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QUALITY MANUAL

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Date:	Latest Revision Date
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Abstract:
This document describes the quality management system processes for ISO 13485.

REVISION LOG

Issue	Date	Comment	Author
Orig			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

TABLE OF CONTENTS

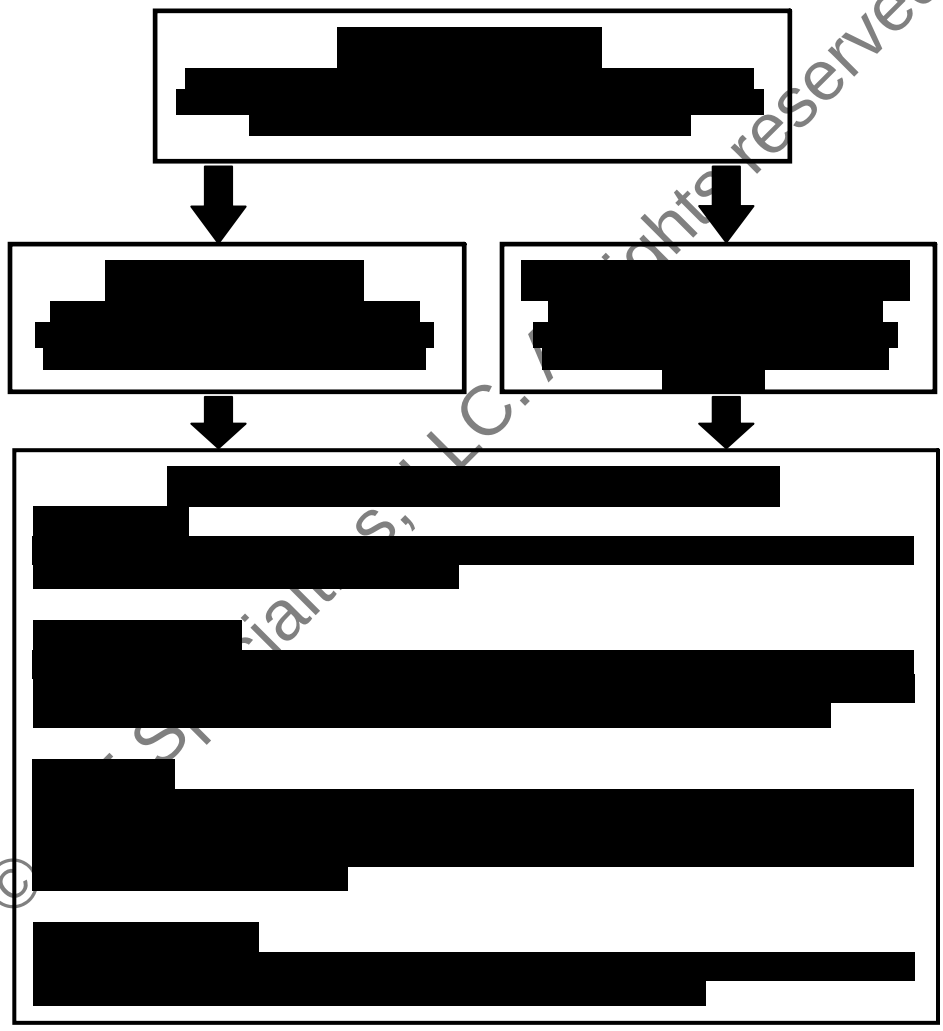
Section 1: Welcome to (Your Company Name)

The Company is a developer and producer of medical devices that include (your product description).

The Company has always applied high quality standards as guidelines for its processes and operations but has revised its systems to fully comply with ***ISO 13485***.

The Company is dedicated to [redacted]

Section 2: Company Vision and Governing Policies



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Section 3: Scope, Exclusions and Definitions

3.1 Scope

The Company's quality management system applies to all functional areas of the Company's business operation. The Company's scope of business is defined as follows:

[redacted]

3.2 Exclusions

The Company cites no exclusions to the ***ISO 13485*** standard.

NOTE: The Company has [redacted]

3.3 Definitions & Conventions

Unless otherwise noted, the Company applies the definitions of key terms according to ***ISO 13485*** and ***QMS-16 Definitions and Abbreviations.*** Subordinate or external documentation is referenced in ***Bold Italics***.

Section 4: Quality Management System

4.1 General Requirements

4.1.1 The Company's quality system has been fully documented and implemented and is [redacted]

The Company has adopted a process-oriented method of management that includes [redacted], and emphasizes the importance of:

1) [redacted]
2)
3)
4)

4.1.2 For each process identified in use at the Company, the sequence and interaction of processes has [redacted] see Figure 1.

