1. **Purpose**

This document defines the policies and procedures for ensuring that purchased product and services conforms to specified requirements. These policies and procedures include purchasing approval procedure, and incoming receipt procedure.

1. **Scope**

This document applies to purchases that are associated with the Quality Management System. Purchases not associated the Quality Management System are exempt from this process.

1. **General** 
   1. **Definitions**

* **Approved Supplier List (ASL) –** A list of suppliers that have been accepted through the qualification process to provide product and/or services.
* **Supplier –** Any organization that provides products or services to the company: manufacturers, distributors, contractors, or consultants.
* **Supplier Corrective Action Request (SCAR) –** The documented request to a supplier for a formal response to an issue or issues regarding a given item or service. The supplier is required to investigate and correct the nonconforming issues providing the appropriate written response.
  1. **Responsibilities**

**Operations** –Operations is responsible for maintaining the Approved Supplier List and completing purchase orders, incoming inspections and maintain associated records.

**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 Operations personnel shall be trained on this procedure and training documented.
  4. **Record Management** – Purchase Order and Incoming Inspection records are managed and maintained by Operations.
  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
* **GHTF/SG3/N17** – Control of Product and Services Obtained from Suppliers
* **QP-0023** – Supplier Management Process
* Approved Supplier List
* Purchase Requisition Form

1. **Purchasing Process**

The purchasing process is managed by Operations and documented on the Purchase Requisition Form and/or Supplier Contracts. Upon receipt of an approved Purchase Requisition Form, Purchasing issues a Purchase Order (PO) to the associated approved supplier. Purchasing may issue a Purchase Order (PO) without a Purchase Requisition Form with a verbal approval. Once the order has been completed and the product delivered, incoming inspections will be completed and upon acceptance, the PO will be closed and the associated documentation filed.

* 1. **Purchasing Information**

Purchasing information shall describe the product, processes, services, or software to be purchased including, where appropriate, the requirements for approval of product, certificates of compliance, procedures, processes, and equipment. This may be in the form of drawings, specification sheets or any other format appropriate to the item being purchased. The adequacy of specified purchase requirements shall be reviewed prior to their communication to the supplier.

* 1. **Planning of Inventory Items**

Purchasing agreements are established with key contract manufacturers and suppliers. These agreements may result in the submission of blanket purchase orders with scheduled releases. It is Purchasing’s responsibility to monitor the receipts and inventory levels of these items to assure there is adequate inventory at all times.

Inventory items are either planned or unplanned. Unplanned items are those that do not require safety stock levels to be established and will be ordered only through the use of a Purchase Order or based upon delivery schedules documented in purchasing agreements. Planned Items are those that require warehouse safety stock levels and reordering based upon vendor economic order quantities (EOQs) and lead time.

* 1. **Purchase Order Processing**
     1. **Purchase Request**

Any employee can communicate the need for a purchase by submitting a purchase requisition to Purchasing. The submission may be submitted utilizing the Purchase Requisition Form or by directly communicating with the Purchasing department. The requisition should include the following:

* Date of Request
* Date Needed
* Type of Purchase or account number to be used
* Description of goods, including part number, quantity, product specification if applicable
  + - * + Special instructions, where appropriate
    1. **Purchase Approval and Execution Procedure**

Upon obtaining the required approvals of the PRF, the purchase order (PO) may be processed. If the purchase is for inventory items or if the item will be sold to a customer, the supplier must be on the Approved Supplier’s List (ASL). POs are sent to the supplier via agreed upon method (see ASL). In the case of credit card purchases, a PO will be completed for record. The PO shall contain applicable data to ensure that the correct product or service is supplied, including:

* A line item for each item ordered, including revision, where applicable.
  + For company designed parts, a copy of any drawings or other specification data shall be communicated.
  + For routine components (parts made to manufacturer’s specifications) the catalog number will be stated.
* The requirements for acceptance of the product, procedures, processes, equipment, qualifications of personnel or quality management systems, that may be appropriate
* The requirement that no changes to product, processes or services may be made without the prior written agreement of the buyer.

A copy of each PO is maintained by Purchasing.

1. **Incoming Receipt Procedure**

All products that impact quality shall undergo acceptance activities prior to being moved into inventory. The required acceptance activities are specific to the product being received and are defined within the associated product/material specification. Inspection criteria are developed upon creation of the product/part specification and utilize a C=0 sampling plan (see Appendix A) based upon the associated risk of the product.

Acceptance activities are completed and documented by designated individuals. All rejections shall be submitted to the Material Review Board (MRB) and a Supplier Corrective Action Request (SCAR) is issued as necessary. Upon acceptance of product, Purchasing is notified and the associated Purchase Order is closed and filed appropriately.

When the company becomes aware of a change to the purchased product, an impact assessment shall be completed and documented to determine whether the changes affect the product realization process or the medical device.

1. **Revision History**

| **Rev #** | **Doc #** | **Effective Date** | **CHO** | **Description of Change** |
| --- | --- | --- | --- | --- |
| 01 | QP-0005 |  |  | Initial implementation of the Purchasing and Receiving Process |

**Appendix A – C=0 Sampling Plan Table**