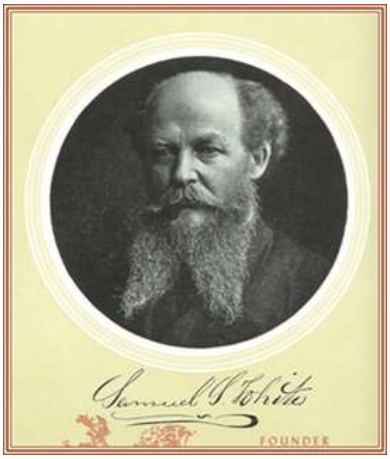
A Brief History of S. S. White Technologies:

Dr. Samuel Stockton White, a practicing dentist who saw a need for innovation, founded S.S. White in 1844 (before electricity!).



The company, known as S.S. White Dental Manufacturing at the time, rapidly became a pioneer in the field of dentistry with the introduction of its high-speed flexible shaft dental drills. In 1915, S.S. White (SSW) found additional uses for its flex shafts as replacements for drive links in automobile speedometers. In 1931, the company published the industry's first handbook, which quickly became "the source" for all engineers interested in rotary motion. Soon the flexible shaft found use in power tools, instrumentation, motor controls, and consumer products. In 1941 (during WW II), the U.S. Military asked S.S. White to design various drive assemblies for the Aircraft Industry. It was this assignment that gave us the expertise of designing complex flexible shaft assemblies of exacting quality. By 1950, S.S. White, known for its progressive management, became the largest employer in Staten Island, New York. Pennwalt Corporation, a Fortune 200 Corporation, acquired S.S. White in 1968. S.S. White Industrial Division relocated in 1972 to its current plant in Piscataway, New Jersey; completely severing its ties with S.S. White Dental Manufacturing.

In 1973, a young engineer, Rahul Shukla, joined the company. Shukla had obtained three engineering degrees but had never come across the term flexible shaft in all of his engineering curriculum. When he looked into it, he realized that no definitive scientific formulas to design these complex shafts ever existed; the void sparked a dream and obsession to develop this knowledge. Shukla carried out many experiments and research studies throughout the 70's. A turning point came when Adam Black III, a senior research engineer, joined the team, resulting in five years of exhaustive work. In 1987, a Doctoral degree was awarded to Dr. Black by The Stevens Institute of Technology for his breakthrough discoveries.

The very next year, 1988, Rahul Shukla took over the stewardship of S.S. White when the company was acquired from Pennwalt. Now, for the first time since the turn of the century, the company has a President / CEO whose commitment and knowledge of flexible shaft is without equal.

Today, the company operates three distinct product lines specializing in Shukla Medical which markets our own line of orthopedic extraction kits for emergency rooms, surgical instruments provided to the medical OEM market, and Flexible Shafts the heart and soul of the company. We are committed to advancing our leadership role with the development of new technologies and products. Our scientific approach to design has brought us great success in the high tech fields of Aeronautics and Medical Instruments. Our breakthrough discoveries with the mathematics governing flex shaft properties has led to the introduction of our STEADY FLEX and POWER FLEX shafts. These shafts took eight years to perfect and perform 30% better on average than current industry standards. We are continually creating new applications for flexible shafts and developing our future markets.

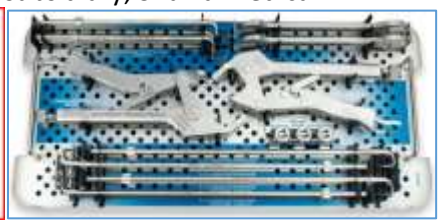
That's our history, setting the standards in technology and backing it up with the best quality and service in the business.

Our Products:

S.S. White Technologies (SSW) is engaged in the design, manufacture and sale of the following types of products:

- Rotary motion flexible shafts, casings, instruments and accessories for commercial use, for aircraft and medical applications and use in the automotive and truck industries. These shafts convey rotary motion without the use of universal joints or gearboxes.
- Custom hand held surgical instruments and extraction kits for the orthopedic industry. These are sold to many

OEM companies as well as to our wholly-owned subsidiary, Shukla Medical.



We are fortunate to have a market presence in many different industries- aerospace, medical, automotive, industrial, etc. and take great pride in our ability to serve many unique customers.

Our Quality Policy Statement:

"We will strive to meet and exceed customer expectations

by continually improving our quality system

and delivering outstanding service

and quality product on-time"

Introduction and Scope:

The S.S. White Quality System for Medical Products Division is modeled after and compliant with the International Standard ISO 13485:2016. S.S. White has established the scope of its management system, which takes into consideration, interested parties and their requirements, external, and internal issues facing the organization, as well as products supplied.

ISO 13485:2016 Scope Statement:

"Design and Manufacture of Non-Active Orthopedic Surgical Instruments"

S.S. White is a privately held, small corporation. It is divided into two primary divisions: (1) Flexible Shaft Division, (2) Medical Products Division. This system is directed and controlled at the corporate level. The President and Chief Executive Officer of SSW has appointed the Director of Corporate Quality (who acts as the Management Representative) to manage the Corporate Quality Organization which entails the implementation, direction, and management of the SSW Total Quality System. The Director of Corporate Quality speaks for the President and CEO on matters regarding the SSW Total Quality System.

Participation in the system is company-wide. Every employee throughout the company participates in the quality system as applicable to individual requirements. The Management Policy Committee (MPC) consists at minimum of the Director of Corporate Quality; heads of IT, Finance, Engineering, Manufacturing, Human Resources, Sales; and the President/CEO. The MPC establishes quality policy objectives, develops corporate strategy, provides resources and leads by example in order to deploy improvement activities and establish the SSW quality culture. Quality activities and decisions are communicated to the organization through the Director of Corporate Quality and/or other members of the executive staff.

