1. **Purpose**

This document defines policies and procedures for identification and traceability of product throughout manufacturing and distribution. These policies and procedures include product identification, traceability, and status identification.

1. **Scope**

This procedure applies to all products manufactured, either in-house or by contract manufacturer, for distribution. Products produced under investigational device exemptions are exempt from this procedure.

1. **General** 
   1. **Definitions** – N/A
   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 Quality Personnel are required to be trained to this procedure and the training documented.
  4. **Record Management** – Final product manufacturing traceability and acceptance records are maintained within the Device History Record (DHR).
  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

1. **Identification and Traceability Procedure**

The company is responsible for the identification and traceability requirements of products manufactured and distributed under the company name. These requirements apply to products manufactured within the company and those produced by contracted manufacturers.

* 1. **Product Identification**

The final product and all components determined to be significant shall be identified throughout the manufacturing process. Identification shall be unique and clearly marked on the product, where appropriate. Specific identification requirements for each product are maintained within the Device History Record.

* 1. **Traceability Procedure**

Traceability records for finished product are specified and maintained within the Device History Record. Traceability requirements are specific to the device produced and are dependent on the product risk.

Manufacturing records provide documentation of the manufacturing processes and assurance the product was built per procedure to approved specifications. At a minimum, the following information is included on the manufacturing record. Critical components are specific to the type of equipment produced and are specified on the manufacturing record. Critical Component ID’s are traceable to batch records for the manufacturing process of each component.

* Unique identifiers of final product and components determined to be significant
* Date of manufacture
* Employee(s) responsible for manufacture
* Equipment critical to manufacturing process
* Quantity manufactured and quantity released for distribution
* Primary identification label and labeling used for final product
* Acceptance records

The acceptance record provides documentation of acceptance activities preformed upon completion of all manufacturing of the associated device. Acceptance activities are a preapproved set of tests and/or reviews utilized to verify the build, operation, and performance of each unit prior to release for distribution.

* 1. **Status Identification**

The identification of product status shall be maintained from receipt through production and storage to distribution. Any product found to be non-conforming shall be identified as such and controls shall be in place to quarantine product until appropriate disposition can be determined. Product that has passed all acceptance criteria and is acceptable for distribution shall be identified and maintained separately from product pending acceptance.

Product returned from external parties shall be appropriately labeled as to not be confused with product for distribution. This label shall remain with the product until the product has been properly dispositioned such as refurbishment, destroyed, etc. Refurbished product shall be differentiated from distributable product until the product has been refurbished and passes all acceptance criteria.

1. **Revision History**

| **Rev #** | **Doc #** | **Effective Date** | **CHO** | **Description of Change** |
| --- | --- | --- | --- | --- |
| 01 | QP-0007 |  |  | Initial Implementation of the Identification and Traceability Process |