Recommendation by the Quality Task Group (127)

Risk assessment of reprocessing-related products

T. Appel, S. Bungardt, A. Hartwig, M. Hunold, A. Jones, G. Kirmse, J. Metzing; E-mail: qualitaet@dgsv-ev.de

RISKS arising for the reprocessing process must be assessed and set out in writing, and the necessary measures must be taken and documented.

In medical device reprocessing there is a large number of influencing factors affecting the quality of the reprocessing processes as well as normative and legal aspects which must be observed.

In this Recommendation we will focus on the myriad of products used in reprocessing processes. For all these products the **RISKS** arising for the reprocessing process must be assessed and set out in writing, and the necessary measures must be taken and documented.

Table 1 serves as a template for risk assessment of reprocessing-related products in one's own establishment and must be adapted accordingly to the respective processes/products.

The list is intended as guidance and must be used as follows:

1. Product data
   Enter into this column all product information, such as Article No., manufacturer, specification, etc.
2. Normative/legal requirements
   The information is this column can be copied from relevant sources
3. Area of use and risk assessment for processes, patients and users
   The recommendation's table gives a detailed explanation of the most important aspects to be taken into account. These specifications must be adapted to the respective areas of use, processes and measures.
4. Requalification required
   This relates to the processes for which requalification is required on changing a product

In general, the following must be documented or kept to hand for the products used:

- Depending on the product, the product data sheet, conformity confirmation and instructions for use
- Possibly, safety data sheet and operating instructions (for all hazardous substances)
- Possibly, biocompatibility certificate if these products could leave residues (e.g. care agents)
- Possibly, manufacturer's quality management certificate as per DIN EN ISO 9001 or 13485
- Conformation of compatibility with the process used (especially for products not classified as medical devices)
- If necessary, the intended use is documented in the respective validation report and/or in the respective standard operating procedures (SOPs)/IT systems. It must be possible to track any changes to the relevant products.

PACKAGING PROCESSES must be validated in accordance with the Guideline for Validation of Packaging Processes pursuant to DIN EN ISO 11607-2:2020

ALL PACKAGING PROCESSES must be validated in accordance with the Guideline for Validation of Packaging Processes pursuant to DIN EN ISO 11607-2:2020.

Table 1: Sample list for assessment of reprocessing-related products and consumables

Product data	Normative/ legal requirements	Area of use and risk assessment for processes, patients and users	Requalification required	Remarks
Cleaning/ Disinfection				
Detergents for the ultrasonic bath	No particular specifications	The product must be compatible with the materials of which the medical devices to be reprocessed are composed as well as with the process.	Cleaning performance (if manual cleaning is part of validation)	
Brushes for cleaning/ precleaning	In general, not a medical device	The product must be compatible with the process.	Cleaning performance (if manual cleaning is part of validation)	
Process chemicals for washer-disinfector (WD)/endoscope washer-disinfector (EWD) processes	The product meets the requirements of MDR Annex I for medical devices	The product meets the requirements of the current KRINKO/BfArM Recommendation*. KRINKO/BfArM Recommendation*: Hygiene requirements for reprocessing medical devices, jointly compiled by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (KRINKO) and the Federal Institute for Drugs and Medical Devices (BfArM) The product is compatible with the materials of which the medical devices to be reprocessed are composed.	Cleaning/disinfection process	
Cleaning indicators	No particular specifications	Cleaning indicator specifications may be included in the validation report as part of the periodic routine tests carried out by users Cleaning indicators should be qualified for the respective process following successful validation and the results continually monitored.		See Quality Task Group Recommendation No. 115
Filter plates for lumened device irrigation system	In general, not a medical device	Evidence that it is compatible with the cleaning and disinfection processes to be used Specification of replacement and cleaning interval Flow resistance can impact validation and must be checked.	Cleaning/disinfection process	
Adapters and distributor connectors/bands		Flow resistance and amount can impact validation and must be checked. Specify replacement interval of tubes and adapters	Cleaning/disinfection process	
Positioning aids	No particular specifications	Positioning and shadowing can impact the cleaning results.	Possibly, cleaning/disinfection process	
Trays/baskets	No particular specifications	Geometry can impact the cleaning results.	Possibly, cleaning/disinfection process	

