STERIS

Assignment of Responsibility Form

This Agreement is made by and between, the following STERIS/STERIS Laboratories facility (ies) (hereinafter referred to as "STERIS") for industrial contract processing services using one or more of the following methods: (Check all appropriate),

☐ ETHYLENE OXIDE ☐ GAMMA IRRADIATION ☐ E-BEAM ☐ X-RAY

☐ DRY HEAT ☐ MOIST HEAT

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
☐ 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
☐ 2 Nucifora Blvd., Chester, NY 10918
☐ 1880 Industrial Drive, Libertyville, IL 60048
☐ 1175 Isuzu Parkway, Grand Prairie, TX 75050
☐ 3459 South Clinton Ave. South Plainfield, NJ 07080

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, Inc.

☐ 9303 W. Broadway, 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, 20102, Costa Rica

☐ B13.1, Street 4, Avenue 1, El Coyol Free Zone
El Coyol, Alajuela, 20102, Costa Rica

Synergy Health AST, LLC

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

AND,

_____
Customer (Company) Name

_____
Address

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RESPONSIBILITY	ASSIGNMENT
I. GENERAL	
A. Ensure that special instructions are provided for sample processing placement requirements, product temperature sensitivity requirements, and time sensitive requirements for product capable of supporting microbial growth.	**CUSTOMER**
B. Responsible for use of radiation sensitive labels (false negatives, false positives, placement)	**CUSTOMER**
C. Determine if 21CFR 801.150 for Device, or 21CFR 201.150 for Drugs are applicable to processing of the Products.	**CUSTOMER**
D. Ensure that Products may be processed without violating any governmental regulations.	**CUSTOMER**
E. Assure compliance with any and all federal, state and local labeling or "right to know" laws, including but not limited to, California's Safe Drinking Water and Toxic Enforcement Act of 1986, if applicable.	**CUSTOMER**
F. Notification of intent to recall product processed at STERIS.	**CUSTOMER**
G. FDA product listing information to FDA and STERIS for: • Medical Devices in accordance with 21 CFR Part 807. • Drugs in accordance with 21 CFR Part 207. • Food in accordance with 21 CFR 1 subpart H and FD&C Section 415. • Tissue in accordance with 21 CFR 1271 and section 361. • Blood products in accordance with 21 CFR Part 607.	**CUSTOMER**
H. Product listing with FDA in accordance with 21 CFR Part 807, 21 CFR Part 207, 21 CFR 1 subpart H and FD&C Section 415, 21 CFR 1271 and section 361 and 21 CFR Part 607.	**STERIS**
I. Canadian Drug product listing information and Drug Identification Number (DIN) provided to STERIS in accordance with GUI-002.	**CUSTOMER**
J. Drug Establishment Licence Holder with Health Canada in accordance with Health Canada Guidance on Drug Establishment Licences (GUI-0002).	**STERIS**
K. Subject to STERIS's reasonable confidentiality obligations, allow customer access to the processing facility, upon reasonable notice, during normal business hours for the purpose of conducting Quality System audits, at Customer's expense, related to the processing of customer products.	**STERIS**
L. Perform periodic internal audits according to Quality System. A record of the audit shall be maintained on file.	**STERIS**
M. Allow the U.S. FDA to inspect its facilities as stated in section 704(a) of the Food, Drug and Cosmetic Act and 21 CFR Part 200.10, if applicable.	**STERIS**
II. PROCESS CONTROL	
A. Ensure that the CUSTOMER process specifications are achieved and that documentation for each load is reviewed by a Qualified STERIS Representative before release to CUSTOMER.	**STERIS**
B. Notify CUSTOMER of equipment changes or other changes that may impact product processing in accordance with STERIS's established change control procedure.	**STERIS**
C. Evaluate STERIS's equipment change control notification per II.B. above and communicate action to STERIS, as needed.	**CUSTOMER**
III. MATERIAL HANDLING AND DOCUMENTATION REQUIREMENTS FOR INCOMING PRODUCT TO STERIS	
A. Ensure proper shipment of Product to STERIS to include Labeling, Packing List, Purchase Order and Process Specifications (or completed Special Radiation Request).	**CUSTOMER**
B. Provide proper labeling and identification for all products / samples. Packing slip shall match product code on case label. All exceptions will be communicated in advance of shipment to STERIS.	**CUSTOMER**
C. Resolve damaged goods disposition.	**CUSTOMER**
D. Complete Non-Sterile Shipping Agreement, if applicable.	**CUSTOMER**
E. Confirm that documentation to satisfy 21CFR 801.150 for Device, or 21CFR 201.150 for Drugs is provided, if applicable.	**STERIS**
F. Receive and record incoming product samples to STERIS.	**STERIS**
G. Resolve count discrepancies with CUSTOMER.	**STERIS**
IV. PROCESSING	
A. Carry out processing parameters in accordance with CUSTOMER specifications.	**STERIS**
B. Control the flow of Products to and from the processing area to prevent mixing of processed and non-processed Products.	**STERIS**

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C. Installation, qualification, operation and maintenance of equipment, calibration of process monitoring equipment and training of operating personnel.	**STERIS**
D. Determine the compatibility of Products and packaging with the processing procedures and for determining the appropriate processing modality and parameters. All tests related to the processing of the Products. Ultimate and full responsibility for Products release into commercial distribution, including labeling of Products as sterile. All tests related to assessing the final sterility assurance of the products.	**CUSTOMER**
E. Ensure specifications are provided in writing to STERIS for all special instructions or special handling requirements prior to processing product.	**CUSTOMER**
F. Prior to product being processed, notify STERIS if products are flammable, corrosive, combustible, bio-hazardous, bio-active, or hazardous in any way. In addition, an MSDS will be provided for all products, prior to processing, if they are flammable, corrosive, combustible, bio-hazardous, bio-active, or hazardous in any way.	**CUSTOMER**
G. Assure that any changes to the manufacturing, packaging, and the product are evaluated for their impact on the continued validation of the processing parameters.	**CUSTOMER**
H. Prior to product being shipped to STERIS, notify STERIS when there is a change to product case size, weight, or any other change to the product that could in any way change processing parameters.	**CUSTOMER**
V. PROCESSING NONCONFORMITIES	
A. Determine and notify CUSTOMER thereof.	**STERIS**
B. Determine corrective action and notify CUSTOMER thereof.	**STERIS**
C. Implement corrective action.	**STERIS**
VI. SHIPMENT FROM STERIS	
A. Document number and destination of samples sent for testing from STERIS on the STERIS Packing List. (If applicable)	**STERIS**
B. Generate a Certificate of Processing and a Packing List for each shipment.	**STERIS**
C. Document the quantity of Product from STERIS on the Certificate of Processing. Any discrepancies will be resolved with CUSTOMER prior to shipment.	**STERIS**
D. Label all processed Product as "Processed" or similar, with no reference to the Product being sterile.	**STERIS**

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

CUSTOMER APPROVAL

Customer (Company) Name

Address

Representative (Print) Title Signature/ Date

STERIS/STERIS LABORATORIES APPROVAL

Location Name

Address

Representative (Print) Title Signature/ Date

Effective Date: _____