STERIS

Non-Sterile Shipping Agreement

WHEREAS, the following STERIS facilities (hereinafter referred to as "STERIS") are in the business of providing industrial contract processing services at the following locations:

{Please check all locations that apply}

Isomedix Operations, Inc.

- ☐ 9 Apollo Drive, Whippany, NJ 07981
- ☐ 4405 Marketing Place, Groveport, OH 43125
- ☐ 1435 Isomedix Place, El Paso, TX 79936
- ☐ 1441 Don Haskins Drive, El Paso, TX 79936
- ☐ 23 Elizabeth Drive, Chester, NY 10918
- ☐ 7685 St. Andrews Av., San Diego, CA 92154
- ☐ 43425 Business Park Drive, Temecula, CA 92590
- ☐ 1000 So. Sarah Place, Ontario, CA 91761
- ☐ 380 90th Avenue Northwest, Minneapolis, MN 55433
- ☐ 3459 South Clinton Ave. South Plainfield, NJ 07080
- ☐ 435 Whitney Street, Northborough, MA 01532
- ☐ 2072 Southport Road, Spartanburg, SC 29306
- ☐ 9120 South 150 East, Sandy, UT 84070
- ☐ 2500 Commerce Drive, Libertyville, IL 60048
- ☐ 1880 Industrial Drive, Libertyville, IL 60048
- ☐ 1175 Isuzu Parkway, Grand Prairie, TX 75050

Isomedix Corporation

- ☐ 184 Crown Court, Whitby, Ontario L1N 7B1 Canada

STERIS Isomedix Puerto Rico, Inc

- ☐ PO Box 415, State Road 690, KM 1.7 Barrio Sabana Hoyos, Vega Alta, PR 00692

Biotest Laboratories

- ☐ 9303 West Broadway Av, Brooklyn Park, MN 55445

PROCESS: ☐ ETHYLENE OXIDE ☐ GAMMA IRRADIATION ☐ EBEAM ☐ STEAM/DRY HEAT

WHEREAS, Customer desires to have certain of its products processed by STERIS and STERIS shall process the products at the applicable facility location(s) checked above.

WHEREAS, the Food and Drug Administration has recognized that it is common industry practice to manufacture and/or assemble, package and fully label a product at one establishment and then ship such product in interstate commerce to another establishment or to a contract sterilizer for processing;

WHEREAS, the Food and Drug Administration will initiate no regulatory action against a medical device or drug as misbranded or adulterated during such shipment when the device or drug is labeled sterile, provided the requirements of 21 CFR Part 801.150 for medical devices and 21 CFR 201.150 for drugs are met.

NOW THEREFORE, it is agreed as follows:

1. **INTENT OF PARTIES**
   a. It is the express intention of the parties hereto to adhere to all the requirements of 21 CFR Part 801.150 and 201.150 for applicable products.
2. **PRODUCT HANDLING**
   a. Both CUSTOMER and STERIS acknowledge that any product(s) transported from CUSTOMER to STERIS pursuant to this Agreement is being shipped for further processing.
   b. All products shipped by CUSTOMER to STERIS shall be conspicuously identified as "Non-Sterile" or "In-Process" and shall not be identified as sterile until products are established as sterile by methods specified by the CUSTOMER Provisions of this paragraph shall apply during all times when the product is introduced or moving through commerce, during processing and when held in quarantine.
   c. Each shipment of product for processing will be accompanied by documents (packing list and/or Bill of Lading) stating the number of cartons or other designated units in the shipment listed by the manufacture's lot and product

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code number. Upon receipt and prior to processing, STERIS will record on its receiving documents the number of cartons or other designated units by manufacture's lot and product code number received from CUSTOMER. All count discrepancies will be handled according to Customer requirements listed on Customer Specification and/or Special Processing forms.

d. STERIS will segregate unprocessed products from processed products in a manner in which will preclude accidental mixing. Furthermore, each party shall be responsible for segregation of processed and non-processed products within their facilities and shipments.

3. **SHIPMENT OF PRODUCT**

a. For product which is shipped from STERIS in a quarantined or "On-Status" state, all products shall be conspicuously identified as waiting test results or Processed, as the customer specifies.

b. CUSTOMER shall ensure that products will not be shipped from locations not listed on this document.

c. CUSTOMER shall ship product from the following manufacturing locations(s):

{List manufacturing locations product will be shipped from}

Name	Name	Name
Address	Address	Address
City, State, Zip	City, State, Zip	City, State, Zip
☐ Same as Address noted in Approval section.		

IN WITNESS WHEREOF, the parties have caused this Shipping Agreement to be executed by their duly authorized representatives.

CUSTOMER APPROVAL

Customer Name

Address

Representative (Print) Title Signature/ Date

STERIS APPROVAL

Location Name

Address

Representative (Print) Title Signature/ Date

Effective Date: _____