BLUE LINE

EO STERILIZATION SERVICES

Sterilization Readiness Checklist

Company Name:	
Contract Manufacturer used (if applicable):	

Product Information	Customer Answer
Is the product design finalized? • If not, will you need EO sterilization before it is finalized?	
Has material compatibility been checked for EO compatibility? • See AAMI TIR-17	
Will the desired product and load qty fit in a 16" x18" x36" chamber?	
Do you have an EO cycle you have used before? • If yes, please provide details of the parameters	
Has the sterile barrier been chosen? • Is the material porous and suitable for EO sterilization? • Has the material been validated for shipping? • Has the seal been validated?	
Has a shipping configuration been determined? • Has the packaging been validated for shipping? • Will it fit in a 16" x18" x36" chamber? ○ (If not, can the product be arranged to fit in a 16" x18" x36" load?)	
What is the current use of the product? • Bench or acute animal testing • Biocompatibility • Chronic animal • Human use ○ Are you preparing for regulatory submission? ○ What is your timeline?	
Do you currently need validation or a batch release? • If so, please complete the protocol development section below (pg 2) • Can you provide samples for destructive testing ○ 22-30 Samples for batch release (QTY dependent on design) ○ 31-65 Samples for validation (QTY dependent on design) • Can you provide product or dunnage needed to complete a full load?	

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EO STERILIZATION SERVICES

Sterilization Protocol Development Questionnaire

Company Name:	
Contract Manufacturer used (if applicable):	
ETO Sterilization Project Type:	☐ Sterilization Validation ☐ Batch Release/Lot Release ☐ Cycle Re-Qualification ☐ Product Adoption ☐ Validated Cycle Migration / Process Equivalence

Product Information	Customer Answer	
What is the Device and/or System Name: **(This will be placed directly into the protocol exactly how it is written)**		
Provide a Detailed Product Description: **(This will be placed directly into the protocol exactly how it is written)**		
Provide a detailed intended use statement: **(This will be placed directly into the protocol exactly how it is written)**		
Please provide a detailed description of the sterile barrier/packaging including material used for the trays and the porous layers and finished dimensions of the device. **(This will be placed directly into the protocol exactly how it is written)**		
Have you created dunnage? Explain a yes or no answer: **(Dunnage must be comprised of the same product material and match the product mass)**		
What is the residence time of the device(s) in the patient:	☐ Limited contact <24 hours exposure ☐ Prolonged contact 24 hours – 30 days exposure ☐ Permanent contact >30 days exposure ☐ Intra-ocular lens device	Contact Time ____Hrs. ___Min.
What is the surface area of the patient contact portion of the device in cm^2? • If there are implant and delivery system, please provide values for each. (Include all open surfaces inner and outer) • Please email a picture AND description of the patient contact portion.	Surface area:	
	Delivery System Surface Area:	Implant Surface Area:
	Description of patient contact portion:	

Product Information	Customer Answer
What is the sterilization configuration you would like to use? (i.e. how many devices per shipper and how many shipper per full load)? **An optimal configuration would be to fit as many device(s) possible into (2) - 18”x18”x16”boxes or (1) – 18”x16”x36” box. These can be purchased at ULINE (our chamber size is 18” 16” x 36”)**	
What are the dimensions of the shipper(s) as presented for sterilization? (See above for optimal dimension configuration)	
What are the dimensions of the packaged device as presented for sterilization?	
What is the mass of the device? Include all the listed measurements below. • In a pouch • In a pouch and carton • Total load mass of shipper(s)	
Please provide a sample of the device in its sterilization packaging or pictures/illustrations that we can use to show the packaging arrangement and the BI location	
Please provide a picture of the inside of the full shipper box(es) for sterilization.	
Has biocompatibility testing for irritation (ISO 10993-10) been performed successfully?	
Is your device heat sensitive? (our standard cycles are either 55C or 37C)- 37C for heat sensitive devices.	

LAL & Method Suitability (if necessary)

Product Information	Customer Answer
What is the LAL endotoxin limit for the device?	
Is there a specific are special way this test must be completed based on intended usage (i.e fully submerge device or fluid pathway if applicable or both?)	
Are we testing the entire device or the patient contact portion only?	
If patient contact portion only is to be tested, please provide a diagram showing the contact portion.	
Is the product growth promoting? If not, the preference is to test for LAL on products that are not sterilized to increase product yield for each load. However, this needs to be noted in your system. See 7.5 and B.7.5 in ANSI/AAMI ST 72 for details.	
Is your device known to have materials that are bacteriostatic/fungistatic?	
Is your device naturally have the potential for anaerobic bacteria? **Examples:** tissue, gels, liquids or other types of materials or coatings	