Exclusions for ISO 13485:2016: Clauses 7.5.3., 7.5.4., and 7.5.9.2. are not applicable to S.S. White as it is not within the scope of our organization nor is it required by any of our interested parties.

SSW does not: a) provide any installation or servicing activities; and b) manufacture any implantable devices.

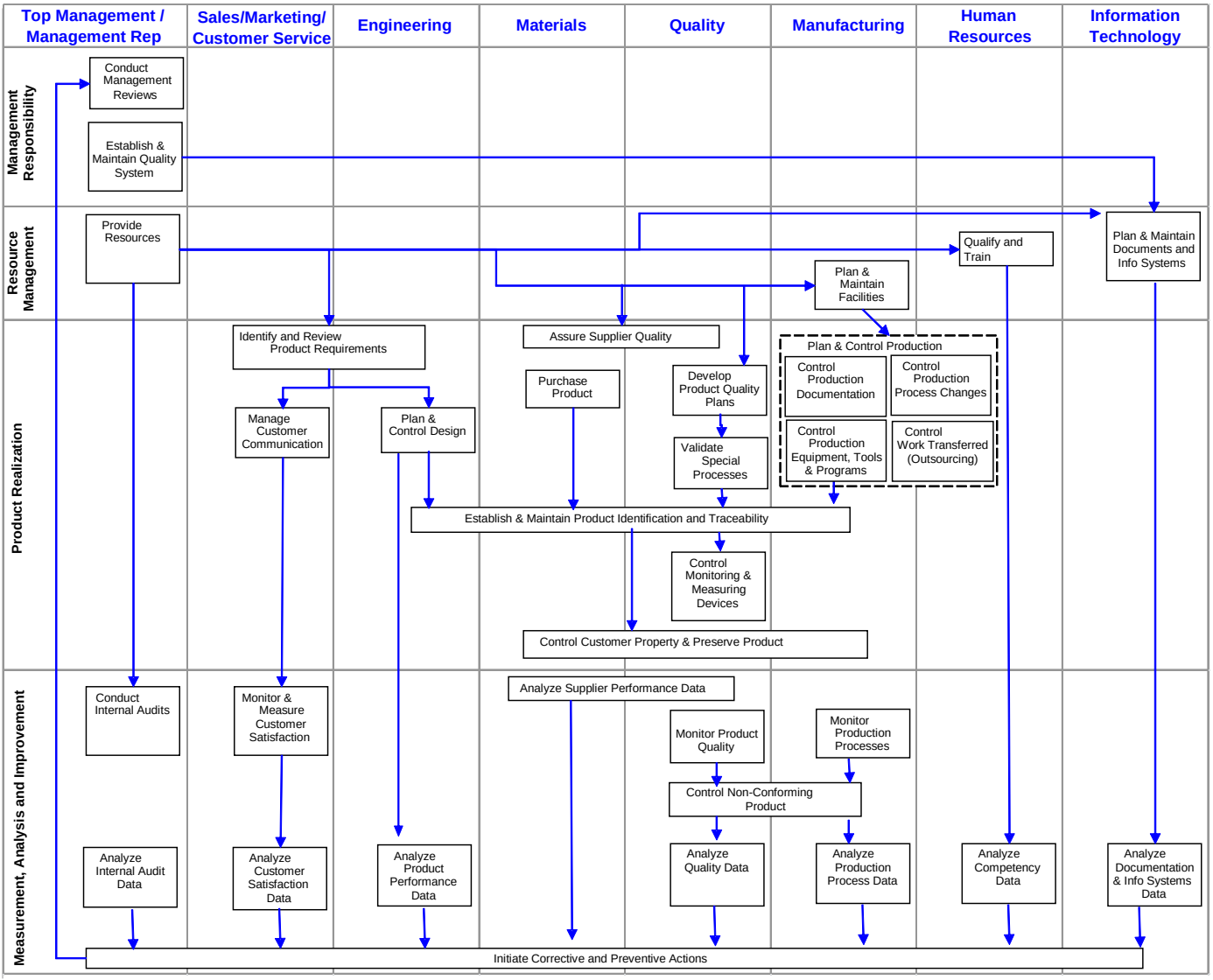
Policy Statements for ISO 13485:2016 compliance:

1. Policy Statement for ISO 13485:2016 Section 4.1. Quality Management System: General requirements

S. S. White Technologies documents, implements and maintains a quality management system in accordance with ISO 13485:2016 requirements and applicable regulations. SSW medical parts division is a manufacturer and a contract manufacturer of medical devices. SSW applies risk-based and process approach to the control and management of all appropriate processes needed for the quality management system including any outsourced processes. SSW applies continuous process improvement methodology to ensure its on-going effectiveness. SSW has documented procedures for the validation of the application of software in the quality management systems. System processes, including their inter-relationships are shown below.

The Management Policy Committee is responsible for establishment, monitoring of effectiveness, and any changes to the quality management system in all the processes affecting quality.

Reference: SOP-0001, SOP-002, SOP-0003, SOP-0005, SOP-0033, SOP-17005, SOP-17012, WI-0450.



