

Recommendations by the Quality Task Group (103)

Management of non-medical devices

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Unlike medical devices within the meaning of the Medical Device Directive (MDD), there are various devices → **(NON-MEDICAL DEVICES)** which are used for patient care and, in the interest of hygiene, must be cleaned, disinfected and in some cases sterilized before use.

→ **NON-MEDICAL DEVICES** do not meet MDD definition criteria. They should still be cleaned, disinfected and in some cases sterilized before use.

Reference is made to non-medical devices in the following:

- EN ISO 15883-6:2016-04
- Recommendation No. 77 (flowchart)
- Various regulations of individual German Federal States

Definition:

Non-medical devices are all devices that do not meet the definition (of a medical device) as set out in the Medical Device Directive, Article 3(1).

The non-medical devices often delivered to the Reprocessing Unit for Medical Devices (RUMED) include:

- Infant feeding bottles, pacifiers, nipple shields
- Feeding cups
- Care/grooming items (e.g. combs, brushes, manicure sets, razors, etc.)
- Toys
- Operating room (OR) shoes
- Transport boxes
- Washbowls
- and many other devices

The RUMED must clarify a number of issues if such devices/items are to be reprocessed or have already been reprocessed.

If available, the manufacturer's instructions should be taken into account.

The following → **ISSUES**, among others, must be clarified in cooperation with the persons responsible for hygiene in the respective department:

→ **ISSUES** to be clarified in cooperation with the persons responsible for hygiene in the respective department.

- Cleaning and disinfection of OR shoes:
 - Lint
 - Temperature
 - Material compatibility
 - Which washer-disinfector (WD) or cleaning process should be used.
- Cleaning and disinfection of pacifiers/infant feeding bottles/nipple shields
 - Water residues
 - Patient assignment
 - Which chemical products
 - Material compatibility
- Cleaning and disinfection, possibly sterilization, of soft toys or other toys (e.g. from the oncology department)
 - Material compatibility
 - Lint
 - Amenability to cleaning

- Cleaning and disinfection of transport boxes as well as of transport carts
 - Material compatibility
 - Space required
 - Drying
- Cleaning and disinfection of washbowls – measuring cups
 - Material compatibility
 - Space required
 - Spray shadowing (loading systems)
- Cleaning and disinfection of care and grooming items (e.g. combs, brushes, manicure sets, razors, etc.)
 - Hair
 - Material compatibility
 - Extraneous rust

→ **SUITABLE PROCESSES** or reprocessing instructions must be available, otherwise the products should not be reprocessed in the RUMED.

→ **USE OF SINGLE-USE DEVICES** may be advisable if because of a product's design, residue-free cleaning and disinfection is not possible.

Devices/items for which no reprocessing instructions or → **SUITABLE PROCESSES** are available should not be reprocessed in the RUMED.

Bearing in mind ecological and economic aspects, and based on risk assessment, a process can be devised to guarantee safe use of non-medical devices for patients.

The use of → **SINGLE-USE DEVICES** may be advisable from the RUMED viewpoint. Because of their design, residue-free cleaning and disinfection of certain devices is not possible. Such examples include nipple shields and feeding bottles teats.

Factors to be borne in mind include, among others, lack of knowledge about the materials of which such devices are made and their potential interaction with the automated reprocessing process.

For these devices there are, in general, no manufacturer's instructions available which correspond to the processes normally used in the RUMED and which are needed or suitable for medical device reprocessing.

In some cases, the use instructions supplied with such devices are intended only for domestic household use (e.g. accessories for a home ventilation device). Based on these instructions, they can generally be cleaned directly on site (e.g. in a dishwasher or washing machine).

The Working Group Instrument Reprocessing (AKI) has issued the following instruction for reprocessing OR shoes:

"From a microbiological viewpoint, the use of alternating processes to reprocess OR shoes and medical devices does not appear to be a problem.

However, when reprocessing OR shoes particles and lint from hosiery also accumulate, in particular, in the filter combinations of the washer-disinfector (WD). These can pass through the filter and risk being carried into narrow-lumened medical devices, such as minimally invasive surgical (MIS) and ophthalmology instruments. Merely running a blank load will not eliminate that problem.

The crucial point to be addressed here on switching from OR shoes to such medical devices is whether prior to switching it is possible to adequately clean the filter fittings and remove any fibres. Only if that can be assured when switching from one process to another should alternating reprocessing processes be used. Otherwise, we recommend that OR shoes be reprocessed in dedicated WDs."

Cleaning in a separate WD, large-capacity WD or bed washing system is recommended. For more information please consult the brochure by the Working Group for Bedframe and Cart Decontamination Systems (AK-BWA). That brochure gives instructions for cleaning and disinfection of OR shoes, distribution containers (transport boxes) and other devices. ■