

Ethylene Oxide Customer Specification

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

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 Product Staging Requirements

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

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4.0 Sample Placement

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

5.0 EO Processing

Preconditioning Specification (if applicable)			
	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 Isomedix
- 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: _____

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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 Isomedix 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