Interactional Process Flow Chart

2. Policy Statement for ISO 13485:2016 Section 4.2. Quality Management System: Documentation requirements

SSW quality management system includes documented procedure(s) for control of documents and storage of records. The structure of documentation flows from the quality manual to the Standard Operating Procedures (SOP) to Work Instructions (WI) to Form Control Documents (FCD), where the results are recorded as demonstrated below. The documented procedure(s) define the controls needed to:

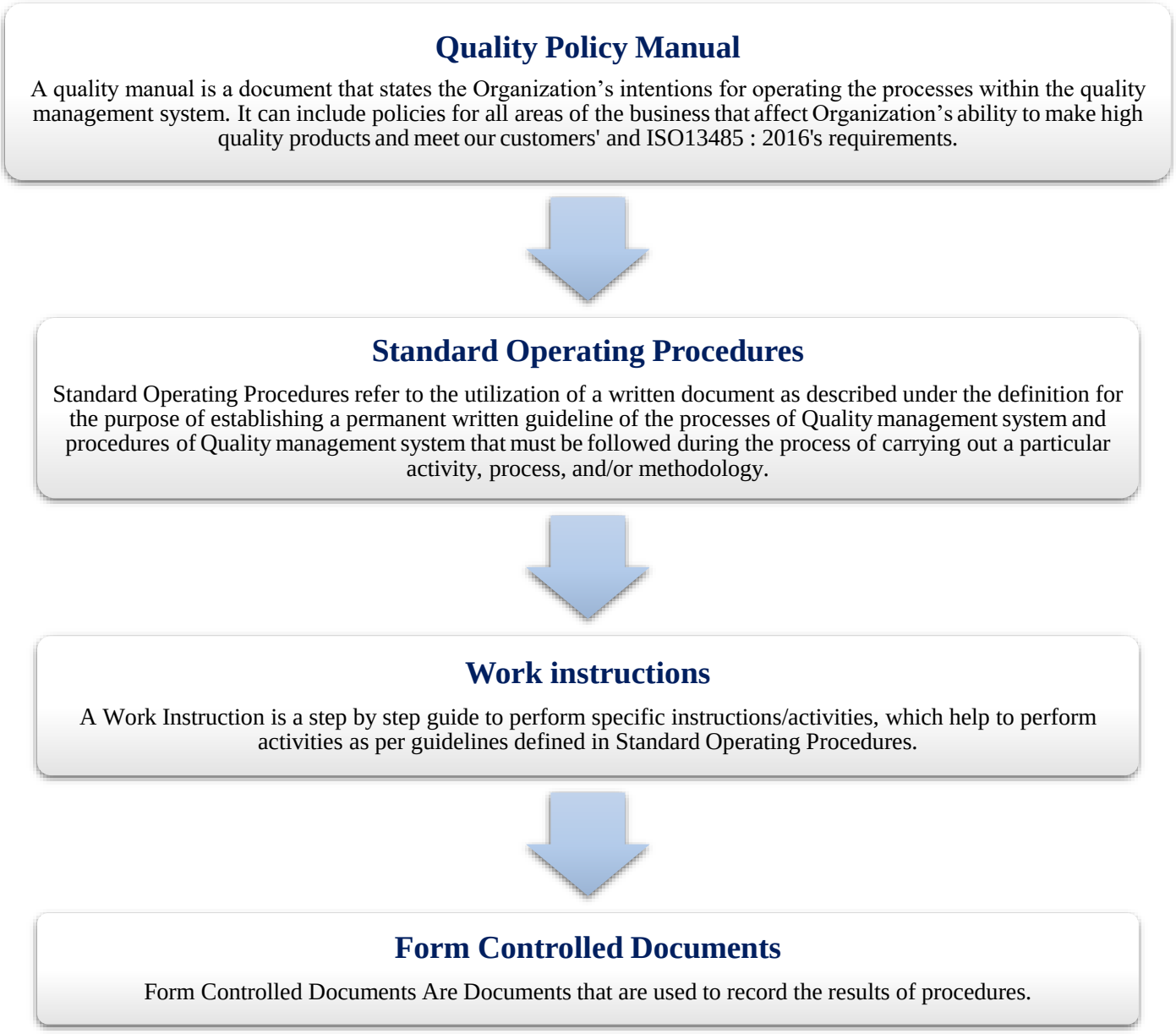
a) review and approve documents for adequacy prior to issue;
b) review, update as necessary and re-approve documents;
c) ensure that the current revision status of and changes to documents are identified;
d) ensure that relevant versions of applicable documents are available at points of use;
e) ensure that documents remain legible and readily identifiable;

f) ensure that documents of external origin, determined by the organization to be necessary for the planning and operation of the quality management system, are identified and their distribution controlled;
g) prevent deterioration or loss of documents;
h) prevent the unintended use of obsoleted documents and apply suitable identification to them
Any changes to documents are reviewed and approved, either by the original approving function or another designated function that has access to pertinent background information upon which to base its decisions. SSW defines the period for which obsolete documents shall be retained per regulatory requirements but not less than the lifetime of the medical device(s).

Control of records: Records shall be maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. SSW documents procedures to define the controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records. SSW has defined and implements methods for protecting confidential health information contained in records in accordance with the applicable regulatory requirements. Records shall remain legible, readily identifiable and retrievable. Changes to a record shall remain identifiable. SSW retains the records for at least the lifetime of the medical device as defined by the organization, or as specified by applicable regulatory requirements, but not less than two years from the medical device release by the organization.

The overall responsibility for this procedure belongs to the President/CEO with the guidance and direction of the Management Representative and Management Policy Committee.

Reference: SOP-0002, SOP-0020



S. S. White Technologies Pvt. Ltd. Document Structure

3. Policy Statement for ISO 13485:2016 Section 5.1. Management Responsibility: Management commitment

SSW's Management Policy Committee shall provide evidence of its commitment to the development and implementation of the quality management system and maintenance of its effectiveness. This is accomplished by: communicating to the organization the importance of meeting customer requirements as well as applicable regulatory requirements; establishing the quality policy; ensuring that quality objectives are established; conducting management reviews; and ensuring the availability of resources.

The overall responsibility for this procedure belongs to the President/CEO with the guidance and direction of the Management Representative and Management Policy Committee.

Reference: SOP-0001, SOP-0002

4. Policy Statement for ISO 13485:2016 Section 5.2. Management Responsibility: Customer focus

SSW's Management Policy Committee shall ensure that customer requirements and applicable regulatory requirements are determined and met.

Reference: SOP-0001

5. Policy Statement for ISO 13485:2016 Section 5.3. Management Responsibility: Quality policy

SSW's Management Policy Committee shall ensure that the quality policy: is applicable to the purpose of the organization; includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system; provides a framework for establishing and reviewing quality objectives; is communicated and understood within the organization; and is reviewed for continuing suitability.