Every process has at least one QMS Procedure that [redacted] The relationship between the listed processes and their applicable ***ISO 13485*** clauses is shown in the tables in ***Appendix A***. Outsourced processes and their controls are defined in ***Appendix C.***

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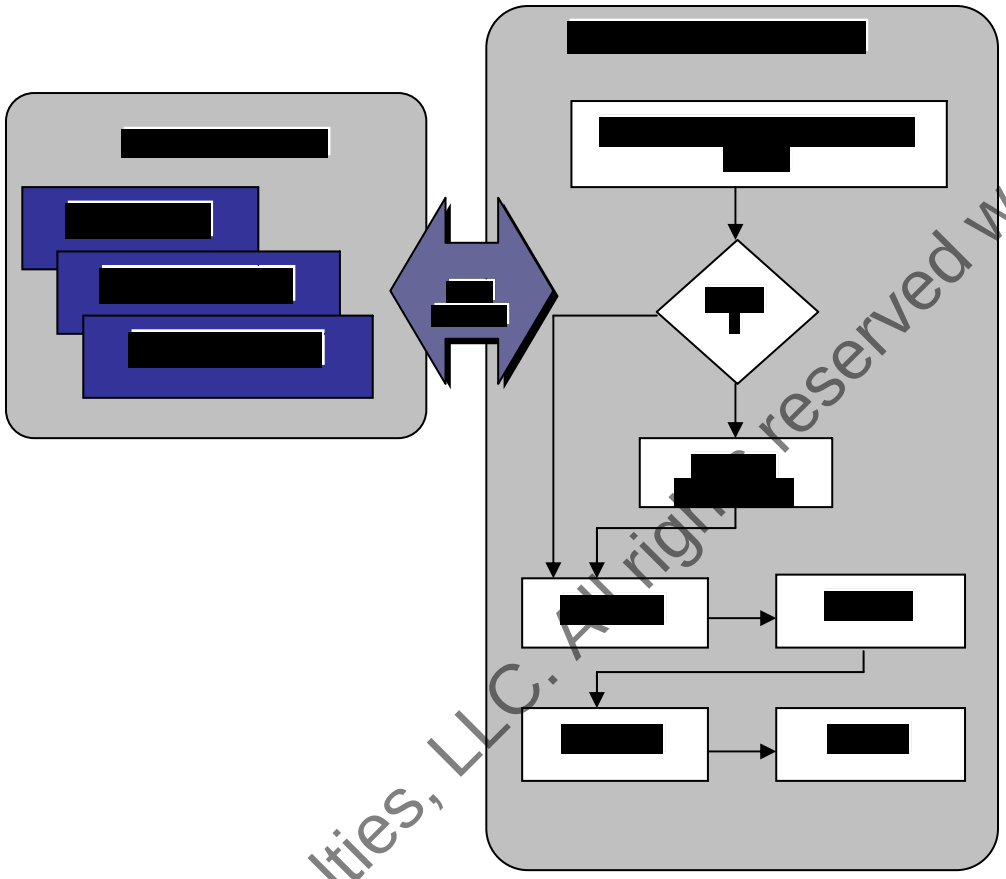
Figure 1: Overall Process Sequence & Interaction



4.1.3 Processes are controlled by way of [redacted]

- [redacted]
- [redacted]
- [redacted]

4.1.4 The Company manages quality management system processes and procedures according to [redacted] Changes to processes and procedures are:

