[Organization logo]

[Organization name]

Commented [AES1]: All fields in this document marked by square brackets [ ] must be filled in.

PROCEDURE FOR STERILE MEDICAL DEVICES

Code:	
Version:	0.1
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Commented [AES2]: The document coding system should be in line with the organization's existing system for document coding; in case such a system is not in place, this line may be deleted.

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Commented [AES3]: This is only necessary if document is in paper form; otherwise, this table should be deleted.

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Change history

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 of 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 QMS.

Commented [AES4]: Adapt to the organization's needs.

Commented [AES5]: Include the name of your organization.

2. Reference documents

- ISO 13485:2016 standard, clauses 6.4.2, 7.5.2, 7.5.5, and 7.5.7
- Quality Manual
- Procedure for Production and Service Provision
- [other documents and regulations specifying document control]

Commented [AES6]: You can find a template for this document in the ISO 13485 Documentation Toolkit, folder "03_Quality_Manual".

Commented [AES7]: You can find a template for this document in the ISO 13485 Documentation Toolkit, folder "11_Production_and_Service_Provision".

3. Sterilization process

Although physical or chemical processes cannot ensure absolute sterilization, an object is considered sterile

3.1. Decontamination

Commented [AES8]: Adapt to the organization's practice.

[Job title] must ensure that the decontamination of contaminated, or presumed contaminated items

Commented [AES9]: E.g., Sterilization Manager, Production Manager

The following rules apply during decontamination:

- **Transport** – [Job title] collects the contaminated or presumed contaminated items and transports them to the decontamination area, avoiding contamination of facilities and employees.

Commented [AES10]: E.g., employee in Sterilization

- **Protective equipment and clothing** – Employees who work in decontamination areas must use protective equipment and clothing.

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

- **Sorting** – Employees must sort the contaminated items immediately after utilization, and avoid any further contact with contaminated items unless using appropriate protective clothing and equipment.
- **Washing** – [Job title] ensures that detergent used for washing is adequate for the materials in the item and ecofriendly.

- **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 [AES12]: 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 correctly adjusted, jaws should meet perfectly, and joints should move effectively.
- [illegible]

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

3.2. Ethylene Oxide sterilization methodology

Commented [AES13]: Ethylene Oxide sterilization is used as an [illegible]

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
- [illegible]

Commented [AES14]: Adapt to the organization's practice.

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

- Pre-conditioning
- Sterilization
- [illegible]

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 [AES15]: E.g., Production Manager, Sterilization [illegible]

Commented [AES16]: These parameters cannot be changed, [illegible]

3.2.2. Sterilization

During the sterilization process, [job title] must ensure that the following requirements are followed:

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

- accurate temperature control
- availability of the control system
- accurate pressure and vacuum control
- easy displays of process phases
- dedicated customer recipes
- [illegible]
- [illegible]
- [illegible]
- [illegible]
- [illegible]

Commented [AES18]: Adapt to the organization's practice.

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 that 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
- Initial vacuum phase
- [illegible]
- [illegible]
- [illegible]

- DEC (Dynamic Environmental Conditioning)
- EtO gas injection
- Sterilization dwell time period under EtO
- Post-dwell vacuum level
- [illegible]

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 [illegible]

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

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

- Temperature levels in aeration cell
- Pressure level changes
- [illegible]

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

3.3. Validation of sterilization process

Commented [AES23]: Adapt to the organization's practice.

[illegible]

3.3.1. Full validation

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

1. Process Challenge Device (PCD) validation
2. Bioburden measurement
3. EtO residual measurement (as per ISO 10993-7:2008/R2012)
4. [illegible]
5. [illegible]
6. [illegible]

Commented [AES24]: Adapt to the organization's practice.

If there have been no problems, and no changes to the product or process, then revalidation is not required at the end of the first year. [illegible]

Commented [AES25]: The organization can expand the revalidation period to two years if the sterilization process and [illegible]

3.3.2. Revalidation

When it is time to revalidate 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. [illegible]
4. [illegible]
5. [illegible]

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

Commented [AES26]: Adapt to the organization's practice.

4. Managing records kept on the basis of this document

Record name	Code	Storage			Responsibility
		[illegible]	[illegible]	[illegible]	[illegible]
Record for Sterilization	PR13.1	[illegible]	[illegible]	[illegible]	[illegible]

Commented [AES27]: Alter these records to match what you [illegible]

Commented [AES29]: Adapt the information in this column to [illegible]

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

Commented [AES30]: If the record is in electronic form, write [illegible]

5. Appendices

- Appendix 1 – Record for Sterilization

[job title]
[name]

_____
[signature]

Commented [AES31]: Only necessary if the Procedure for Document and Record Control prescribes that paper documents must be signed.