Reference: SOP-0001, SOP-0002

6. Policy Statement for ISO 13485:2016 Section 5.4. Management Responsibility: Planning

The Management Policy Committee ensures that quality objectives, including those needed to meet applicable regulatory requirements and requirements for product, are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy. The MPC also ensures that the planning of the quality management system is implemented in order to meet the requirements, as well as the quality objectives; and ensures the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

Reference: SOP-0001

7. Policy Statement for ISO 13485:2016 Section 5.5. Management Responsibility: Responsibilities, authority and communication

SSW's Management Policy Committee shall appoint a management representative who is responsible for: ensuring that processes needed for the quality management system are documented; reporting to the MPC on the effectiveness of the quality management system and any need for improvement; and ensuring the promotion of awareness of applicable regulatory requirements and quality management system requirements throughout the organization.

The MPC shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

Reference: SOP-0001

8. Policy Statement for ISO 13485:2016 Section 5.6. Management Responsibility: Management review

SSW shall document procedures for management review. Top management shall review the organization's quality management system at documented planned intervals to ensure its continuing suitability, adequacy and effectiveness. The review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

The input to management review shall include, but not limited to, information arising from: feedback; complaint handling; reporting to regulatory authorities; audits; monitoring and measurement of processes; monitoring and measurement of product; corrective action; preventive action; follow-up actions from previous management reviews; changes that could affect the quality management system; recommendations for improvement; and applicable new or revised regulatory requirements.

The outputs from the management review shall include the inputs reviewed and any decisions or actions related to improvement needed to maintain the sustainability, adequacy, and effectiveness of the quality management system and its processes; improvement of product related to customer requirements; changes needed to respond to applicable new or revised regulatory requirements; and resource needs.

The overall responsibility for this procedure belongs to the President/CEO with the guidance and direction of the Management Representative and Management Policy Committee.

Reference: SOP-0001, SOP-0016, SOP-0017, SOP-0021, SOP-0033, SOP-17012

9. Policy Statement for ISO 13485:2016 Section 6. Resource Management

9.1 Provision of resources: SSW determines and provides the resources needed to:

a) implement the quality management system and to maintain its effectiveness;
b) meet applicable regulatory and customer requirements.
Personnel performing work affecting product quality shall be competent based on appropriate education, training, skills and experience. The organization shall document the process(es) for establishing competence, providing needed training, and ensuring awareness of personnel.

9.2. Human resources: The organization shall:

a) determine the necessary competence for personnel performing work affecting product quality;
b) provide training or take other actions to achieve or maintain the necessary competence;
c) evaluate the effectiveness of the actions taken;
d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives;
e) maintain appropriate records of education, training, skills and experience

9.3. The organization shall document the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product. Infrastructure includes, as appropriate:

a) buildings, workspace and associated utilities;
b) process equipment (both hardware and software);
c) supporting services (such as transport, communication, or information systems).

The organization shall document requirements for the maintenance activities, including the interval of performing the maintenance activities, when such maintenance activities, or lack thereof, can affect product quality. As appropriate, the requirements shall apply to equipment used in production, the control of the work environment and monitoring and measurement.

9.4. Work environment and contamination policy

The organization shall document the requirements for the work environment needed to achieve conformity to product requirements. If the conditions for the work environment can have an adverse effect on product quality, the organization shall document the requirements for the work environment and the procedures to monitor and control the work environment.

The organization shall:
a) document requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could affect medical device safety or performance;
b) ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are competent or supervised by a competent person.

9.5. Contamination control
As appropriate, the organization shall plan and document arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of the work environment, personnel, or product.

The overall responsibility for this procedure belongs to the President/CEO with the guidance and direction of the Management Representative and Management Policy Committee.

Reference: SOP-0001, SOP-0019, SOP-0022, SOP-0036, SOP-17008.

10. Policy Statement for ISO 13485:2016 Section 7.1. Product Realization: Planning of product realization

The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system. The organization shall document one or more processes for risk management in product realization. Records of risk management activities shall be maintained per 2.

In planning product realization, the organization shall determine the following, as appropriate:

a) quality objectives and requirements for the product;
b) the need to establish processes and documents and to provide resources specific to the product, including infrastructure and work environment;
c) required verification, validation, monitoring, measurement, inspection and test, handling, storage, distribution and traceability activities specific to the product together with the criteria for product acceptance;
d) records needed to provide evidence that the realization processes and resulting product meet requirements
The output of this planning shall be documented in a form suitable for the organization's method of operations.

The overall responsibility for this procedure belongs to the President/CEO with the guidance and direction of the Management Representative and Management Policy Committee.

Reference: SOP-0001, SOP-0003, SOP-0005, SOP-0008, SOP-0007, SOP-0010, SOP-0011, SOP-0012, SOP-0016, SOP-0019, SOP-0020, SOP-0028.

11. Policy Statement for ISO 13485:2016 Section 7.2. Product Realization: Customer-related processes

11.1. Determination of requirements related to product

SSW shall determine:

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities;
b) requirements not stated by the customer but necessary for specified or intended use, as known;
c) applicable regulatory requirements related to the product;
d) any user training needed to ensure specified performance and safe use of the medical device;
e) any additional requirements determined by the organization.

11.2. Review of requirements related to product

SSW shall review requirements related to product(s). This review shall be conducted prior to the organization's commitment to supply product to the customer (e.g. submission of purchase orders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that:

a) product requirements are defined and documented;
b) contract or order requirements differing from those previously expressed are resolved;
c) applicable regulatory requirements are met;
d) any user training identified in accordance with 11.1. is available or planned to be available;
e) the organization has the ability to meet the defined requirements.
Records of the results of the review and actions arising from the review shall be maintained (see 2.).

