[Organization logo]

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PROCEDURE FOR ETHYLENE OXIDE (EtO) STERILIZATION

Code:	
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Date	Version	Created by	Description of change
	0.1	Advisera	Basic document outline

Table of contents

1. Purpose, scope, and users

The purpose of this Procedure is to define the sterilization process for medical devices in the production and service provision process.

This Procedure applies to all processes where requirements for sterile medical devices are applied.

Users of this document are all employees of [organization name] inside the scope of the Quality Management System (QMS).

2. Reference documents

- ISO 13485:2016 standard, clauses 6.4.2, 7.5.2, 7.5.5, and 7.5.7
- ISO 14971:2019
- MDR 2017/745 Annex IX – Chapter I
- Quality Manual
- Procedure for Production and Service Provision
- Harmonized or valid ISO standards regarding EtO sterilization
- [other documents and regulations specifying document control]

3. Sterilization process

Although physical or chemical processes cannot ensure absolute sterilization, an object is considered to be sterile [illegible]

3.1. Decontamination

[Job title] must ensure the decontamination of contaminated, or presumed contaminated items (e.g., supplies, equipment, medical devices, etc.), is carried out, [illegible]

The following rules apply during decontamination:

- **Transport** – [Job title] collects the contaminated or presumed contaminated items and transports them into the decontamination area, avoiding contamination of facilities and employees. [illegible]
- **Protective equipment and clothing** – Employees who work in the decontamination area must use protective equipment and clothing. [illegible]
- **Sorting** – Employees must sort the contaminated items immediately after utilization, and avoid any further contact with the contaminated items unless using appropriate protective

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You can find the full text of the MDR on the following link: https://advisera.com/13485academy/mdr/

Commented [AES7]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "03_Quality_Manual".

Commented [AES8]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "12_Production_and_Service_Provision".

Commented [AES9]: If you are in the EU market, then use the harmonized standards https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices_en

If you are in the USA market, use the approved standards by the FDA https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

Commented [AES10]: Adapt to the organization's practice.

Commented [AES11]: E.g., Sterilization Manager, Production Manager

Commented [AES12]: E.g., employee in Sterilization [illegible]

Commented [AES13]: E.g., Production Manager, Sterilization [illegible]

clothing and equipment. [illegible]

- **Washing** – [Job title] ensures that detergent used for washing is adequate to the materials in the item and ecofriendly. [illegible]
- **Inspection** – [Job title] inspects all decontaminated items for cleanliness and sends them to packaging. [illegible]

[Job title] must ensure the following during the inspection:

Commented [AES14]: E.g., Production Manager, Sterilization [illegible]

- Instruments with cutting edges should be checked for sharpness. Items with dull spots, chips, or dents should be discarded.
- Pivoted instruments, for example, clamps and forceps, ought to be checked for solidness and arrangement of jaws and teeth. Tips ought to be properly adjusted, jaws should meet perfectly, and joints should move effectively.
- [illegible]
- [illegible]
- [illegible]

In case of any irregularities during the inspection and checking, [job title] must send the suspect items to be decontaminated again or repaired.

3.2. Ethylene Oxide sterilization methodology

Ethylene Oxide (EtO) sterilization is a chemical process that is effective against microorganisms, and is suitable for the sterilization of a wide range of materials not compatible with other methods of sterilization:

- assembled complex devices
- catheters
- custom procedure packs
- equipment with integrated electronics
- [illegible]
- [illegible]
- [illegible]

Commented [AES15]: Adapt to the organization's practice.

