1. **Purpose**

This document defines the policies and procedures for controlling and maintaining the documentation associated with the Quality Management System. These policies and procedures include document numbering scheme, standardization, change control, review and approval, new/revision/obsolete documents, distribution, and control of external documentation.

1. **Scope**

This procedure applies to all documentation that is required by the Quality Management System. Document Control may maintain other company relevant documentation such as Research Material and Non-Disclosure Agreements; these documents are exempt from this procedure.

1. **General** 
   1. **Definitions**

**Controlled Document** – Any document that affects the quality of the product and/or service and is reviewed and approved prior to release for use or reference.

**Document Control Library** – The physical and electronic databases of controlled documents.

* 1. **Responsibilities**

**Quality Management** – Quality Management is responsible for the implementation and continued compliance with the procedures specified in this document and by the regulatory authorities.

* 1. **Equipment and Materials** – N/A
  2. **Safety Precautions** – N/A
  3. **Training Requirement** – All Quality personnel shall be trained to this procedure and the training documented.
  4. **Record Management** – All Document Change Orders are managed and maintained by the Quality Department. Obsolete documents are archived for a minimum of five years**.**
  5. **Reference Documents and Materials**

**21 CFR 820 FDA** Quality System Regulations

**SOR/98-282** – Canadian Medical Device Regulations

**MDR 2017/745** – EU Medical Device Regulation

**MDD 93/42/EEC** – EU Medical Device Directive

**ISO 13485** – Medical Device Quality Management Systems

**QF-0003-1** – Document Change Order (DCO) Form

**Attachment 1 –** Document Control Approval Matrix

**Document Control Reference** - Document Control Index, Part Number Index, External Document Index,

1. **Document Control Procedure**

The procedures described in this document work in conjunction to establish a controlled environment in which changes and improvements can introduced into the quality systems while mitigating risk and ensuring the quality of the products and services provided. The Document Control Library is restricted access and only designated personnel have the ability to add, remove, or change the contents of the databases. The Document Control Administrator maintains a Controlled Document Index of all approved documents.

* 1. **Document Numbering System**

Each controlled document is given a unique document identification (Doc ID) assigned by the Document Control Admin. This Doc ID is made up of an abbreviation for the document type and a four digit number separated by a dash. A list of approved document type abbreviations is maintained by Doc Control. Examples include QP – Quality Procedure, SOP – Standard Operating Procedure, and PS – Product Specification. The four digit number follows a consecutive numbering pattern for all document types.

Part Numbers have a separate document identification system that is a unique five digit code for each part or product. Part number documents include drawings, spec sheets, and other product specifying documentation.

* 1. **Document Standardization and Templates**

A consistent document format has been established to ensure necessary information is included within the document, the documents remain legible, and assist the review/approval process. The sections required within a document are dependent upon the document type. Existing Document Templates are maintained in the Doc Control Library. Doc Control Admin will provide templates for all document types as needed.

* 1. **Document Change Control Procedure**



Additions, modifications, and removal of controlled documents are managed utilizing the following procedure and recorded on Document Change Order (DCO) Form. All introductions, modification, and, removal of controlled documents require the completion, review, and approval of DCO Form. The information provided in the form is utilized during the approval process to ensure the changes are necessary, justified, and associated risks are mitigated.

**Section 1-4 – General Information**

These sections provide the general information and identification of the document change order. Each section shall be completed by the Doc Author as indicated by the form.

Each Document Change Orders is given a unique identification number by Doc Control Admin utilizing three letters and a consecutive four digit numbering scheme separated by a dash (DCO-####).

**Section 5-6 – Product Disposition and Disposition Details**

The Product Disposition section specifies if the changes will affect product and how to incorporate the change, if applicable. Disposition Detail is required if Product Disposition is applicable. The details shall include information to substantiate the product disposition and a plan to implement change with effectiveness checks as necessary.