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

When product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

11.3. Communication

The organization shall plan and document arrangements for communicating with customers in relation to:

a) product information;
b) enquiries, contracts or order handling, including amendments;
c) customer feedback, including complaints;
d) advisory notices.
The organization shall communicate with regulatory authorities in accordance with applicable regulatory requirements.

The overall responsibility for this procedure belongs to the President/CEO with the guidance and direction of the Management Representative and Management Policy Committee.

Reference: SOP-0003, SOP-0016, SOP-0017, SOP-0022, SOP-0028, SOP-17012.

12. Policy Statement for ISO 13485:2016 Section 7.3. Product Realization: Design and development

12.1. Design and development planning

SSW shall plan and control the design and development of product. As appropriate, design and development planning documents shall be maintained and updated as the design and development progresses. During design and development planning, the organization shall document:

a) the design and development stages;
b) the review(s) needed at each design and development stage;
c) the verification, validation, and design transfer activities that are appropriate at each design and development stage;
d) the responsibilities and authorities for design and development;

e) the methods to ensure traceability of design and development outputs to design and development inputs;
f) the resources needed, including necessary competence of personnel.

12. 2. Design and development inputs

Inputs relating to product requirements shall be determined and records maintained (see 2). These inputs shall include:
a) functional, performance, usability and safety requirements, according to the intended use;
b) applicable regulatory requirements and standards;
c) applicable output(s) of risk management;
d) as appropriate, information derived from previous similar designs;
e) other requirements essential for design and development of the product and processes.
These inputs shall be reviewed for adequacy and approved.
Requirements shall be complete, unambiguous, able to be verified or validated, and not in conflict with each other.

12.3. Design and development outputs

Design and development outputs shall:
a) meet the input requirements for design and development;
b) provide appropriate information for purchasing, production and service provision;
c) contain or reference product acceptance criteria;
d) specify the characteristics of the product that are essential for its safe and proper use.
The outputs of design and development shall be in a form suitable for verification against the design and development inputs and shall be approved prior to release.
Records of the design and development outputs shall be maintained per 2.

12.4. Design and development review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned and documented arrangements to:
a) evaluate the ability of the results of design and development to meet requirements;
b) identify and propose necessary actions.
Participants in such reviews shall include representatives of functions concerned with the design and development stage being reviewed, as well as other specialist personnel.
Records of the results of the reviews and any necessary actions shall be maintained and include the identification of the design under review, the participants involved and the date of the review.

12.5. Design and development verification
Design and development verification shall be performed in accordance with planned and documented arrangements to ensure that the design and development outputs have met the design and development input requirements. The organization shall document verification plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size. [f the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), verification shall include confirmation that the design outputs meet design inputs when so connected or interfaced.
Records of the results and conclusions of the verification and necessary actions shall be maintained per 2.

12.6. Design and development validation
Design and development validation shall be performed in accordance with planned and documented arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use. The organization shall document validation plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size. Design validation shall be conducted on representative product. Representative

product includes initial production units, batches or their equivalents. The rationale for the choice of product used for validation shall be recorded per 2.
As part of design and development validation, the organization shall perform clinical evaluations or performance evaluations of the medical device when applicable. A medical device used for clinical evaluation or performance evaluation is not considered to be released for use to the customer. If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), validation shall include confirmation that the requirements for the specified application or intended use have been met when so connected or interfaced. Validation shall be completed prior to release for use of the product to the customer. Records of the results and conclusion of validation and necessary actions shall be maintained per 2.

12.7. Design and development transfer
The organization shall document procedures for transfer of design and development outputs to manufacturing. These procedures shall ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications and that production capability can meet product requirements. Results and conclusions of the transfer shall be recorded per 2.

12.8. Control of design and development changes

The organization shall document procedures to control design and development changes. The organization shall determine the significance of the change to function, performance, usability, safety and applicable regulatory requirements for the medical device and its intended use. Design and development changes shall be identified. Before implementation, the changes shall be:
a) reviewed;
b) verified;
c) validated, as appropriate;
d) approved.
The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product in process or already delivered, inputs or outputs of risk management and product realization processes. Records of changes, their review and any necessary actions shall be maintained per 2.

12.9. Design and development files

The organization shall maintain a design and development file for each medical device type or medical device family. This file shall include or reference records generated to demonstrate conformity to the requirements for design and development and records for design and development changes.

The overall responsibility for this procedure belongs to the President/CEO with the guidance and direction of the Management Representative and Management Policy Committee.

Reference: SOP-0003, SOP-0007, SOP-0008, SOP-0020, SOP-0028, SOP-0035

13. Policy Statement for ISO 13485:2016 Section 7.4. Product Realization: Purchasing

13.1. Purchasing process

The organization shall document procedures to ensure that purchased product conforms to specified purchasing information. The organization shall establish criteria for the evaluation and selection of suppliers. The criteria shall be:

a) based on the supplier's ability to provide product that meets the organization's requirements;
b) based on the performance of the supplier;

c) based on the effect of the purchased product on the quality of the medical device;
d) proportionate to the risk associated with the medical device.
The organization shall plan the monitoring and re-evaluation of suppliers. Supplier performance in meeting requirements for the purchased product shall be monitored. The results of the monitoring shall provide an input into the supplier re-evaluation process. Non-fulfilment of purchasing requirements shall be addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements. Records of the results of evaluation, selection, monitoring and re-evaluation of supplier capability or performance and any necessary actions arising from these activities shall be maintained per 2.

13.2. Purchasing information

Purchasing information shall describe or reference the product to be purchased, including as appropriate:

a) product specifications;
b) requirements for product acceptance, procedures, processes and equipment;
c) requirements for qualification of supplier personnel;
d) quality management system requirements.
The organization shall ensure the adequacy of specified purchasing requirements prior to their communication to the supplier. Purchasing information shall include, as applicable, a written agreement that the supplier notify the organization of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements. Documentation shall be maintained per 2.