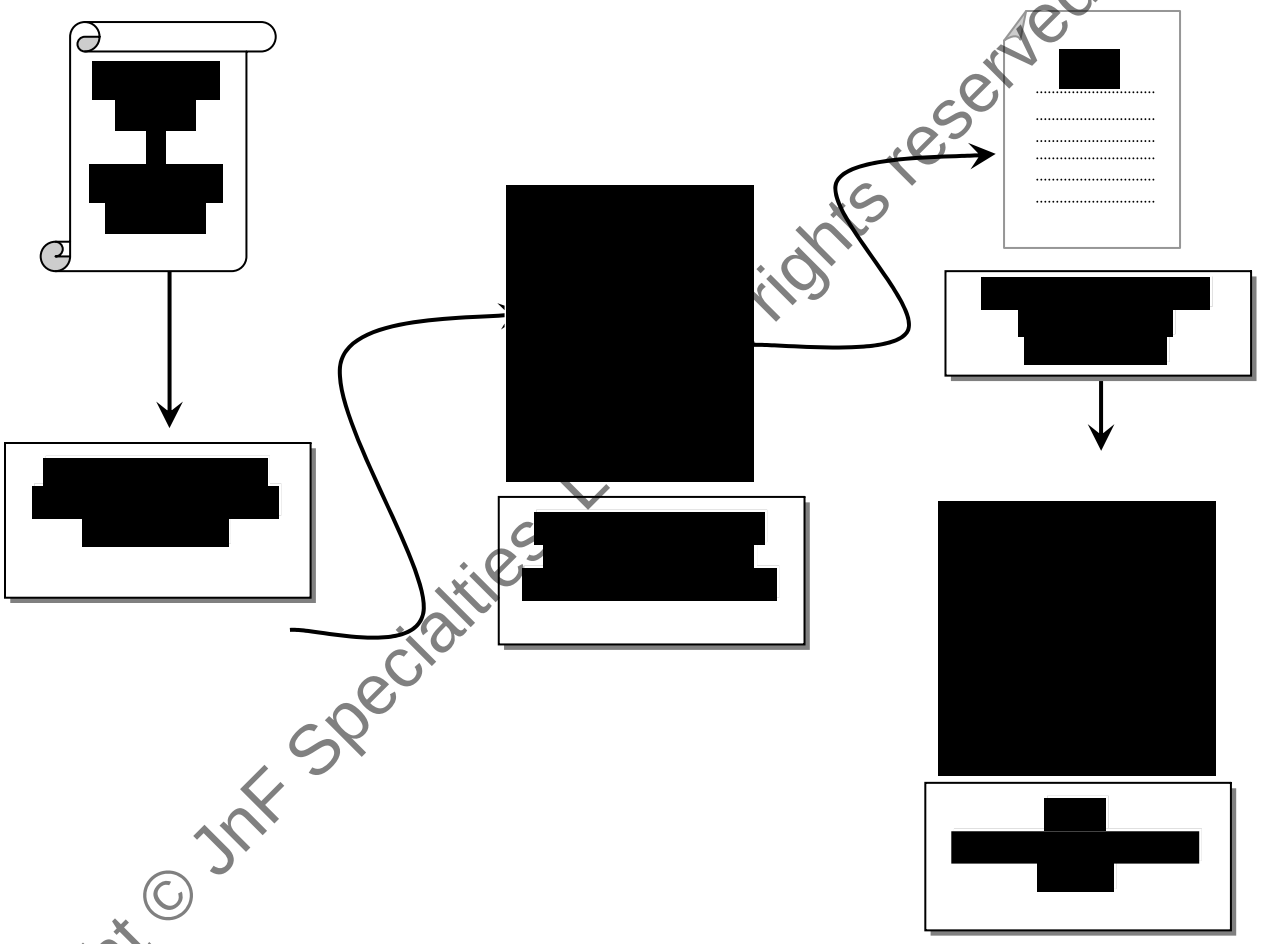
- [redacted]
- [redacted]
- [redacted]

4.1.5 When the Company elects to outsource any process that affects product conformity to requirements, the Company [redacted] The controls for outsourced activities are [redacted] according to the ***QMS-08 Purchasing Procedure***, which includes [redacted]

4.1.6 The Company controls the application of [redacted]. The specific approach and activities associated with [redacted] according to the ***QMS-01 Control of Documented Information Procedure***.

4.2 Documentation Requirements

The quality system documentation is comprised of a hierarchy of documents that flow from this Quality Manual. All documents support and [redacted]



4.2.1 General

Documentation for the Company's quality management system includes:

a) [redacted]
b)
c)
d)

The order of precedence of order-specific documentation is [redacted]

1. [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]

4.2.2 Quality Manual

The primary purpose of the Quality Manual and QMS Procedures [redacted] Changes to the Quality Manual are controlled according to the ***QMS-02 Configuration Management Procedure***. Additional procedures and work instructions are [redacted] Where subordinate documents are referenced, they are shown in ***bold italics***.

a) [redacted]
b) [redacted]
c) [redacted]

4.2.3 Medical Device File

For each medical device type or medical device family, the Company establishes and maintains one or more files that contain or reference [redacted]

The content of the files include:

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]
e) [redacted]
f) [redacted]

4.2.4 Control of Documents

The controls for documents are defined in ***QMS-01 Control of Documented Information Procedure.*** Previous versions and legacy documents are [redacted]

Documents are controlled to:

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]
e) [redacted]
f) [redacted]
g) [redacted]

h) [redacted]

Changes to documents are [redacted] according to the ***QMS-02 Configuration Management Procedure***.

Obsolete documents are retained and maintained according to the ***QMS-01 Control of Documented Information Procedure***.

