Special Radiation Request

Customer Information:

Company Name:	**Company Address:**	☐ Chester NY ☐ El Paso TX	☐ Spartanburg SC ☐ Vega Alta PR
Contact Name:		☐ Groveport OH ☐ Ontario CA	☐ Libertyville S. (2500 Commerce) ☐ Libertyville N. (1880 Industrial)
Email Address:	**Billing Address (if different from above):**	☐ Sandy UT ☐ Northborough MA	☐ Whippany NJ ☐ Whitby Canada
Phone:		**Estimated Delivery Date to STERIS:** _____	
Fax:	**Purchase Order #** _____ (Cannot process without PO)	**Qty Shipping Boxes or Pallets:** _____	

Reason for Request (check any that may apply): ☐ N/A

☐ **Samples (R&D or Other Tests)** ☐ **Salvage** ☐ **Dose Mapping** ☐ **Back-up processing for other STERIS plant**

Expedited processing (check if applicable): ☐ N/A

☐ **24** hr ☐ **48** hr **Note:** For expedited processing, additional charges may apply.

Product Information:

NOTE: For expedited processing, if product code already exists, contact STERIS. Product code & lot must match label on product. Product code & lot must match label on cases. Cases that will be shipped to a separate location, must be included on a separate line below and the case clearly labeled. Samples going to STERIS Labs must include the Test Request Form inside the sample case.

Product Code (or Product Description)	Lot Number	# of Cases	Open box & remove contents prior to processing?	Minimum Dose (kGy)	Maximum Dose (kGy)	Send to Lab Post-Processing
			☐ Yes ☐ No			☐
			☐ Yes ☐ No			☐
			☐ Yes ☐ No			☐
			☐ Yes ☐ No			☐
			☐ Yes ☐ No			☐
			☐ Yes ☐ No			☐

☐ **Check here if any of the above product codes are mixed density material.**

☐ **N/A**

Special Processing Instructions: ☐ N/A

Handling of Damaged Product

☐ **Process all damaged cases** (Customer will be notified when damage occurs)

☐ **Do not process damaged cases** (when damage is noted upon receipt, product will be placed on hold and returned to the Customer)

☐ **Disposition each damaged case** (once damages are identified, product will be placed on hold until a customer disposition is obtained) **Note: Processing and/or shipping delays may result.**

☐ **Other** (Specify):

Handling of Count Discrepancies

☐ **Continue processing at STERIS count** (customer will be notified of discrepancy after processing)

☐ **Disposition discrepancy prior to processing** (when discrepancy is noted upon receipt, product will be placed on hold until customer disposition is obtained)

☐ **Disposition discrepancy prior to shipping** (when discrepancy is noted during processing, product will be placed on hold until customer disposition is obtained)

☐ **Other** (Specify):

Is the material labeled "Sterile"? ☐ **No** ☐ **Yes** (If Yes, a Non-Sterile Shipping Agreement *must* be in place before submitting material for processing (Not applicable for product processed and distributed in Canada). Contact the processing facility if agreement is needed.

Documentation: Certificate of Processing & Dosimetry Record will be provided, note in special instructions if additional documentation needed.

Documentation Transmittal: ☐ Include with Product ☐ Email ☐ Fax ☐ Mail Separately

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Product Classification & Safety Information:

☐ Finished Medical Device	☐ Generic Drug	☐ Human Drug/API	☐ Animal Drug	☐ Animal Food/Human Food
☐ Human Tissue Product **(Form 10 Required)**	☐ Human Blood Product **(Form 11 Required)**	☐ Food Packaging	☐ Labware	☐ Food/Spice
☐ Botanicals	☐ Cosmetics	☐ Other (Specify): _____		

☐ **Check here if any of the above listed codes is an implantable medical device.**

☐ **Check here if any of the above listed codes contain hazardous, flammable, corrosive, explosive, combustible, biohazardous, or bio active materials.** (If checked, STERIS management: Contact the Senior Radiation Safety Manager)

☐ **Check here if any of the above listed codes are harmful, in anyway, to humans.** *(If checked, MSDS must be provided before processing)*

☐ **Check here if your product will support microbial growth during an interruption of the irradiation process?** *(If checked, product cannot be augmented without Customer approval which may cause delays in processing and shipping.)*

Return Shipping Instructions: (if a third party is to be billed, please provide address, phone number, and contact)

☐ **Call for Pick Up**

Individual Case Shipments	☐ **UPS** **Account #:** _____ Service type: ☐ Next day Air ☐ 2nd Day Air ☐ Ground ☐ Other: _____	☐ **FEDEX** **Account #:** _____ Service Type: ☐ FedEx Priority Overnight ☐ FedEx Standard Overnight ☐ FedEx 2 Day ☐ Other: _____	**Ship to Address:**
Freight Shipments	**Carrier:** _____	**ACCOUNT #** _____	**Service Type:** ☐ Next Day Freight ☐ 2nd Day Freight ☐ 3rd Day Freight ☐ Other:
Additional Ship to Address:	Cases Labeled as: _____ Ship to: ☐ STERIS Labs: Libertyville, IL (*Test Request Forms must accompany samples)* ☐ STERIS Labs: Brooklyn Park, MN (*Test Request Forms must accompany samples)* ☐ Other: _____		
Special Shipping Instructions: ☐ N/A			

***Note: If no service type is selected in the Return Shipping Instructions, product will ship back the way it was received.**

Liability shall be limited to the lesser of the manufacturing cost of the products or ten (10) times the processing charge. The Assignment of Responsibilities, attached as Exhibit A and incorporated herein by reference, shall apply to all processing services rendered pursuant to this agreement. Notwithstanding the foregoing, the terms and conditions of a Processing Agreement between STERIS and Customer shall take precedence over this Special Radiation Request agreement in the event of a conflict.

Customer Authorization: (signature): _____ **Date:** _____

Print Name: _____ **Title:** _____

STERIS Approvals: (Production / Date): _____ (QS/RC / Date): _____

EXHIBIT A

ASSIGNMENT OF RESPONSIBILITY

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**

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RESPONSIBILITY	Assignment
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. Medical Device Manufacturer provision of FDA product listing information to FDA and STERIS in accordance with 21 CFR, Part 807	**CUSTOMER**
H. Product listing with FDA in accordance with 21 CFR, Part 807	**STERIS**
I. 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**
J. Perform periodic internal audits according to Quality System. A record of the audit shall be maintained on file.	**STERIS**
K. 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 in accordance with STERIS's established change control procedure.	**STERIS**
C. Evaluate STERIS's equipment change control notification 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**
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**