1. **Purpose**

This document defines the policies and procedures for the preservation of medical devices during production, storage, and distribution.

1. **Scope**

This procedure applies to all products manufactured, stored, and/or distributed at company facilities. Product stored in inventory of a contracted party is excluded from this process and shall be covered by the contracted party’s Quality Management System. This procedure includes processing, storage, handling, and distribution of product.

1. **General** 
   1. **Definitions**
      * **Room Conditions** – Standard work environment conditions for temperature, pressure and humidity.
   2. **Responsibilities**

**Operations** – Operation Management is responsible for ensuring compliance to this procedure.

**Quality** – 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** – Operations and Quality personnel shall be trained to the procedures specified in this document.
  4. **Record Management** – N/A
  5. **Reference Documents and Materials**

**21 CFR 820** – FDA Quality System Regulations

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

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

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

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

**QP-0008 –** Nonconforming Product Process

1. **General Storage and Handling Procedure**

Products with special conditions for the preservation of product and, unless otherwise stated (SOP’s, Work Instructions, Product Specifications), the storage and handling of product does not introduce significant risk to product quality and does not require specialized monitoring. Any product or materials found to be stored or handled out of the requirements of this procedure shall be labeled as nonconforming product and managed appropriately, see QP-0008.

* 1. **Processing**

All controls necessary to protect the product and components of the product during the production process shall be documented in the appropriate work instructions and SOP’s.

* 1. **Storage**

Finish products, components, and materials shall be stored in appropriately designated and identified areas (i.e. Raw Materials, Finished Goods, etc.). Unless otherwise stated, products/materials shall be stored in room temperature and humidity conditions out of direct sunlight. Storage facilities shall be appropriately controlled to protect against alteration, contamination or damage.

* 1. **Handling**

All products shall be handled in a manner as to not inadvertently cause damage and stored in room conditions out of direct sunlight. Specified handling and storage instruction may be included in product specifications and shall supersede the following procedures.

* 1. **Distribution**

All products shall be distributed in suitable packaging and shipping containers to protect product from alteration, contamination, or damage when exposed to anticipated conditions and hazards.

1. **Revision History**

| **Rev #** | **Doc #** | **Effective Date** | **CHO** | **Description of Change** |
| --- | --- | --- | --- | --- |
| 01 | QP-0016 |  |  | Initial implementation of the Preservation of Product Process |