[Organization logo]

[Organization name]

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PROCEDURE FOR STEAM STERILIZATION

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

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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.

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 steam 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 safe for which necessary conditions have been met during a sterilization process.

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, by physical or chemical process, to ensure they are safe for further handling.

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. During the transportation, the items must be covered and transported by carts and containers that prevent contamination of facilities and personnel.
- **Protective equipment and clothing –** Employees who work in the decontamination area must use protective equipment and clothing. [Job title] defines what protective equipment and clothing will be applied and checks whether the employees follow the rules.
- **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. In areas and facilities where no protective clothing or equipment is required, the only sorting to be performed is disposal of sharps and other disposable items.

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

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

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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

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

- **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:

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

3.2. Steam sterilization methodology

[Job title] must ensure that a written sterilization procedure that is based on the manufacturer's instructions is at the place of application, and that it contains guidelines on loading, sterilization cycle, post-sterilization treatment, and adequate record keeping. [illegible]

Application: Surgical instruments are mostly treated with a steam sterilizer, which shouldn't be used for heat-sensitive materials and instruments. [illegible]

3.2.1. Water used in the sterilization process

Sterilization must be done with water that is free of chemicals and endotoxins. [Job title] is responsible for ensuring that only sterilized or purified water of appropriate specifications is used in the sterilization process, [illegible]

Commented [AES14]: The key consideration when determining sterilization operating procedures is the type of sterilizer and sterilization cycle that are being used, because this [illegible]

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

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

[Job title] will fill the empty sterilizer reservoir with water of adequate quality. Water from the sterilizer reservoir will be changed daily, or more often in the case of deterioration of the water quality. [illegible]

3.2.2. *Before sterilization*

Prior to handling the cleaned [medical device], [job title] will change gloves and plastic apron. When carrying the cleaned [medical device] to a sterilizer in another location, [job title] must have an adequate container that is labeled and has a lid.

[illegible]

[Job title] needs to load the [medical devices] correctly. Prior to selection and starting the sterilization cycle, [job title] must correctly load the [medical device].

[illegible]

3.2.3. *Sterilization and after the sterilization*

[Job title] checks that the sterilizer indicates that the cycle was satisfactory.

[illegible]

The Record for Sterilization can be used if there is no printer or data logger that contains related information.

[illegible]

In the event of any nonconformity in the above-mentioned cycle, [job title] must record the information, notify the user, and put those medical devices through an additional full decontamination cycle.

[illegible]

3.2.4. *Unwrapped instruments (all sterilizers)*

When using a non-vacuum sterilizer, [job title] must ensure that the instruments are processed unwrapped. [Job title] must classify as "sterilized" instruments that have been processed unwrapped, but they are not sterile.

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

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Commented [AES20]: E.g., Production Manager, Sterilization Manager

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

In any type of sterilizer, solid instruments can be sterilized unwrapped. Hollow or lumened instruments can only be sterilized with a vacuum sterilizer.

[Job title] must unwrap the instruments when process them using a non-vacuum sterilizer.

Take into account that sterilization of the internal surfaces of instruments with lumens processed in a non-vacuum sterilizer may not be fully achieved.

[Job title] must conduct a drying stage when using a vacuum sterilizer, if the load includes hollow or lumened instruments.

3.2.5. Wrapped instruments (vacuum sterilizers)

Commented [AES25]: Delete if not applicable to your organization.

[Job title] ensures that wrapped instruments are only processed in a vacuum sterilizer that is designed for wrapped instruments. Note that wrapping and labeling are part of the validation process. When introducing new wrapping and labeling, the sterilizer should be re-validated by [job title].

To wrap instruments in a vacuum sterilizer prior to sterilization, [job title] must ensure:

- that manufacturer's instructions are followed for each part of the process
- that materials used for wrapping are adequate to the process
- that material used for wrapping only has one layer
- that each instrument or set of instruments for a single treatment is wrapped individually and kept in a container, in a way that avoids overlapping
- that the basket used is of proper size (i.e., it must be slightly bigger than the instruments)
- that sealing is performed in a way that preserves the microbiological properties of the wrapping and enables aseptic opening of the pack (for example, the pack can be self-sealing or folded three times and sealed with autoclave tape).

To each pack that has the word "Sterile," and that contains information regarding the process date, sterilizer, and identification number, [job title] attaches a pre-written or pre-printed adhesive label. To avoid damaging the label after attaching it to the wrapping, ballpoint pens should never be used to write directly on the wrapping.