4.2.5 Control of Records

Records are controlled to provide evidence of conformity to requirements and [redacted]. The Company protects confidential [redacted]. Records subject to control are defined in the ***QMS-01 Control of Documented Information Procedure***.

Section 5: Management Responsibility

5.1 Management Commitment

The Company is committed to [redacted] according to the ***QMS-04 Management Process Procedure*** and [redacted]:

a) [redacted]
b) [redacted]
c) [redacted] s
d) [redacted]
e) [redacted]

5.2 Customer Focus

The Company demonstrates leadership and commitment with respect to Customer focus by [redacted] Management pays particular attention [redacted] according to the ***QMS-04 Management Process Procedure***. Applicable regulatory/statutory requirements are [redacted] according to the ***QMS-07 Proposal Development and Contract Review Procedure***.

5.3 Quality Policy

The Company's Quality Policy is defined in Section 2.0, which is [redacted] according to the ***QMS-04 Management Process Procedure***. The Quality Policy is [redacted] according the ***QMS-01 Control of Documented Information Procedure.*** The Quality Policy may [redacted]

The Company's quality policy:

a) [redacted]
b) [redacted]
c) [redacted]

d) [redacted]
e) [redacted]

5.4 Planning

5.4.1 Quality Objectives

Every process within the Company has [redacted] Objectives are [redacted] Objectives are subject to [redacted] The table in ***Appendix D*** defines the quality objectives in place at the Company. Quality objectives are [redacted] The records of management reviews include [redacted] - see the ***QMS-04 Management Process Procedure***.

5.4.2 Quality Management System Planning

The impact on the conformity of products and services [redacted] are used to [redacted] according to the ***QMS-04 Management Process Procedure***.

Planning for the quality management system includes [redacted] ***QMS-04 Management Process Procedure*** is used to address [redacted]

The quality system has been planned in advance and its documented policies and procedures [redacted] Subsequent major changes that may affect [redacted] The QMS documentation [redacted]

Changes to the quality management system are performed according to the ***QMS-02 Configuration Management Procedure***, which considers [redacted] The quality management system is [redacted]

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

The organizational chart in Figure 2 defines the basic management structure of the Company. In all cases, the appropriate person has [redacted] which are further defined in the ***QMS-05 Responsibilities and Authorities Procedure***. All Employees are [redacted] The Quality Manager oversees this effort and [redacted]

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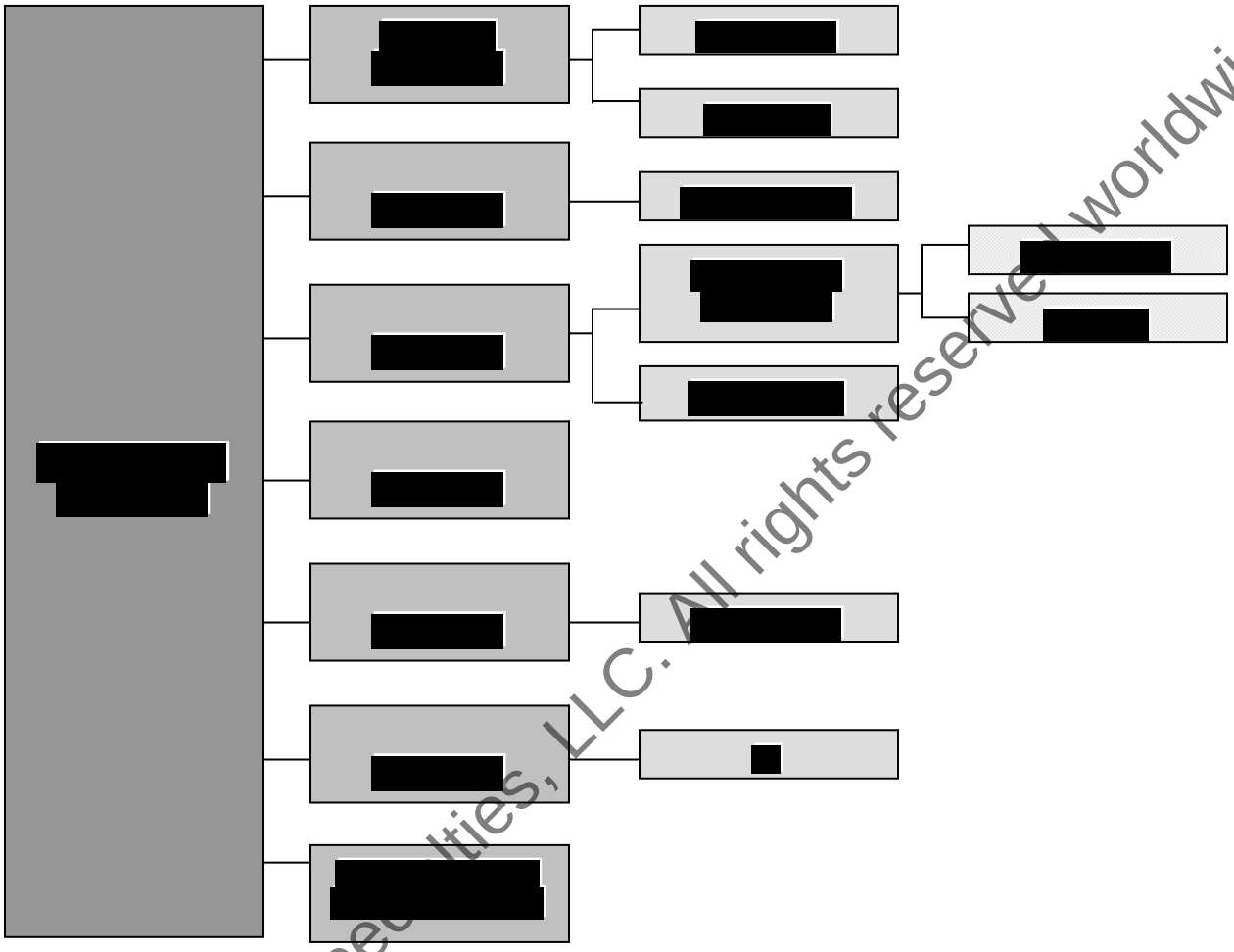
Figure 2: Responsibilities and Authorities



