1. **Purpose**

The purpose of this document is to define the policies and procedures for managing records associated with the quality management system (QMS). These policies and procedures include record retention, record management, and record control.

1. **Scope**

This procedure applies to all records required by the quality management system. Records not associated with quality systems, such as human resources and financial records, are exempt from this procedure.

1. **General**
   1. **Definitions** – N/A
   2. **Responsibilities**
      * **Quality** – Quality is responsible for the implementation and continued compliance with the procedures specified in the document.
      * **Operations** – Operations is responsible for complying with the procedures specified in the document
      * **Engineering** – Engineering is responsible for complying with the procedures specified in the document
   3. **Equipment and Materials** – N/A
   4. **Safety Precautions** – N/A
   5. **Training Requirements** – Quality, Operations, and Engineering personnel shall be trained to this procedure and the training documented.
   6. **Record Management** – N/A
   7. **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. **Procedure**

The following procedures are utilized to ensure the records that provide evidence of conformity and effective operation of the quality management system are properly maintained and accessible.

* 1. **Record Retention Periods**

Records associated with the Quality Management System must be retained for a period of time at least equivalent to the lifetime of the medical device, but not less than two years from the date of product release for distribution. The retention time for a specific record is defined within the process associated with the record (i.e. the retention time for CAPA records is defined in the Corrective and Preventive Action Process). If the retention time is not specified, the retention time shall default to five (5) years.

* 1. **Record Management**

All quality system records are required to be readily identifiable and legible. Identification of records is achieved utilizing a unique identifier for each record. The record identification is defined within the associated procedure. If the identification is not defined, the default ID is comprised of a 2 to 4 letter identifier of the process (i.e. SCAR, NCR, CAPA, etc) and a 4 digit number (i.e. 0001, 0002, etc).

Records shall be completed in a manner that is legible to all necessary parties. All corrections to records shall be made by a single line through item needed modification, followed by the correction and the initials and date of the person making the change.



* 1. **Record Controls**

All quality system records are stored with appropriate protection and retrievable by with Quality Department. All records (physical and electronic) are stored and organized by the associated processes and the numeric identifier assigned to the record. Physical records are maintained under lock and key in fireproof storage. Electronic records are maintained on the company server under access rights protection and routine server backups.

Records that require disposition shall be destroyed. Physical records shall be shredded and electronic records permanently deleted from the company server.

1. **Revision History**

| **Rev #** | **Doc #** | **Effective Date** | **CHO** | **Description of Change** |
| --- | --- | --- | --- | --- |
| 01 | QP-0018 |  |  | This is the initial implementation of the record management process. |