For adequate labeling, [job title] must use a chemical process indicator printed on the pouch or label/tape. This will not indicate sterility level, but it will help in separation of sterilized and non-sterilized items.

[Job title] must include a drying stage at the selected sterilization cycle. To avoid sterility loss of the wrapped instruments, the load must be dry before the sterilizer chamber is opened.

3.2.6. Handling and storage of unwrapped instruments immediately after sterilization

[Job title] ensures that instruments that have been sterilized unwrapped are designated as "sterilized only." Unwrapped instruments that are sterilized can be kept for later use. However, [job title] must ensure that they are:

- dry – if instruments are not stored completely dry, that will lead to contamination by various microorganisms and instrument corrosion
- [illegible]
- [illegible]

Before handling unwrapped instruments that have been removed from the sterilizer, [job title] must ensure that his/her hands, gloves, and apron are clean prior to manipulation. In case of manipulation with hot instruments, [job title] must take additional precautions.

[illegible]

[Job title] must ensure that sterilized instruments are not left in the uncontrolled clinical environment.

[illegible]

When labeling wrapped instruments, [job title] writes on the labels before attaching them to the wrapping. Ballpoint or felt pen are not suitable for writing on the wrapping.

[illegible]

3.2.7. Handling and storage of wrapped instruments immediately after sterilization

[Job title] ensures careful handling and storage of sterilized packs so that the contents remain sterile until the pack is opened.

[illegible]

[Job title] handles the packs according to safety protocols, to avoid dropping or damaging. Newly sterilized wrapped instruments must not be placed on a cool or solid surface, as doing so could cause damage to the instrument.

[illegible]

If wrapped sterile instrument packs are to be stored for some time, [job title] confirms that the process date is marked clearly on the wrapping to enable stock rotation.

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Commented [AES27]: E.g., Warehouse Manager, Sterilization Manager

Chemical process indicators must be checked regularly by [job title], to ensure that color has changed correctly. In cases where color has not changed correctly, [job title] investigates the problem, and reprocesses the instruments from the beginning.

[Job title] stores wrapped instruments in clean cupboards, drawers, or bases in a way that prevents damaging the wrapping (for example, in a way that requires minimal handling, in a dry environment that maintains a constant temperature).

[Job title] ensures that instruments are not stored on open shelves or in places where recontamination may occur. FIFO stock rotation should be used to reduce the time that sterile instruments spend in storage.

3.3. Validation of sterilization process

There is no reliable method that can confirm that the steam sterilization process was successful. That is why this treatment requires testing to check if each sterilization cycle was successful in the sense of effectiveness of operating conditions. Testing is used to confirm that the machine doesn't have any operational issues.

Validation is a documented process used to review the consistency of expected sterilization outputs. Selection of operating conditions includes, but is not limited to: sterilization cycle, wrapping, loading pattern and its nature, trays, and labeling. Validation includes necessary annual tests and reviews as a part of the commissioning process, which are mandatory after installation of a new sterilizer. [Job title] must perform all above-mentioned checks and tests.

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

3.3.1. Daily housekeeping checks for all sterilizers

At the start of each day, [job title] will:

Commented [AES28]: E.g., employee in the Sterilization department

- Wipe the door seal with a clean, disposable, damp, non-linting cloth and carry out any other checks required by the manufacturer.
- Check the cleanliness of the chamber and shelves.
- Use specified water to refill the reservoir.
- Check ventilation louvres before switching the power on, to make sure they are not covered and to avoid overheating.
- Preheat the sterilizer chamber before daily tests, if recommended by the manufacturer.

3.3.2. Weekly safety checks for all sterilizers

Before carrying out any weekly tests, the following checks are carried out by [job title] in addition to the daily housekeeping checks. Every week, [job title] will:

- Examine the door seal to check if there is any damage.
- Follow manufacturer's instructions to examine the performance and security of door safety features – including locking mechanisms.

- Repair door seal damage or safety feature faults before sterilizer usage or weekly tests.

4. Managing records kept on the basis of this document

Record name	Code	Storage			
Record for Sterilization	PR14.6				

Commented [AES30]: Adapt the information in this column to

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

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5. Appendices

- Appendix 1 – Record for Sterilization

[job title]
[name]

_____
[signature]

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