

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) _____
- Check here if any of the above listed codes is an implantable medical device.
- Check here if any of the above listed codes include a battery or similar energy source.

1.0 General (any special comments):

2.0 Handling of Damaged Product and Count Discrepancies

Damage:

- Process all damaged cases (*customer will be notified when damage occurs*)
- Do not process damaged cases (*damage to be returned to customer non-processed, customer will be notified when damage occurs*)
- Disposition each damaged case (*damages will be 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 (*customer will be notified of discrepancy*)
- 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): _____

3.0 Sample Placement

- Samples Placed by: Customer STERIS
 - Number and type of Samples: _____
 - Sample Placement Instructions: _____
- _____
- _____
- _____

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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
- Stop process and transfer product to warehouse
- Other: _____

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Aeration Special Instructions

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
- 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
- Customer Account Number: _____
- Ship to: _____
- Additional Information: _____

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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: _____

QS/RC Signature: _____ Date: _____

11.0 Change Description

Revision	Description of Changes	Effective Date