5.5.2 Management Representative

The Quality Manager of the Company has been assigned [redacted] The Quality Manager is responsible for [redacted]

The Quality Manager reports [redacted]

The Quality Manager has the responsibility and authority to [redacted] The Quality Manager may [redacted]

5.5.3 Internal Communication

To ensure proper communication between and throughout all levels of Employees within the Company, internal communication is [redacted] according to the ***QMS-04 Management Process Procedure***. Management holds periodic meetings with Employees to [redacted] Employees are encouraged [redacted] according to the ***QMS-14 Control of Nonconformities Procedure***.

5.6 Management Review

5.6.1 General

Management Review meetings are conducted according to the ***QMS-04 Management Process Procedure***, which defines [redacted]

5.6.2 Review Input

See the ***QMS-04 Management Process Procedure*** for details regarding review inputs.

5.6.3 Review Output

See the ***QMS-04 Management Process Procedure*** for details regarding review outputs.

Section 6: Resource Management

6.1 Provision of Resources

During management review, the Company's management [redacted] The processes of Management and Proposal Development and Contract Review have been developed and implemented to [redacted] Employees may [redacted] Resource management is addressed in the ***QMS-04 Management Process Procedure***.

6.2 Human Resources

6.2.1 General

Employees are selected, trained and evaluated to [redacted] Personnel undergo training to provide [redacted] according to the ***QMS-06 Training Program***.

6.2.2 Competence, Training and Awareness

All Company personnel are hired on the basis [redacted] according to the ***QMS-06 Training Program***.

The Company's training program:

a) [redacted]

b) [redacted]

c) [redacted]

d) [redacted]

e) [redacted]

The training program is defined in the ***QMS-06 Training Procedure***.

6.3 Infrastructure

The Company has determined and provided the infrastructure needed to [redacted] Infrastructure requirements are regularly reviewed during Management Review and include a review of:

- [redacted]
- [redacted]
- [redacted]
- [redacted]

The Company utilizes maintenance routines that [redacted] Records of maintenance activities are retained and maintained according to the ***QMS-01 Control of Documented Information Procedure***. Monitoring and measurement equipment is controlled according to the ***QMS-15 Calibration Procedure***. The Facilities Manager [redacted] For more on management's controls over the infrastructure, see the ***QMS-04 Management Process Procedure***.

6.4 Work Environment and Contamination Control

The Company has determined and provided [redacted] The work environment is [redacted] For more on management's controls over the work environment see ***QMS-04 Management Process Procedure***.

