1. **Purpose**

This document defines the policies and procedures for controlling and maintaining the labeling associated with distributed products. These policies and procedures include labeling review and approval and labeling first article inspection.

1. **Scope**

This procedure applies to all labeling that is required by the Quality Management System and applicable regulatory requirements. Labeling includes product labels, package inserts, packaging graphics, marketing materials, and other material related to identification, technical description, and use of the device as defined below. Engineering changes to packaging that do not impact labeling are exempt from this procedure.

1. **General** 
   1. **Definitions**
      * **Label** – A display of written, printed, or graphic matter upon the immediate container of any article.
      * **Labeling** – Any written, printed, or graphic matter affixed to or accompanying the medical device or any of its containers/wrappers that are related to identification, technical description, and use of the device; labeling excludes shipping documents.
      * **Final Proof** – The production master or first article sample for a new or revised labeling/packaging item.
   2. **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 Requirements** – All personnel responsible for the approval of labeling shall be competent in relevant areas.
  4. **Record Management** – Labeling records are managed and maintained by the Quality Department.
  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

**FDA Guidance** – Labeling: Regulatory Requirements for Medical Devices

**FDA Guidance** – Deciding When to Submit a 510(k) for a Change to an Existing Device

**GHFT/SG1/N70** – Label and Instructions for Use for Medical Devices

**QF-0006-1** – Labeling Review and Approval Form

1. **Procedure**

The company utilizes the following procedures to ensure labeling achieves the required objectives, is manufactured correctly, and meets all quality, regulatory, and customer/user requirements. All labeling documentation is required to be approved and archived within the Document Control Library. Examples of labeling documentation, if applicable, may include: Artwork, Proofs, Material Specifications, Label Index, Label First Articles, and Labeling Review and Approval Forms.

All labeling associated with a product will be documented and controlled within the associated Device Master Record (DMR). The primary identification label and labeling used for each production unit shall be maintained with the Device History Record (DHR).

* 1. **Label Content**

The following information is required to be presented in a legible, permanent, and prominent manner on the product labeling. The Indications for Use, Directions for Use, and special storage conditions may accompany the product (e.g. IFU) if there is insufficient space on the outer package label. Specific requirements may be imposed by regulatory authorities based upon product risk and/or specific product types.

* The name of the device
* The name and address of the manufacturer
* the identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;
* The contents of the package, expressed in terms appropriate to the device
* The word “Sterile”, device to be sold in a sterile condition;
* The expiration date of the device, if applicable
* Indication for Use: unless self-evident, provides the medical conditions, purposes and function of the device, including the performance specifications
* Directions for Use: full information as to the procedure recommended for achieving the optimum performance of the device, including cautions, warnings, contraindications and possible side effects
* Any special storage conditions applicable to the device.
  1. **Label Translations**

Labels may require translation based upon international distribution. Labeling items containing foreign languages require Certifications of Translation. These certifications shall be circulated during the review and approval process. A list of labeling translations and approved regulatory jurisdiction is maintained with the Device Master Record (DMR)

* 1. **Labeling Change Control**

The labeling review and approval process is documented on the Labeling Review and Approval Form. All new labeling and labeling modifications require a completed and approved form prior to implementation. When submitting labeling for review, the party responsible for initiating the changes shall provide each reviewer with a properly filled out approval form and associated documentation including clear identification and rationale for all changes. If applicable, proofs provided by the vendor shall be submitted along with the form. Completed approval forms and attachments are stored and maintained by the Quality Department.

For all labeling changes that impact documents with the Document Control Library, the initiating party is responsible for ensuring updates are completed.

* + 1. **Labeling Information**

Section 1 of QF-0004-1 provides background information regarding the proposed submission or changes and any documentation that will be impacted by the change. This section shall be completed prior to submitting to reviewers for approval.

**4.1.2 Review and Approval Process**

The approval process is documented in Section 2 of the Labeling and Approval Form. The appropriate parties shall review the changes relative to their area of expertise and items to be considered. Approval is designated by a signature and date.

External reviews may be required for labeling that is managed by external vendors or requires approval by a customer, partner, or external party prior to use.

**4.1.3 Reconciliation of Labels**

For labeling changes that render the previous versions invalid, a labeling reconciliation shall be completed to ensure the appropriate disposition of the previous version of labeling. Label reconciliation documentation shall be stored and maintained by the Quality Department.

* 1. **Labeling First Article Inspection**

When the first production lot of updated labeling is received, the labeling shall be inspected against approved specifications/drawings and verified to be correct. Verification documentation along with first lot samples, where possible, shall be submitted to the Quality Department to be maintained along with the associated QF-0004-1. Where physical samples cannot be submitted along for approval, photographs or electronic files shall be acceptable.

Products containing new or updated labeling shall not be released for distribution until the labeling first article inspection has been completed.

1. **Revision History**

| **Rev #** | **Doc #** | **Effective Date** | **CHO** | **Description of Change** |
| --- | --- | --- | --- | --- |
| 01 | QP-0006 |  |  | Initial Implementation of the Labeling and Packaging Control Process |

1. **Appendix A**