**Section 7 – Description of Change(s) and Justification**

This section provides the basis for the change order and describes what changes are being made, why the change is necessary, and technical rationale for the change.

**Section 8 – Impact Assessment**

This section specifies any impacts the changes may have on the Quality Management System. The following potential impacts shall be assessed:

* Training requirements
* Validation or Re-validation of products or processes
* Supplier notification requirements
* The systems that make up the Quality Management System
* The quality, safety, and/or efficacy of the associated medical devices
* Any applicable regulatory requirements
* Other impacts as applicable

**Section 9 – Approvals**

The approval section provides documented evidence that the appropriate departments have reviewed and agreed with the changes that are being proposed. The Document Approval Matrix is contained in Attachment 1; however, additional approvals may be required by Quality Management depending on the severity of the change and associated risk.

All new documents and changes to existing documents require a copy of associated document to circulate with the DCO Form during the review and approval process. All changes to existing documents shall have the changes clearly identified on the associated document.

**Section 10 – Effective Date and Final Release**

This section is to be completed by Doc Control Administrator only. Upon review and verification of completion, Doc Control Admin will give the changes an effective date and release the associated document changes into the active library.

* 1. **New Document Submission**

New documents are introduced into Document Control Library by the document author submitting physical and electronic copies of the new document, in the appropriate format established by the document templates, with an approved DCO to the Doc Control Admin. The Doc Control Admin will verify the submission, designate the effective date, and entered the document into the active library.

* 1. **Document Revisions**

Changes to existing documents are made utilizing the document revision process. The document author shall submit physical and electronic copies of the modified document with an approved DCO to Quality Department. The modified documents shall have all changes clearly identified. The Doc Control Admin will verify the submission and designate the effective date. The new revision will then be entered the document into the active library; the previous revision will be removed and stored in accordance with the Record Retention Policy.

* 1. **Obsolete Document Removal**

Obsolete documents are removed from Document Control by submitting a completed and approved Document Change Order. Once received the Doc Control Admin will remove the document from the active library and store in accordance with the Record Retention Policy.

* 1. **Document Availability and Distribution**

Document Control maintains both electronic and physical copies of all controlled documentation. All employees have access to electronic copies of controlled documents. Printed documents are not considered controlled and are for reference only. Forms shall be printed from electronic master files and utilized in accordance with the appropriate procedures.

1. **External Documentation**

External documents associated with the Quality Management System may be incorporated into the Document Control Database at the discretion of Quality Management. Personnel outside of Quality shall submit a formal request for inclusion of external documents by submitting a completed Document Change Order (CHO) Form. Examples of external documents include, but are not limited to the following:

* ISO Standards
* Regulatory Guidance Documents (FDA, MEDDEV, Health Canada, etc)
* Industry Standards
* Research Papers for External Sources

1. **Revision History**

| **Rev #** | **Doc #** | **Effective Date** | **CHO** | **Description of Change** |
| --- | --- | --- | --- | --- |
| 01 | QP-0003 |  |  | Initial implementation of the Document Control Process |

**Attachment 1 – Document Control Approval Matrix.**

| **Department** | **Quality** | **Design and Development** | **Manufacturing** | **Marketing and Sales** |
| --- | --- | --- | --- | --- |
| **Quality Procedure** | Quality Assurance Operations |  |  |  |
| **Development Report** |  | Quality Assurance Engineering  Operations | Quality Assurance Engineering  Operations |  |
| **Standard Operating Procedure** | Quality Assurance Engineering  Operations | Quality Assurance Engineering  Operations | Quality Assurance Engineering  Operations |  |
| **Work Instruction** | Quality Assurance Engineering  Operations |  | Quality Assurance Engineering  Operations |  |
| **Material Specification** |  |  | Quality Assurance Engineering  Operations |  |
| **Product Specification** |  |  | Quality Assurance Engineering  Operations |  |
| **Labeling** |  |  |  | Quality Assurance Engineering  Operations Sales and Marketing |