1. **Purpose**

The purpose of this process is to document the policies and procedures for maintaining customer property while under company control.

1. **Scope**

The process specified in this document applies to all customer property maintained or controlled by the company.

1. **General**
   1. **Definitions –** N/A
   2. **Responsibilities**

* **Quality –** Quality is responsible for implementing and maintaining compliance to the physical safeguards specified in this procedure. Quality is responsible for ensuring the company’s implementation and compliance to this procedure.
  1. **Equipment and Materials –** N/A
  2. **Safety Precautions –** N/A
  3. **Training Requirements –** All employees with access to customer and clinical data shall be trained to this procedure and the training documented.
  4. **Record Management –** All customer property records shall be stored 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

1. **Customer Property Control Procedure**

The company utilizes the following process to ensure customer property is appropriately controlled and maintained. All records associated with customer property will be stored by identification number and maintained until at minimum two (2) years following the returned of the property or the useful lifetime.

* 1. **Identification**

All customer property that is under the control of the company is provide with a unique identification number. This ID number shall be attached the property when possible and provides traceability to any specialized requirements or instructions associated with the property.

* 1. **Verification**

All customer property taken into care of the company are verified to compliant with the associated specification and quantities expected. Any deviations require the property to be placed in quarantined pending resolution.

* 1. **Protect and Safeguard**

Any Instructions for Use, User Manual, etc. will be obtained with the customer property, if applicable, and the company will exercise appropriate control to ensure the protection and safeguard of the property. Documented procedures and training will be utilized, if appropriate based upon risk associated with the property.

1. **Revision History**

| **Rev #** | **Doc #** | **Effective Date** | **CHO** | **Description of Change** |
| --- | --- | --- | --- | --- |
| 01 | QP-0019 |  |  | Initial implementation of the Customer Property Control Process. |