Packaging/ Sterile barrier				
Test materials for functional tests	In general, not a medical device			See Red Brochure
Diverse process chemicals (list each separately, e.g. surgical spirit, isopropanol, etc.)	In general, not a medical device	Intended to remove residues of adhesive tape and labels Describe intended use and subsequent treatment in SOP Assess effects on process and patient safety (possibly, clean and disinfect again)		Possibly, include in hazardous substances register
Care agents (instrument lubricants, etc.)	No normative specifications Requirements of MDR Annex I	Describe intended use and area of use in SOP Evidence that they are compatible with the sterilization processes to be used Assessment of biological compatibility (evidence to be provided by manufacturer)		Possibly, include in hazardous substances register
Instrument protection products (caps, pouches, etc.)	In general, not a medical device	Evidence that they are compatible with the sterilization processes to be used and with the intended use		
Test materials for sealing seams (sealing seam indicator, ink test) for transparent packaging	DIN EN ISO 11607-2	Specifications may be included in the validation report as part of the periodic routine tests carried out by users. Ensure compatibility with the material of which the sterile barrier is composed (paper, Tyvek, etc.)		
Sterilization nonwovens (fleece)	DIN EN ISO 11607-1 DIN EN 868-2	Each type of nonwoven must be assessed separately, e.g. container nonwovens/ fleece, nonwovens for low-temperature processes, one step, etc. Evidence must be provided that the products are compatible with processes used and conform to the applicable standard. All sterile barrier systems must be taken into account/documented in validation of the sterilization processes.	Packaging process Sterilization process	
Adhesive tape with indicator Each type of adhesive tape (for steam sterilization, low-temperature sterilization, etc.) must be assessed separately.	DIN EN ISO 11607-2 DIN EN ISO 11140-1	Evidence must be provided that the products are compatible with the processes used. Adhesive tapes are part of the sterile barrier system and must therefore be taken into account/documented in validation of the packaging processes (see packaging guideline).	Packaging process	

Adhesive tape without indicator Each type of adhesive tape (for steam sterilization, low-temperature sterilization, etc.) must be assessed separately.	DIN EN ISO 11607-2	Evidence must be provided that the products are compatible with the processes used. Adhesive tapes are part of the sterile barrier system and must therefore be taken into account/documented in validation of the packaging processes (see packaging guideline).	Packaging process	
Accessories for purely soft packaging (e.g. absorbent nonwovens/ tray liners or corner protectors)	DIN EN ISO 11607-2	Evidence must be provided that the products are compatible with the sterilization processes used. Tray liners and/or corner protectors form part of the sterile barrier system in some departments and impact the packaging process (stability or transport safety) and the sterilization process (drying). They must therefore be taken into account/documented in validation of the packaging processes and sterilization processes.	Packaging process Sterilization process	
Container filters of any type (disposable filters, permanent filters)	DIN EN 868-2	Evidence must be provided that the products are compatible with the process used and conform to the applicable standard. Container filters must have been approved for the containers used. All sterile barrier systems must be taken into account/documented in validation of the sterilization processes.	Packaging process Sterilization process	If necessary, compatibility certificate (filters + containers from different manufacturers)
List all types of labels separately (e.g. donation or cutting labels, with and without indicator)	DIN EN ISO 11140-1	For documentation and process tracking Assess biological compatibility (evidence to be provided by the manufacturer) Evidence must be provided that the products are compatible with the sterilization processes used.		
Cable binders, tray plates/signs, bag/ case tags	In general, not a medical device	Evidence must be provided that the products are compatible with the process used (depending on use, cleaning/disinfection and sterilization).		
Pens	In general, not a medical device	Describe intended use and area of use in SOP Assess biological compatibility (evidence to be provided by the manufacturer) Evidence must be provided that the products are compatible with the process used (depending on use, cleaning/disinfection and sterilization).		
Sterilization				
Chemical indicators Type 4/5/6 sterilization indicators	DIN EN ISO 11140-1	To be used in the packaging, use in consultation with the validation engineer Can be used for routine checks, see manufacturer's instructions		

