[Organization logo]

[Organization name]

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

# PROCEDURE FOR FILTRATION STERILIZATION

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| Code: | |
| Version: | 0.1 |
| Created by: | |
| Approved by: | |
| Date of version: | |
| Signature: | |

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.

## Distribution list

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## Change history

| Date | Version | Created by | Description of change |
|---|---|---|---|
| | 0.1 | Advisera | Basic document outline |
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## 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 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
- ISO 14971:2019
- MDR 2017/745 Annex IX – Chapter I
- Quality Manual
- Procedure for Production and Service Provision
- Harmonized or valid ISO standards regarding filtration sterilization
- [other documents and regulations specifying document control]

**Commented [AES6]:** Delete this if your organization does not need to be compliant with MDR.

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

## 3. Filtration sterilization process

Filtration sterilization is a process for removing particulate matter from a liquid. [illegible]

The Sterility Assurance Level (SAL) for sterilizing a solution by filtration is normally accepted as 1:1000 (10-3).

### 3.1. Filter selection

[Job title] ensures that sterile filters used to sterilize the fluid shall:

**Commented [AES10]:** E.g., Sterilization Manager, Production Manager

- allow nominal porosity of 0.2 µm or 0.22 µm and be pyrogen-free
- retain at least 107 microorganisms of a strain of Brevundimonas diminuta per $cm^2$ of filter surface; this needs to be certified by the manufacturer
- complete the sterilization process quickly, thanks to characteristics of the liquids and dimensions of the filter, without changing the filters during the process
- [illegible]
- [illegible]

**Commented [AES11]:** Brevundimonas diminuta is non-lactose-[illegible]

- be appropriate to the product being filtered in terms of physical and chemical compatibility, and be able to endure the constant pressure, temperature, and hydrostatic stress of the filtration process

[illegible]

### 3.2. Membrane filtration of liquids

Commented [AES12]: Adapt to the method applied by your organization.

[Job title] must first ensure that the area in which the sterilization will be performed is clean, and then wash and autoclave the membrane holder.

In the membrane holder, [job title] sets up the new membrane, together with 2-20µm prefilter, and connects a nitrogen tube to the pressurized container. [illegible]

The liquid to be filtered is poured into the pressure vessel by [job title], who releases the nitrogen in the vessel at the pressure of 3 to 4 kg/cm², which will pump the solution to the membrane holder.

The liquid passes through the membrane assembly, is filtered and poured into a container labeled as "sterilized" by [job title], [illegible]

Commented [AES13]: Adapt to the organization's needs.

[illegible]

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

### 3.3. Validation of the sterilization process

[Job title] must ensure that FDA-approved/challenged filters are used, and that filter integrity testing is performed regularly.

The filter integrity testing covers the following activities by [job title]:

1. Use appropriate liquid, usually water for hydrophilic membranes or a mixture of alcohol/water for hydrophobic membranes.
2. [illegible]
3. [illegible]
4. If the liquid begins bubbling at a pressure that is lower than the value mentioned in the specifications, it could be an indicator of the following:
    - difference in surface tension between recommended fluid and fluid in use
    - appropriate filter with inappropriate pore size
    - [illegible]
    - [illegible]
    - [illegible]

[Job title] documents the validation results in the [Record for Sterilization].

Commented [AES15]: If the record is prescribed by legal or [illegible]

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 | | | |
|---|---|---|---|---|---|
| | | [illegible] | [illegible] | [illegible] | [illegible] |
| Record for Sterilization | PR14.6 | [illegible] | [illegible] | [illegible] | [illegible] |

**Commented [AES17]:** Adapt the information in this column to [illegible]

**Commented [AES16]:** Adapt the information in this column to [illegible]

**Commented [AES18]:** If the record is in electronic form, write [illegible]

## 5. Appendices

- Appendix 1 – Record for Sterilization

[job title]
[name]

[signature]

**Commented [AES19]:** Only necessary if the Procedure for Document and Record Control prescribes that paper documents must be signed.