13.3. Verification of purchased product

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements. The extent of verification activities shall be based on the supplier evaluation results and proportionate to the risks associated with the purchased product. When the organization becomes aware of any changes to the purchased product, the organization shall determine whether these changes affect the product realization process or the medical device. When the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification activities and method of product release in the purchasing information. Records of the verification shall be maintained per 2.

The overall responsibility for this procedure belongs to the President/CEO with the guidance and direction of the Management Representative and Management Policy Committee.

Reference: SOP-0005, SOP-0007, SOP-0010, SOP-0013, SOP-0035, SOP-0036

14. Policy Statement for ISO 13485:2016 Section 7.5. Product Realization: Production and service provision

14.1. Control of production and service provision

Production and service provision shall be planned, carried out, monitored and controlled to ensure that product conforms to specification. As appropriate, production controls shall include but are not limited to:

a) documentation of procedures and methods for the control of production (see 2.);
b) qualification of infrastructure;
c) implementation of monitoring and measurement of process parameters and product characteristics;
d) availability and use of monitoring and measuring equipment;
e) implementation of defined operations for labelling and packaging;

f) implementation of product release, delivery and post-delivery activities.
The organization shall establish and maintain a record (see 2) for each medical device or batch of medical devices that provides traceability to the extent specified in 2.5.2 and identifies the amount manufactured and amount approved for distribution. The record shall be verified and approved.

14.2. Cleanliness of product

SSW shall document requirements for cleanliness of product or contamination control of products. SSW medical parts are supplied both in sterile and non-sterile conditions. Products supplied in non-sterile condition are subject to cleaning process prior to sterilization or use. Products supplied in sterile condition are subject to cleaning process prior to sterile packaging.

14.3. Installation and service activities

SSW does not provide any installation or servicing activities, and hence 7.5.3 and 7.5.4 in ISO 13485:2016 do not apply.

14.4. Particular requirements for sterile medical devices

The organization shall maintain records of the sterilization process parameters used for each sterilization batch of the sterile packaged products. Sterilization records shall be traceable to each production batch of the sterile packaged products.

14.5. Validation of processes for production

The organization shall validate any processes for production where the resulting output cannot be or is not verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use. Validation shall demonstrate the ability of these processes to achieve planned results consistently. The organization shall document procedures for validation of processes, including:
a) defined criteria for review and approval of the processes;
b) equipment qualification and qualification of personnel;
c) use of specific methods, procedures and acceptance criteria;
d) as appropriate, statistical techniques with rationale for sample sizes;
e) requirements for records (see 2);
f) revalidation, including criteria for revalidation;
g) approval of changes to the processes.
The organization shall document procedures for the validation of the application of computer software used in production and service provision. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software, including the effect on the ability of the product to conform to specifications. Records of the results and conclusion of validation and necessary actions from the validation shall be maintained per 2.

14.6. Particular requirements for validation of processes for sterilization and sterile barrier systems

The organization shall document procedures for the validation of processes for sterilization, when applicable. Shukla Medical products shall be evaluated if re-validation for sterilization processes prior to implementation and following product changes is required. All records of the processes, results, and conclusion shall be maintained per 2.

14.7. Identification

The organization shall document procedures for product identification and identify product by suitable means throughout product realization. The organization shall identify product status with respect to monitoring and measurement requirements throughout product realization. Identification of product status shall be maintained throughout production,

storage, installation and servicing of product to ensure that only product that has passed the required inspections and tests or released under an authorized concession is dispatched, used or installed. If required by applicable regulatory requirements, the organization shall document a system to assign unique device identification to the medical device. The organization shall document procedures to ensure that medical devices returned to the organization are identified and distinguished from conforming product.

The overall responsibility for the traceability procedure(s) belongs to the President/CEO with the guidance and direction of the Management Representative and Management Policy Committee.

14.8. Traceability

14.8.1. General

The organization shall document procedures for traceability. These procedures shall define the extent of traceability in accordance with applicable regulatory requirements and the records to be maintained per 2.

14.8.2. Particular requirements for implantable medical devices

SSW does not manufacture any implantable devices and 7.5.9.2 in ISO 13485:2016 is not applicable.

14.8.3. Customer property

The organization shall identify, verify, protect, and safeguard customer property provided for use or incorporation into the product while it is under the organization's control or being used by the organization. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records per 2.

14.8.4. Preservation of product

The organization shall document procedures for preserving the conformity of product to requirements during processing, storage, handling, and distribution. Preservation shall apply to the constituent parts of a medical device. The organization shall protect product from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling, and distribution by:

a) designing and constructing suitable packaging and shipping containers;
b) documenting requirements for special conditions needed if packaging alone cannot provide preservation.
If special conditions are required, they shall be controlled and recorded per 2.

The overall responsibility for the validation of processes for production procedure(s) belong to the President/CEO with the guidance and direction of the Management Representative and Management Policy Committee.

Reference: SOP-0006, SOP-0007, SOP-0008, SOP-0009, SOP-0013, SOP-0019, SOP-0036

15. Policy Statement for ISO 13485:2016 Section 7.6. Product Realization: Control of monitoring and measuring equipment

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements. The organization shall document procedures to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements. As necessary to ensure valid results, measuring equipment shall:

a) be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards: when no such standards exist, the basis used for calibration or verification shall be recorded (see 2.);
b) be adjusted or re-adjusted as necessary: such adjustments or re-adjustments shall be recorded (see 2.);
c) have identification in order to determine its calibration status;
d) be safeguarded from adjustments that would invalidate the measurement result;
e) be protected from damage and deterioration during handling, maintenance and storage.

The organization shall perform calibration or verification in accordance with documented procedures. In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action in regard to the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 2).