6.4.1 Work Environment

The Company documents requirements for the work environment needed to [redacted]

The Company documents the requirements to [redacted]

The Company:

a) [redacted]

b) [redacted]

6.4.2 Contamination Control

To prevent contamination [redacted] the Company [redacted]

For sterile medical devices, the Company documents:

a) [redacted]

b) [redacted]

6.5 Corrective Maintenance

The Company utilizes corrective maintenance and skilled maintenance personnel [redacted] Preventive maintenance activities are [redacted] It is acceptable to [redacted] Correcting the problem is [redacted] The cost for preventive maintenance is [redacted]

Section 7: Product Realization

7.1 Planning of Product Realization

In planning the processes for product realization, the Company has [redacted] according to the ***QMS-18 Risk Mitigation and Planning Procedure***. Proportionate actions are [redacted] At times, additional [redacted] The creation, review and approval [redacted] ensures [redacted]

a) [redacted]

b) [redacted]

c) [redacted]

d) [redacted]

7.2 Customer-Related Processes

7.2.1 Determination of Requirements Related to Product

The Company determines [redacted] The Company captures [redacted] which is defined in the ***QMS-07 Proposal Development & Contract Review Procedure***, and includes:

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]

7.2.2 Review of Requirements Related to Product

Once requirements are captured, they are [redacted] This occurs [redacted] as defined in the ***QMS-07 Proposal Development & Contract Review Procedure***, which includes:

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]
e) [redacted]

Records of the results of the review and actions arising from the review are retained and maintained according to the ***QMS-01 Control of Documented Information Procedure***. Where the Customer provides [redacted] Where product requirements are [redacted]

7.2.3 Communication

The Company treats Customer communication [redacted], which includes:

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]
e) [redacted]

Communication methods may include [redacted]

7.3 Design and Development

7.3.1 General

The Design and Development process ensures design activities are conducted in a controlled manner that is defined in ***QMS-17 Design and Development***, which includes provisions for [redacted]

7.4 Purchasing

Purchasing is treated as [redacted] The Company does not [redacted] The purchasing process is fully defined in the ***QMS-08 Purchasing Procedure***.

7.4.1 Purchasing Process

The purchasing process [redacted] The Company determines [redacted] according to the ***QMS-09 Receiving Procedure***.

The criteria applied for the evaluation and selection of Suppliers is:

a) [redacted]
b)
c)
d)

The Company monitors Supplier performance and applies [redacted] according to the ***QMS-09 Receiving Procedure*** taking into account [redacted]

Records of the results [redacted] according to the ***QMS-01 Control of Documented Information Procedure***.

7.4.2 Purchasing Information

Purchase orders are used to [redacted]

Purchasing information describes or references the product to be purchased, including as appropriate:

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]

The Company confirms the adequacy of [redacted]

Purchasing information includes, as applicable, [redacted]

The Company retains and maintains purchasing documents and records according to the ***QMS-01 Control of Documented Information Procedure***.

7.4.3 Verification of Purchased Product

Incoming materials are [redacted] which is based upon [redacted] as defined in the ***QMS-09 Receiving Procedure***.

When changes to the purchased product are discovered, the Company [redacted]

When external provider test reports are [redacted], the Company implements [redacted] When a Customer or External Party has [redacted] the Company implements [redacted] according to the ***QMS-09 Receiving Procedure***.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

Production and services are [redacted] according to the ***QMS-10 Production Procedure*** to [redacted] which includes:

a) [redacted]
b) [redacted]
c) [redacted]

[redacted] These activities are fully defined in the ***QMS-02 Configuration Management Procedure***

d) [redacted]

e) [redacted]

f) [redacted]

The Company has established and retains/maintains [redacted]

7.5.1.1 Production Documentation

Production operations are performed according to [redacted] Work instruction, drawings and other documents define [redacted] In addition, the Company may [redacted]. These activities are fully defined in the ***QMS-10 Production Procedure*** and the ***QMS-17 Design and Development Procedure***.

7.5.1.2 Control of Production Process Changes

Only the Configuration Control Board (CCB) is authorized [redacted]. The results of changes to production processes are [redacted]

These activities are fully defined in the ***QMS-10 Production Procedure*** and the ***QMS-17 Design and Development Procedure***.

7.5.1.3 Control of Production Equipment & Tools

Production equipment and tools [redacted] according to the ***QMS-10 Production Procedure***. The ***QMS-12 Internal Auditing Procedure*** [redacted]

7.5.1.4 Control of Work Transferred on a Temporary Basis Outside the Organization's Facilities

When the Company provides supplies for outside processing, such as [redacted] work is performed under the following controls:

- [redacted]
- [redacted]

- [redacted]
- [redacted]

7.5.1.5 Control of Service Operations

The Company services supplies returned to it for [redacted]

7.5.2 Cleanliness of Product

The Company produces documented information for cleanliness of product [redacted] according to the ***QMS-10 Production Procedure***, when:

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]
e) [redacted]

If product is cleaned according to a) or b) above, the requirements for the work environment [redacted] do not [redacted]

7.5.3 Installation Activities

The Company produces documented information [redacted] according to the ***QMS-07 Proposal Development and Contract Review Procedure***.