Type 2 indicators Bowie & Dick test Helix test (with type 4/5)	DIN EN ISO 11140-3 DIN EN ISO 11140-4 DIN EN ISO 11140-6	Use in consultation with the validation engineer Can be used for routine checks, see manufacturer's instructions
Dust protection pouch	In general, not a medical device	For transporting cleaned and disinfected medical devices Protection of sterile barrier systems The product must be suitable for the intended use
Bioindicators	DIN EN ISO 11138	Bioindicators for monitoring VH2O2 sterilization process
Heat protection gloves	In general, not a medical device	For unloading hot items from the continuous tunnel washers (CTWs), WDs and sterilizers. The product must be suitable for the intended use. Avoid contamination. May possibly be cleaned and disinfected

References

1. Verordnung über das Errichten, Betreiben und Anwenden von Medizinprodukten Medizinprodukte-Betreiberverordnung) MPBetreibV), Fassung der Bekanntmachung vom 21. August 2002 (BGBl. I S. 3396), die zuletzt durch Artikel 7 der Verordnung vom 21. April 2021 (BGBl. I S. 833) geändert worden ist MPBetreibV.pdf (gesetze-im-internet.de)
2. Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten, Empfehlung der Kommission für Krankenhaushygiene und Infektionsprävention (KRINKO) beim Robert Koch-Institut (RKI) und des Bundesinstitutes für Arzneimittel und Medizinprodukte (BfArM) Bundesgesundheitsbl 2012 · 55:1244–1310 DOI 10.1007/s00103-012-1548-6 © Springer-Verlag 2012
3. Leitlinie der DGSV für die Validierung der Verpackungsprozesse nach DIN EN ISO 11607-2:2020 mhp Verlag, Wiesbaden
4. Leitlinie von DGKH, DGSV und AKI für die Validierung und Routineüberwachung maschineller Reinigungs und thermischer Desinfektionsprozesse für Medizinprodukte 5. Auflage 2017, mhp Verlag, Wiesbaden
5. „Rote Broschüre": Instrumentenaufbereitung – Instrumente werterhaltend Aufbereiten, Publikation des Arbeitskreis Instrumentenaufbereitung, 11. Auflage , AKI-Broschüren PDF Shop | AKI (a-k-i.org)
6. DIN EN ISO 11607-1:2020-05 Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte – Teil 1: Anforderungen an Materialien, Sterilbarrieresysteme und Verpackungssysteme (ISO 11607-1:2019)
7. DIN EN ISO 11607-2:2024-02 Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte – Teil 2: Validierungsanforderungen an Prozesse der Formgebung, Siegelung und des Zusammenstellens (ISO 11607-2:2019 + Amd 1:2023)
8. DIN EN 868-2:2017-05 Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte – Teil 2: Sterilisierverpackung – Anforderungen und Prüfverfahren; Deutsche Fassung EN 868-2:2017
9. DIN EN ISO 11138-1:2017-07 Sterilisation von Produkten für die Gesundheitsfürsorge – Biologische Indikatoren – Teil 1: Allgemeine Anforderungen (ISO 11138-1:2017)
10. DIN EN ISO 11140-1:2015-03 Sterilisation von Produkten für die Gesundheitsfürsorge – Chemische Indikatoren – Teil 1: Allgemeine Anforderungen (ISO 11140-1:2014)
11. DIN EN ISO 11140-3:2009-09 Sterilisation von Produkten für die Gesundheitsfürsorge – Chemische Indikatoren – Teil 3: Indikatorsysteme der Klasse 2 zur Verwendung im Bowie-Dick-Dampfdurchdringungstest (ISO 11140-3:2007, einschließlich Cor 1:2007);
12. DIN EN ISO 11140-4:2007-07 Sterilisation von Produkten für die Gesundheitsvorsorge – Chemische Indikatoren – Teil 4: Indikatoren der Klasse 2, die alternativ zum Bowie-Dick-Test für den Nachweis der Dampfdurchdringung verwendet werden (ISO 11140-4:2007)
13. DIN EN ISO 11140-6:2023-02 Sterilisation von Produkten für die Gesundheitsfürsorge – Chemische Indikatoren – Teil 6: Indikatoren der Klasse 2 und Prüfkörper für die Leistungsprüfung von Dampf-Klein-Sterilisatoren (ISO 11140-6:2022)