The organization shall document procedures for the validation of the application of computer software used for the monitoring and measurement of requirements. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software, including the effect on the ability of the product to conform to specifications. Records of the results and conclusion of validation and necessary actions from the validation shall be maintained (see 2.).

The overall responsibility for this procedure belongs to the President/CEO with the guidance and direction of the Management Representative and Management Policy Committee.

Reference: SOP-0014, SOP-0020, SOP-0022, SOP-0036.

16. Policy Statement for ISO 13485:2016 Section 8.1. Measurement, Analysis and Improvement: General requirements

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed to:

a) demonstrate conformity of product;
b) ensure conformity of the quality management system;
c) maintain the effectiveness of the quality management system.
This shall include determination of appropriate methods, including statistical techniques, and the extent of their use.

The overall responsibility for this procedure belongs to the President / CEO with the guidance and direction of the Management Representative and Management Policy Committee.

Reference: SOP-0014, SOP-0016, SOP-0017, SOP-0021, SOP-0024, SOP-0033, SOP-17012.

17. Policy Statement for ISO 13485:2016 Section 8.2. Measurement, Analysis and Improvement: Monitoring and measurement

17.1. Feedback

As one of the measurements of the effectiveness of the quality management system, the organization shall gather and monitor information relating to whether the organization has met customer requirements. The methods for obtaining and using this information shall be documented. The organization shall document procedures for the feedback process. This

feedback process shall include provisions to gather data from production as well as post-production activities. 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. If applicable regulatory requirements require the organization to gain specific experience from postproduction activities, the review of this experience shall form part of the feedback process.

17.2. Complaint handling

The organization shall document procedures for timely complaint handling in accordance with applicable regulatory requirements. These procedures shall include at a minimum requirements and responsibilities for:
a) receiving and recording information;
b) evaluating information to determine if the feedback constitutes a complaint;
c) investigating complaints;
d) determining the need to report the information to the appropriate regulatory authorities;
e) handling of complaint-related product;
f) determining the need to initiate corrections or corrective actions.
If any complaint is not investigated, justification shall be documented. Any correction or corrective action resulting from the complaint handling process shall be documented. If an investigation determines activities outside the organization contributed to the complaint, relevant information shall be exchanged between the organization and the external party involved.
Complaint handling records shall be maintained (see 2).

17.3. Reporting to regulatory authorities

If applicable regulatory requirements require notification of complaints that meet specified reporting criteria of adverse events or issuance of advisory notices, the organization shall document procedures for providing notification to the appropriate regulatory authorities. Records of reporting to regulatory authorities shall be maintained per 2.

17.4. Internal audit

The organization shall conduct internal audits at planned intervals to determine whether the quality management system:
a) conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements established by the organization, and applicable regulatory requirements;
b) is effectively implemented and maintained.
The organization shall document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results. An audit program shall be planned, taking into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits. The audit criteria, scope, interval and methods shall be defined and recorded (see 12.5.). The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. Records of the audits and their results, including identification of the processes and areas audited and the conclusions, shall be maintained (see 2). The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results.

17.5. Monitoring and measurement of processes

The organization shall apply suitable methods for monitoring and, as appropriate, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

17.6. Monitoring and measurement of products

The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at applicable stages of the product realization process in accordance with the planned and documented arrangements and documented procedures. Evidence of conformity to the acceptance criteria shall be maintained. The identity of the person authorizing release of product shall be recorded (see 2.). As appropriate, records shall identify the test equipment used to perform measurement activities. Product release and service delivery shall not proceed until the planned and documented arrangements have been satisfactorily completed.

The overall responsibility for this procedure belongs to the President/CEO with the guidance and direction of the Management Representative and Management Policy Committee.

Reference: SOP-0016, SOP-0017, SOP-0021, SOP-0033, SOP-17012.

18. Policy Statement for ISO 13485:2016 Section 8.3. Measurement, Analysis and Improvement: Control of non-conforming product

18.1. General

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The organization shall document a procedure to define the controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation and disposition of nonconforming product. The evaluation of nonconformity shall include a determination of the need for an investigation and notification of any external party responsible for the nonconformity. Records of the nature of the nonconformities and any subsequent action taken, including the evaluation, any investigation and the rationale for decisions shall be maintained per 2.

18.2. Actions in response to nonconforming product detected before delivery

The organization shall deal with nonconforming product by one or more of the following ways:

a) taking action to eliminate the detected nonconformity;
b) taking action to preclude its original intended use or application;
c) authorizing its use, release or acceptance under concession.
The organization shall ensure that nonconforming product is accepted by concession only if the justification is provided, approval is obtained and applicable regulatory requirements are met. Records of the acceptance by concession and the identity of the person authorizing the concession shall be maintained per 2.

18.3. Actions in response to nonconforming product detected after delivery

When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity. Records of actions taken shall be maintained per 2.

The organization shall document procedures for issuing advisory notices in accordance with applicable regulatory requirements. These procedures shall be capable of being put into effect at any time. Records of actions relating to the issuance of advisory notices shall be maintained per 2.

18.4. Rework

The organization shall perform rework in accordance with documented procedures that takes into account the potential adverse effect of the rework on the product. These procedures shall undergo the same review and approval as the original

procedure. After the completion of rework, product shall be verified to ensure that it meets applicable acceptance criteria and regulatory requirements. Records of rework shall be maintained per 2.

The overall responsibility for this procedure belongs to the President/CEO with the guidance and direction of the Management Representative and Management Policy Committee.

Reference: SOP-0016, SOP-0017, SOP-17012.

19. Policy Statement for ISO 13485:2016 Section 8.4. Measurement, Analysis and Improvement: Analysis of data

The organization shall document procedures to determine, collect and analyse appropriate data to demonstrate the suitability, adequacy and effectiveness of the quality management system. The procedures shall include determination of appropriate methods, including statistical techniques and the extent of their use.

