

Ethylene Oxide Customer Specification

Customer: _____ Cycle/Specification #: _____ Rev: _____

Customer Contact: _____ Phone Number: _____

After-Hours Customer Contact: _____ Phone Number: _____

Approved Chambers: _____ Applicable Product/Item: _____

Product Classification (Check all that apply):

☐ Medical Device ☐ Pharmaceutical ☐ Active Pharmaceutical Ingredient ☐ Labware ☐ Botanicals ☐ Food / Spice
☐ Food Packaging ☐ Cosmetics ☐ Animal Food / Pet Treats ☐ Other (define) _____

- ☐ Above listed codes include implantable medical device.
- ☐ Above listed codes include a battery or similar energy source.

1.0 General

Facility: _____

Special Comments:

Release Type:

<input type="checkbox"/> BI Release	<input type="checkbox"/> Parametric Release	<input type="checkbox"/> Validation Cycle	<input type="checkbox"/> 2X Qualified
<input type="checkbox"/> Other: _____			

Pallet Binding:

<input type="checkbox"/> Wrap	<input type="checkbox"/> Perforated Wrap	<input type="checkbox"/> Netting	<input type="checkbox"/> Banding	<input type="checkbox"/> Corner Boards
<input type="checkbox"/> Remove wrap <input type="checkbox"/> Other (specify) _____				

EO Concentration: Calculated Concentration: _____ mg/liter (for sustainability reference only)

<input type="checkbox"/> SEO	<input type="checkbox"/> Not SEO
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2.0 Handling of Damaged Product and Count Discrepancies (Customer notified on occurrence)

Damage:

- ☐ Process all damaged cases
- ☐ Do not process damaged cases (Returned to Customer non-processed)
- ☐ Disposition each damaged case (placed on hold until a Customer disposition is obtained)
 - Note: Processing and/or shipping delays may result
- ☐ Other (Specify): _____

Count Discrepancies:

- ☐ Continue processing at STERIS count
- ☐ Disposition discrepancy prior to processing (placed on hold until Customer disposition is obtained)

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☐ Disposition discrepancy prior to shipping *(placed on hold until Customer disposition is obtained)*

☐ Other (Specify): _____

3.0 Sample Placement

- Samples Placed by: ☐ Customer ☐ STERIS ☐ N/A
- Number and type of Samples: _____
- Sample Placement Instructions: _____

4.0 Product Staging Requirements

- First Pallet into Chamber: _____
- Load Temperature requirements: _____
- Pallets per Load: Minimum _____ Maximum: _____
- Other: _____
- Other: _____

5.0 EO Processing

Preconditioning Specification (if applicable)			
Process variables	Units	Set point	Tolerance
Temperature			
Relative Humidity			
Dwell Time			
Transfer Time to Chamber			

Preconditioning Special Instructions

Handling of PCR Nonconformities

Temperature/RH low:

- ☐ Add time to meet minimum specified time in specification
- ☐ Other: _____

Temperature/RH high:

- ☐ Continue process and evaluate after processing

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☐ Stop process and transfer product to warehouse

☐ Other _____

Cycle Parameters				
Process Variables	Unit	Set point	Tolerance	Rate
Exposure time				
Temperature				
Humidity				
EO Concentration				
Pressure				

Add rows or attach additional sheet as necessary

Cycle Special Instructions

Heated Aeration (if applicable)			
Process Variables	Units	Set point	Tolerance
Temperature			
Dwell Time			

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Approved Aeration Cells

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Aeration Special Instructions

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Handling of Aeration Nonconformities

Time Short or Temperature Low

- ☐ Add time to meet minimum specified in heated aeration
- ☐ Other: _____

Temperature High

- ☐ Continue process and evaluate after processing
- ☐ Other: _____

6.0 Sample Retrieval:

- Samples Retrieved by: ☐ Customer ☐ STERIS ☐ N/A
- Number and type of Samples: _____
- Sample Retrieval Instructions: _____

7.0 Sample Shipping Instructions:

Ship Via: _____

Charge to Customer Account: ☐ Yes ☐ No

Customer Account Number: _____

Ship to: _____

Additional Information: _____

8.0 Document Transmittal:

- ☐ Electronic (check if yes) E-mail addresses: _____
- ☐ Hard Copy (check if yes)
- Ship Via: _____
- Charge to Customer Account: ☐ Yes ☐ No

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Customer Account Number: _____

Ship to: _____

Additional Information: _____

Documentation Required (check if yes)

Record	Electronically	Hard Copy
Cycle Printout	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>

9.0 Shipping Instructions

- ☐ Customer to arrange shipping
- ☐ STERIS to arrange shipping

Trucking Company #1

Preferred Carrier	Contact Name	Phone Number	Freight Terms	If Third Party, please provide billing Information:
			<input type="checkbox"/> Collect <input type="checkbox"/> Third Party	Address: Contact Name: Phone Number:

Trucking Company #2 (if applicable)

Preferred Carrier	Contact Name	Phone Number	Freight Terms	If Third Party, please provide billing Information:
			<input type="checkbox"/> Collect <input type="checkbox"/> Third Party	Address: Contact Name: Phone Number:

Special Instructions (Include all special loading, processing or shipping instructions. Attach separate sheet if necessary):

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10.0 Approvals

CUSTOMER Approval

Customer Signature: _____ Date: _____

Print Name: _____ Title: _____

Note: If form is completed electronically, please print out and sign in ink.

STERIS Approval

Production Signature: _____ Date: _____

Quality Signature: _____ Date: _____

11.0 Change Description

Revision	Description of Changes	Effective Date