If the agreed Customer requirements allow [redacted] the Company provides [redacted]

Records of medical device installation [redacted] according to the ***QMS-01 Control of Documented Information Procedure***.

7.5.4 Servicing Activities

When servicing of a medical device is required, the Company [redacted] according to the ***QMS-07 Proposal Development and Contract Review Procedure***.

The Company analyses records of servicing activities produced by itself and its Suppliers:

a) [redacted]
b) [redacted]

Records of servicing activities are retained and maintained according to the ***QMS-01 Control of Documented Information Procedure***.

7.5.5 Particular Requirements for Sterile Medical Devices

The Company retains and maintains records of sterilization process parameters [redacted] according to the ***QMS-01 Control of Documented Information Procedure***, which are [redacted]

7.5.6 Validation of Processes for Production and Service Provision

The Company validates any processes for production and service provision where the resulting output [redacted]

The Company produces documented information for validation of processes [redacted] according to the ***QMS-10 Production Procedure*** that includes:

a) [redacted]
b)
c)
d)
e)
f)
g)

The Company produces documented information [redacted] according to the ***QMS-10 Production Procedure***. Software applications are [redacted]

Records of the results [redacted] according to the ***QMS-01 Control of Documented Procedure***.

7.5.7 Particular Requirements for Validation of Processes for Sterilization and Sterile Barrier Systems

The Company produces documented information [redacted] according to the ***QMS-10 Production Procedure***.

Processes for sterilization and sterile barrier systems are [redacted]

Records of the results [redacted] according to the ***QMS-01 Control of Documented Procedure***.

7.5.8 Identification

The Company produces documented information [redacted] according to the ***QMS-10 Production Procedure***.

The Company identifies [redacted] Identification of product status i [redacted]

If required by applicable regulatory requirements, the Company [redacted] according to the ***QMS-10 Production Procedure***.

The Company produces documented information [redacted] according to the ***QMS-14 Control of Nonconformities Procedure***.

All products are identified [redacted] which is fully defined in the ***QMS-10 Production Procedure***. Other identification and traceability requirements are [redacted]

7.5.9 Traceability

7.5.9.1 General

The Company produces documented information [redacted] according to the ***QMS-10 Production Procedure***. Records of traceability are [redacted] according to the ***QMS-01 Control of Documented Information Procedure***.

7.5.9.2 Particular Requirements for Implantable Medical Devices

Records required for traceability include [redacted]

The Company requires Suppliers [redacted]

Records [redacted] are retained and maintained according to the ***QMS-01 Control of Documented Information Procedure***.

7.5.10 Customer Property

The Company identifies, [redacted] under the Company's control. Customer property is [redacted] If the property is designated [redacted] according to the ***QMS-14 Control of Nonoconformities Procedure***. Records produced for the control of Customer property are retained and maintained according to the ***QMS-01 Control of Documented Information Procedure***.

7.5.11 Preservation of Product

The Responsible Authority specifies, where required [redacted] The instructions are

[redacted] defined in the ***QMS-10 Production Procedure***. Preservation applies to all elements of the deliverable medical device.

The Company protects product [redacted] by:

a) [redacted]
b) [redacted]

Special conditions required for preservation of product are controlled and recorded according to the ***QMS-01 Control of Documented Information Procedure***.

7.6 Control of Monitoring and Measuring Equipment

The Company determines the monitoring and measurement [redacted]

The Company produces documented information [redacted] according to the ***QMS-10 Production Procedure***.

All measuring and test equipment instruments and devices [redacted] The controls [redacted] are maintained as defined in the ***QMS-15 Calibration Procedure***.

To ensure valid measurement results, measuring equipment:

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]
e) [redacted]

In addition, the Company [redacted]

When computer software [redacted]

The specific approach and activities associated with software [redacted] including [redacted]

Records of the results [redacted] according to the ***QMS-01 Control of Documented Information Procedure***.

Section 8: Measurement, Analysis and Improvement

8.1 General

Appropriate methods of measuring, monitoring, analyzing and improvement are [redacted]:

a) [redacted]
b)
c)

Where statistical techniques are used, these are [redacted]

The Responsible Authority [redacted] which may include:

- [redacted]

8.2 Monitoring and Measurement

8.2.1 Feedback

As one of the measurements of the effectiveness of the quality management system, the Company [redacted] according to the ***QMS-04 Management Process Procedure***.

The Company's feedback process includes [redacted] according to the ***QMS-01 Control of Documented Information Procedure***.