The analysis of data shall include data generated as a result of monitoring and measurement and from other relevant sources and include, at a minimum, input from:

a) feedback;
b) conformity to product requirements;
c) characteristics and trends of processes and product, including opportunities for improvement;
d) suppliers;
e) audits;
f) service reports, as appropriate.

If the analysis of data shows that the quality management system is not suitable, adequate or effective, the organization shall use this analysis as input for improvement as required in 2. Records of the results of analyses shall be maintained per 2.

The overall responsibility for this procedure belongs to the President/CEO with the guidance and direction of the Management Representative and Management Policy Committee.

Reference: SOP-0005, SOP-0019, SOP-0020, SOP-0021, SOP-0033.

20. Policy Statement for ISO 13485:2016 Section 8.5. Measurement, Analysis and Improvement: Improvement

20.1 General
The organization shall identify and implement any changes necessary to ensure and maintain the continued suitability, adequacy and effectiveness of the quality management system as well as medical device safety and performance through the use of the quality policy, quality objectives, audit results, postmarket surveillance, analysis of data, corrective actions, preventive actions and management review.

20.2. Corrective action
The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Any necessary corrective actions shall be taken without undue delay based on risk to quality. Corrective actions shall be proportionate to the effects of the nonconformities encountered.
The organization shall document a procedure to define requirements for:
a) reviewing nonconformities (including complaints);

b) determining the causes of nonconformities;
c) evaluating the need for action to ensure that nonconformities do not recur;
d) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;
e) verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device;
f) reviewing the effectiveness of corrective action taken.
Records of the results of any investigation and of action taken shall be maintained per section 2.

20.3. Preventive action
The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be proportionate to the effects of the potential problems.
The organization shall document a procedure to describe requirements for:
a) determining potential nonconformities and their causes;
b) evaluating the need for action to prevent occurrence of nonconformities;
c) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;
d) verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device;
e) reviewing the effectiveness of the preventive action taken, as appropriate.
Records of the results of any investigations and of action taken shall be maintained per section 2.

The overall responsibility for this procedure belongs to the President / CEO with the guidance and direction of the Management Representative and Management Policy Committee.
Reference: SOP-0001, SOP-0002, SOP-0010, SOP-0011, SOP-0012, SOP-0016, SOP-0017, SOP-0020.

List of referenced documents

Document ID	Description
SOP-0001	MANAGEMENT RESPONSIBILITY PROCEDURE
SOP-0002	QUALITY SYSTEMS PROCEDURE
SOP-0003	CONTRACT REVIEW PROCEDURE
SOP-0005	PURCHASING PROCEDURE
SOP-0006	CONTROL OF CUSTOMER SUPPLIED PRODUCT
SOP-0007	TRACEABILITY PROCEDURE
SOP-0008	PRODUCT IDENTIFICATION PROCEDURE
SOP-0009	PROCESS CONTROL PROCEDURE
SOP-0010	INCOMING INSPECTION PROCEDURE
SOP-0011	IN-PROCESS INSPECTION PROCEDURE
SOP-0012	FINAL INSPECTION PROCEDURE
SOP-0013	USE OF AGE-SENSITIVE MATERIALS
SOP-0014	CONTROL OF INSPECTION MEASURING AND TEST EQUIPMENT PROCEDURE
SOP-0016	CONTROL OF NON-CONFORMING PRODUCT PROCEDURE
SOP-0017	CORRECTIVE AND PREVENTIVE ACTION PROCEDURE
SOP-0019	COMPONENT STOCKROOM CONTROL PROCEDURE
SOP-0020	CONTROL OF QUALITY RECORDS PROCEDURE
SOP-0021	INTERNAL AUDITING PROCEDURE
SOP-0022	TRAINING PROCEDURE
SOP-0024	Statistical Techniques Procedure
SOP-0025	WIRE AND SHAFT STOCKROOM CONTROL PROCEDURE
SOP-0026	Tooling Control Procedure
SOP-0028	DESIGN REVIEW PROCEDURE
SOP-0033	CONTINUOUS IMPROVEMENT
SOP-0035	Production Part Approval Process
SOP-0036	FOREIGN OBJECT DEBRIS (FOD) PREVENTION
SOP-17001	ACCEPTABLE USE POLICY
SOP-17002	AUDIT VULNERABILITY SCAN POLICY
SOP-17003	EMAIL USE POLICY
SOP-17004	INFORMATION SENSITIVITY POLICY
SOP-17005	APPLICATION DEVELOPMENT POLICY
SOP-17008	ONBOARDING POLICY
SOP-17012	POST MARKET SURVEILLANCE PROCEDURE
SOP-17013	PLAN OF ACTION AND MILESTONES
WI-0450	INSTRUCTION FOR EQUIPMENT AND SOFTWARE VALIDATION

Quality Policy Manual Revision History

Rev	Section(s) Changed	Change(s) Made	Date	Editor
1	Initial release	Initial release	03/27/2020	Santosh Rohit Yerrabolu
2	Exclusions for ISO 13485:2016	Replaced 7.5.9.1 with 7.5.9.2; added: “SSW does not: a) provide any installation or servicing activities; b) produce any sterile medical devices; and c) manufacture any implantable devices.”	04/20/2020	Santosh Rohit Yerrabolu
3	1) Exclusions for ISO 13485:2016; 2) Section 14.2; 3) Section 14.4	1) Removed references to 7.5.5 and “produce any sterile medical devices”. 2) 14.2 updated to include -"SSW medical parts are supplied both in sterile and non-sterile conditions. Products supplied in non-sterile condition are subject to cleaning process prior to sterilization or use. Products supplied in sterile condition are subject to cleaning process prior to sterile packaging." 3) Section 14.4 updated to "The organization shall maintain records of the sterilization process parameters used for each sterilization batch of the sterile packaged products. Sterilization records shall be traceable to each production batch of the sterile packaged products."	04/18/2025	Santosh Rohit Yerrabolu

