

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.

- | | |
|---|---|
| <input type="checkbox"/> 9 Apollo Drive, Whippany, NJ 07981 | <input type="checkbox"/> 3459 South Clinton Ave. South Plainfield, NJ 07080 |
| <input type="checkbox"/> 4405 Marketing Place, Groveport, OH 43125 | <input type="checkbox"/> 435 Whitney Street, Northborough, MA 01532 |
| <input type="checkbox"/> 1435 Isomedix Place, El Paso, TX 79936 | <input type="checkbox"/> 2072 Southport Road, Spartanburg, SC 29306 |
| <input type="checkbox"/> 1441 Don Haskins Drive, El Paso, TX 79936 | <input type="checkbox"/> 9120 South 150 East, Sandy, UT 84070 |
| <input type="checkbox"/> 23 Elizabeth Drive, Chester, NY 10918 | <input type="checkbox"/> 2500 Commerce Drive, Libertyville, IL 60048 |
| <input type="checkbox"/> 7685 St. Andrews Av., San Diego, CA 92154 | <input type="checkbox"/> 2 Nucifora Blvd., Chester, NY 10918 |
| <input type="checkbox"/> 43425 Business Park Drive, Temecula, CA 92590 | <input type="checkbox"/> 1880 Industrial Drive, Libertyville, IL 60048 |
| <input type="checkbox"/> 1000 So. Sarah Place, Ontario, CA 91761 | <input type="checkbox"/> 1175 Isuzu Parkway, Grand Prairie, TX 75050 |
| <input type="checkbox"/> 380 90th Avenue Northwest, Minneapolis, MN 55433 | |

STERIS Applied Sterilization Technologies ULC

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

STERIS Isomedix Puerto Rico LLC

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

STERIS Laboratories

- 9303 West Broadway Av, Brooklyn Park, MN 55445
- 1880 Industrial Drive, Libertyville, IL 60048

Synergy Health AST, SRL

- B16, Street 4, Avenue 0, El Coyol Free Zone
El Coyol, Alajuela, Costa Rica
- B13.1, Street 4, Avenue 1, El Coyol Free Zone
El Coyol, Alajuela, Costa Rica

Synergy Health AST, LLC

- 7225 North Noah Drive, Saxonburg, PA 16056
- 9020 Activity Road, Suite D, San Diego, CA 92126
- 3200 Lakeville Hwy, #120, Petaluma, CA 94954

PROCESS:

- | | | |
|---|-----------------------------------|-------------------------------------|
| <input type="checkbox"/> ETHYLENE OXIDE | <input type="checkbox"/> GAMMA | <input type="checkbox"/> E-BEAM |
| <input type="checkbox"/> X-RAY | <input type="checkbox"/> DRY HEAT | <input type="checkbox"/> MOIST HEAT |

Non-Sterile Shipping Agreement

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 code number. Upon receipt and prior to processing, STERIS will record on its receiving documents the number of cartons or other designated units by manufacturer’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 separate unprocessed products from processed products in a manner in which will preclude accidental mixing. Furthermore, each party shall be responsible for separation 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):

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{List manufacturing locations from which product will be shipped}

Name	Name	Name
Address	Address	Address
City, State, Zip	City, State, Zip	City, State, Zip
<input type="checkbox"/> 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 (Company Name) APPROVAL

Customer (Company) Name

Address

Representative (Print) Title Signature/ Date

STERIS APPROVAL

Location Name

Address

Representative (Print) Title Signature/ Date

Effective Date: _____