The EtO sterilization process consists of the following three phases, which can be performed separately in the case of bigger instruments or a higher number of instruments:

- pre-conditioning
- [illegible]

- aeration

3.2.1. Preconditioning

In order to prevent the growth of microorganisms, [job title] must send the items for preconditioning. [Job title] must ensure that the following conditions are maintained during loading of the batch:

- Temperature (Common range: +120 °F to +135 °F (+48 °C – +57 °C))
- [illegible]

Commented [AES16]: E.g., Production Manager, Sterilization [illegible]

3.2.2. Sterilization

[Job title] sends the load through a long and complex sterilization cycle. Requirements of such a system are:

- accurate temperature control
- availability of the control system
- [illegible]
- [illegible]
- dedicated customer guidelines
- auto batching release through tolerance tests
- [illegible]
- [illegible]
- alarming
- shut-down strategies

Commented [AES17]: E.g., Production Manager, Sterilization Manager

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During this cycle, [job title] ensures that accurate temperature control is applied and a heating jacket is used.

Usually, the sterilization process lasts approximately 60 hours, and during this time [job title] must ensure backup for the system in case of any incident or emergency. [illegible]

Commented [AES19]: Adapt to the organization's practice.

The sterilization process begins when [job title] closes the doors of the sterilization facility and checks whether the doors are sealed. [illegible]

During the sterilization process, [job title] must monitor the stage of the sterilization process and other important process values.

[illegible]

The sterilization phases are:

- cycle start delay, enabling the system to start in stable conditions
- general cell temperature check
- [illegible]
- [illegible]
- first flush
- second flush
- [illegible]
- [illegible]
- sterilization dwell time period under EtO
- post-dwell vacuum level
- [illegible]
- [illegible]
- final air admission
- final chamber re-evacuation delay

Commented [AES20]: Adapt to the organization's practice.

[Job title] monitors the execution of each phase in the sterilization process and creates the batch report, which must include information on key parameters being measured and monitored during the sterilization process. [illegible]

3.2.3. Aeration

[Job title] ensures that heated air is continuously circulated throughout the aeration area, and that residual gases are removed via an abatement system to eliminate any remaining EtO from the sterilization load.

Commented [AES21]: E.g., Production Manager, Sterilization Manager

During the aeration phase, [job title] is responsible for monitoring:

- temperature levels in the aeration cell
- [illegible]
- [illegible]

Commented [AES22]: Adapt to the organization's practice.

3.3. Validation of sterilization process

Commented [AES23]: Adapt to the organization's practice. Ethylene Oxide sterilization is typically outsourced to a contract [illegible]

3.3.1. Full validation

The EtO sterilization process cannot be qualified without a successful full validation. [Job title] is responsible for the full validation, which consists of the following:

1. Process Challenge Device (PCD) validation
2. Bioburden measurement
3. [illegible]
4. [illegible]
5. [illegible]

Commented [AES24]: E.g., Production Manager, Sterilization Manager

6. 3x Full Cycle

If there have been no problems, and no changes to the product or process, then re-validation is not required at the end of the first year. Revalidation of the process must be conducted every two years by [job title].

[redacted]

3.3.2. Revalidation

When it is time to re-validate the EtO process, [job title] must perform the following tests:

1. Bioburden measurement – The purpose of this step is to confirm that bioburden levels remained the same.
2. EtO residual measurement – The purpose of this test is to verify that there was no alteration of the process or the item that would increase the presence of EtO, Ethylene Chlorohydrin, or Ethylene Glycol above the Tolerable Contact Limit.
3. [redacted]
4. [redacted]
5. [redacted]

Items subjected to the full cycle are later used for EtO residual testing.

The validation report must be prepared in accordance with applicable standards and regulations stated in Section 2 of this procedure.

4. Managing records kept on the basis of this document

Record name	Code	Storage			Responsibility
		[redacted]	[redacted]	[redacted]	[redacted]
Record for Sterilization	PR14.6	[redacted]	[redacted]	[redacted]	[redacted]

5. Appendices

- Appendix 1 – Record for Sterilization

Commented [AES25]: Adapt to the organization's practice.

Commented [AES26]: The organization can expand the revalidation period to two years if the sterilization process and [redacted]

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Commented [AES28]: Adapt the information in this column to [redacted]

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[organization name]

[job title]
[name]

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[signature]

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