Revision Control

Revision	Issued Date	Description of change
1.0	22-May-2018	Initial Release
2.0	16-Feb-2021	Remove ISO 13485:2003 from policy references

Quality Policy

Prepared by:

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Reviewed by:

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Position	Name	Date and Signature

Approved by:

CEO	Joseph Flomenblit	16-02-2021
Position	Name	Date and Signature

1. **Purpose**

   The purpose of this procedure is to affirm the commitment of STS Medical management and employees to deliver to its customer's high quality and reliable products and services according to the requirements of: ISO 13485:2016, FDA QSR 21 CFR part 820, EU Medical Device Directive (93/42/EEC) and the the European Medical Device Regulation (MDR) EU 2017/745.

2. **Scope**

   2.1. The scope of this procedure is STS Medical Quality Policy in order to be able to supply its customers with products and services that fulfill their requirements and meet the applicable procedures.

3. **Applicable & reference documents**

   3.1. ISO 13485:2016 - Medical devices - quality management systems - requirements for regulatory purposes - sections 5.1, 5.3, 5.4.1, 6.1, 6.2.1

   3.2. EU Medical Device Directive (93/42/EEC)

   3.3. EU Medical Device Regulation (EU 2017/745)

   3.4. FDA Requirements QSR - § 820.20

4. **Definitions**

   4.1. **FDA** – Food and Drug Administration

   4.2. **ISO** – International Standard Organization

   4.3. **QSR** – Quality System Procedure

   4.4. **MDD** – Medical Device Directive

5. **Responsibility**

   5.1. The CEO is responsible for the implementation of this procedure, and for assimilation of quality policy amongst all company employees, at all levels.

   5.2. The QA/RA Manager is responsible for verifying the implementation of the above procedure as stated.

6. **Procedure**

   6.1. Approach to quality

   6.1.1. The company management and the employees are committed to supply to its customers products and services at a level of quality and reliability detailed directly in the product specifications and indirectly in the relevant national and international standards, continuously produce products that are safe and

effective. Understanding the needs of the customer and the market is the key to success.

6.1.2. The company management considers quality a means of increasing work efficiency and profitability. The company allocates suitable equipment and skilled personnel toward actualizing quality activities.

6.1.3. The company management considers its employees of all levels the basis for the company's success in research and development, in production, and in the provision of services at a high level of quality and reliability. Fostering professionalism, interpersonal / interdepartmental communication and enhancement of motivation are an impetus to success.

6.1.4. The company management encourages the involvement of employees of all levels in the company's activities, thereby ensuring the preservation of the efficacy of the quality system and the quality of the company's products and services.

6.1.5. Focus on the customer:
The company fosters the customer's sense of confidence that the quality of the products / services for which he strives is in fact reached and has a high level of customer satisfaction. Understanding the needs of the customer and the targeted market are at the basis for the company's success.

6.1.6. Conformance to quality standards:
STS Medical quality system is in compliance with ISO 13485:2016, the EU Medical Device Directive (93/42/EEC), and FDA QSR 21 CFR part 820. STS Medical considers the quality system a tool for increasing efficiency and profitability, and therefore allocates all resources necessary for maintaining an effective quality system.

6.1.7. The company management considers its suppliers and subcontractors full partners in the quality and the excellence of STS Medical products and/or services. Therefore the company is committed to engage solely with suppliers / subcontractors who meet STS Medical quality requirements and who are capable of supplying products and/or services at the required level of quality.

6.2. Means of action

6.2.1. The company management has appointed the QA/RA Manager as responsible for coordinating all the company's quality activities. The QA/RA Manager reports directly to the CEO.

6.2.2. The company management shall present its periodic targets for quality improvement (Quality Objectives), and shall define measures for testing them.

6.2.3. These targets and measures shall be documented in an annual program, and their attainment monitored at the Management Review and at Internal Quality Audits.

6.2.4. The company management considers its quality system employees to be representatives of the customer in all matters relating to quality, reliability and the compliance of the company's products and services.

6.2.5. The processes in the company are documented in the framework of "Quality System Procedure". The QA/RA Manager is responsible for the continual updating of the procedures, their implementation and training of employees of all levels.

6.2.6. Quality procedures shall be written in English and shall be translated to other languages as needed / required (uncontrolled – for reference only).

6.2.7. The company management shall assure that the quality policy is understood and implemented by all the company employees, and shall allocate all necessary resources in order to implement this policy, and meet the targets it set out.

6.2.8. An employee who performs an activity that affects product quality shall possess suitable competence, skills, and experience.

6.3. Feedback and control

The Company's CEO or the QA/RA Manager shall initiate Management Review meetings that deal with quality-related subjects, refer to "Management Review" procedure.

6.4. The Quality Policy will be the included in the training of new employees, consultants and other outside personnel performing work for STS Medical or on behalf of STS Medical, and in periodic refresher training of all personnel.

6.5. The Quality Policy should be signed by STS Medical's top management and shall be publicly displayed and visible for all employees.

6.6. The Quality Policy will be reviewed and updated annually and displayed at appropriate locations in STS Medical site. See Appendix A for STS Medical Quality Policy.

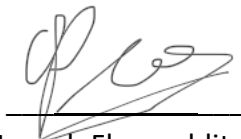
Appendix A – STS Medical Quality Policy

The management and employees of STS Medical, commit:

- To continually aspire to the highest level of quality and reliability of our products;
- To be a company whose standards will be emulated by other companies;
- To be recognized as a company that stands for dedication, integrity, perfection, and service.

The principles and implementation of this policy include the following areas:

- Development, manufacturing and supply of products that meet customer expectations and requirements while complying with international regulatory requirements. Understanding the market and customer needs is the key to success.
- Development and implementation of a system that complies with the requirements of ISO 13485:2016, European Medical Device Directive (MDD) 93/42/EEC, European Medical Device Regulation (MDR) EU 2017/745 FDA-QSR and the regulatory bodies of Europe and U.S.
- STS Medical sees the quality system as a tool for improving the company's efficiency and profitability, and we allocating appropriate resources to substantiate the quality activities.
- STS Medical employees and subcontractors are at the base of the company's capability of developing and manufacturing reliable and high quality products. Professional promotion, internal communication, and motivating employees and subcontractors provide the key to success.
- STS Medicalmanagement encourages each and every employee and subcontractor to become an active partner in the company's activities, thereby ensuring the continuous improvement, preservation and effectiveness of the quality system, and quality of the company’s products and services.
- The company ensures that all employees understand its objectives and quality policy by means of training them in the performance of their activities.



Joseph Flomenblit , CEO

16-02-2021

Date