8.2.2 Complaint Handling

The Company produces documented information [redacted] according to [redacted] the ***QMS-14 Control of Nonconformities Procedure***.

Documented information includes requirements and responsibilities for:

a) [redacted]
b)
c)
d)
e)
f)

Justification is documented in the ***Request for Support*** form [redacted], which includes [redacted]

If an investigation determines [redacted]

Complaint handling records are retained and maintained according to the ***QMS-01 Control of Documented Information Procedure***.

8.2.3 Reporting to Regulatory Authorities

If applicable regulatory requirements require [redacted] according to the ***QMS-14 Control of Nonconformities Procedure***.

Records of reporting to regulatory authorities are retained and maintained according to the ***QMS-01 Control of Documented Information Procedure***.

8.2.4 Internal Audit

Internal quality audits are conducted to ensure ongoing compliance with requirements of the Company's policies and procedures. This is accomplished by [redacted] Audit requirements include [redacted] The internal audit process is fully defined in the ***QMS-12 Internal Auditing Procedure***, which determines if the quality management system:

a) [redacted]
b)

The audit program is planned, taking into consideration [redacted] The audit criteria, scope, frequency and methods [redacted] according to the ***QMS-01 Control of Documented Information Procedure***. The management responsible for the area being audited [redacted]

[redacted]

8.2.5 Monitoring and Measurement of Processes

Quality management system processes [redacted] according to the ***QMS-04 Management Process Procedure***. When planned results [redacted]

8.2.6 Monitoring and Measurement of Product

The Company monitors and measures [redacted] which is performed [redacted]

Evidence of conformity to the acceptance criteria is retained and maintained according to the ***QMS-01 Control of Documented Information Procedure***, which [redacted] Product release and service delivery does not [redacted]

For implantable medical devices, the Company [redacted]

8.3 Control of Nonconforming Product

8.3.1 General

All supplies found to be nonconforming [redacted] according to the ***QMS-14 Control of Nonconformities Procedure***, which includes [redacted]

8.3.2 Actions in Response to Nonconforming Product Detected Before Delivery

Nonconforming product [redacted] Records of the acceptance [redacted] according to the ***QMS-01 Control of Documented Information Procedure***.

Nonconformities are processed by:

a) [redacted]
b)
c)
d)

When nonconforming product [redacted] according to the ***QMS-01 Control of Documented Information Procedure***.

8.3.3 Actions in Response to Nonconforming Product Detected After Delivery

When nonconforming product [redacted] according to the ***QMS-01 Control of Documented Information Procedure***.

The Company has produced documented information for [redacted] according to the ***QMS-01 Control of Documented Information Procedure***.

8.3.4 Rework

The Company performs rework according to [redacted] After the completion of rework, [redacted] according to the ***QMS-01 Control of Documented Information Procedure***.

8.4 Analysis of Data

The Company determines, [redacted] The data is used to [redacted] In addition [redacted] For more on analysis of data, see ***QMS-04 Management Process Procedure***.

The analysis of data includes [redacted] and includes [redacted]:

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]
e) [redacted]
f) [redacted]

If the analysis of data [redacted] according to the ***QMS-01 Control of Documented Information Procedure***.

8.5 Improvement

8.5.1 General

The Company identifies and implements [redacted] to continually improve [redacted]

8.5.2 Corrective Action

The Company has implemented and maintains [redacted] Nonconformity reports [redacted] Actions are [redacted] The corrective action process is defined in the ***QMS-13 Corrective Action Procedure***, which defines requirements for:

a) [redacted]
b)
c)
d)
e)
f)

Records of the results of any investigation and applied actions are retained and maintained according to the ***QMS-01 Control of Documented Information Procedure***.

8.5.3 Preventive Action

In addition to the preventive measures [redacted] the corrective action process is used to [redacted] Nonconformity reports result in [redacted] This process is defined in the ***QMS-13 Corrective Action Procedure***, which defines requirements for:

a) [redacted]
b)
c)
d)
e)

Records of the results of any investigation and applied actions are retained and maintained according to the ***QMS-01 Control of Documented Information Procedure***.

Appendix A: Company Processes and Applicable *ISO 13485* Clauses

Process	Applicable ISO 13485 Clauses
[redacted]	[redacted]

Appendix B: Company Processes and Applicable Documents

Process	Applicable Company QMS Procedures	Applicable Company Records
[redacted]	[redacted]	[redacted]

Appendix C: Outsourced Processes

The following processes are outsourced and controlled as indicated:

- [redacted]
- [redacted]
- [redacted]

Appendix D: Quality Objectives

Process	Quality Objective	Metric
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Appendix E: Identification of Key Realization Processes