

Recommendations by the Quality Task Group (82)

Release of medical devices after sterilization

This recommendation replaces Recommendation 15 «Release and storage of medical device after sterilization» from 2001.

Based on the «Recommendation for hygienic processing practices for medical devices» (called the KRINKO/BfArM Recommendation in the following), jointly compiled by the German Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute and the German Federal Institute for Drugs and Medical Devices (BfArM), processing ends with documented release of the medical device for reuse or storage.

Pursuant to Section 4 of the Medical Devices Operator Ordinance (MPBetreibV), medical devices must be processed using suitable validated processes. Based on Annex 6 of the KRINKO/BfArM Recommendation, the medical devices must be released by qualified, → **EXPERIENCED PERSONNEL**. Staff will be presumed to be suitably qualified if they can demonstrate that they have successfully completed a technical and/or specialist training course as specified in the qualification directive of the German Society of Sterile Supplies (DGSV e. V). The staff members authorized to release medical devices must be set out in writing.

The release process must be executed in accordance with the «recognized rules of technology» and comply with the «state of the art in science and technology». National and international standards reflect the state of the art in science and technology and must be implemented in practice as the recognized rules. As part of its quality management policy, the respective sterile supply department must compile → **REGULATIONS FOR DOCUMENTED RELEASE**.

Release is based on:

- verification and documentation that the process has been fully and properly carried out
- verification and documentation of routine tests (if performed; these do not come within the scope of this Recommendation)
- verification that the documented batch sequence complies with the process parameters defined at the time of validation
- verification of the integrity and dryness of the packaging
- verification of labelling on all items of packaging

The minimum requirements for medical device release after sterilization are set out in the KRINKO/BfArM Recommendation and include:

1. Assessment of the process sequence

The → **PROCESS SEQUENCE** must be checked to ensure that the correct program was selected and that the process-relevant parameters were observed, e. g. for steam sterilization, these are the temperature, pressure and time; for low-temperature sterilization processes, the concentration of the sterilization agent must be verified additionally. These parameters must correspond to the results obtained during validation of the sterilization process.

→ **ONLY EXPERIENCED PERSONNEL** may release sterilized medical devices.

→ **REGULATIONS FOR DOCUMENTED RELEASE** must be compiled as part of the quality management policy.

→ **THE PROCESS SEQUENCE** must be checked to ensure it was correct.

→ **VISUAL INSPECTION** of packaging must be carried out.

→ **CORRECT LABELLING** of sterile supplies must be assured.

→ **PROCESS INDICATORS** must have undergone a complete change of colour.

→ **CORRECT BATCH DOCUMENTATION** is a precondition for release.

→ **STERILE SUPPLY RELEASE** must be documented. This is absolutely necessary to prove that a sterilization process has been properly conducted.

2. Visual inspection of sterilized medical devices

During → **VISUAL INSPECTION** the integrity of the packaging is checked. Soft packaging must be checked to ensure that there are no tears, defects or moisture penetration due to condensate residues. For sterile supplies packed in containers, the container closure integrity must be tested using seals and/or signalling systems.

3. Verification of labelling and, if applicable, of process indicators

Based on standard series DIN 58953, the packaging → **LABELLING** consists of the following details:

- Identity of the person entrusted with packing
- Product designation
- Batch designation
- Sterilization date
- Expiry date
- if applicable, special instructions for storage and/or handling and use
- if applicable, special instructions for precautionary measures and warnings
- Designation as «STERILE» and type of sterilization process
- Quantity, if not clearly discernible.

Process indicators (Class 1) pursuant to EN ISO 11140-1 and/or other equivalent means used to make clear to user that the medical devices in the terminal packaging were exposed to a sterilization process. The → **PROCESS INDICATORS** and/or other equivalent means must be checked to ensure proper functions and results (e. g. complete change of colour change for a process indicator).

4. Compilation of batch documentation

Medical devices may be released only after batch documentation has been compiled. The → **BATCH DOCUMENTATION** must ensure that the sterilized medical device can be clearly assigned to the batch and that all process-relevant parameters are recorded. The name of the sterilizer operator must be documented.

The records must be preserved and archived in hard-copy or digital format. The specified retention period varies, e. g. based on the KRINKO/BfArM Recommendation it is at least five years.

→ **RELEASE** of sterilized medical devices must be documented. How the decision to release the supplies is documented must be specified in a standard operating procedure. It must be possible to differentiate between released and non-released medical devices, for example on the basis of a unique release or non-release code and/or spatial separation.

It is permitted to release certain medical devices of a batch and withhold others while explaining and documenting the reason. ■