Recommendations by the Quality Task Group (AKQ) (36:2024):

Risk management in the RUMED

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Medical devices are used or operated in or on patients. For that reason, a high quality level is essential for these devices.
Therefore, to protect the health and life of patients and users, medical device reprocessing is subject to legal regulations. In the case of Germany, for example, the following regulations apply:

- Recommendation for hygienic processing practices for medical devices, jointly compiled by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (*BfArM*) (*KRINKO/BfArM Recommendation*)
- Medical Device Operator Ordinance (*MPBetreibV*)
- Medical Device Regulation (MDR) EU Regulation 2017/745 on medical devices
- Medical Devices Implementation Act (MPDG)

The medical device reprocessing process is viewed in principle as a manageable risk. Therefore, even an attempt to use a medical device that could present a risk to patients, users or third parties is prohibited in accordance with MPDG(12).
To ensure that these high quality requirements can be met, a **RISK MANAGEMENT SYSTEM** is needed to detect and analyse potential errors and risks already before they occur and take suitable preventive measures.

A **RISK MANAGEMENT SYSTEM** is intended to detect potential errors and risks already before they occur.

Risk management is always future-oriented, whereas error management always evaluates the past.
Different methods can be used to achieve this. For example, the Failure Mode and Effects Analysis (**FMEA**) has proved its worth here*.

The **FMEA** is a tool for identifying and evaluating potential risks throughout the entire medical device reprocessing circuit

With this method, potential errors and risks can be identified and evaluated across the entire medical device reprocessing landscape and can be prevented by implementing suitable preventive measures and control steps.
This method consists of three steps:

1. Identification of potential error sources

For identification of potential error sources (risks), each individual process step of the medical device reprocessing circuit must be reviewed and evaluated.
At the outset, the potential risks and errors must be systematically identified and recorded for each individual process step of the reprocessing circuit.
The risks associated with medical device reprocessing can be assigned to different categories.
This list is not exhaustive and is intended as guidance. New process errors can be added to the list at any time.

Existential risks

- Fire
- Power failure
- Steam supply failure
- Water supply failure
- Staff shortage
- Multiple equipment failure (list separately according to equipment group)
- Supply shortage of consumer goods
  - Knowledge of, and adherence to, recurring deadlines: servicing (according to specified deadlines)
  - Validation (according to specified deadlines)
  - Briefings (annually)
- Data security concept
- Antivirus protection
- Occupational medical and safety support

* Details can be found in EN ISO 14971 and VDI-Guidance VDI 5700-1-1.

- Regular uptake of occupational medical check-ups
- Hazard assessment
- Assessment of potential accident hazards (tripping, slipping, falling, impact hazards)
- Hazardous substances known; list of hazardous substances available
- Infection prevention measures (personal protection equipment (PPE), work system methodology)
- Structural and functional requirements

Process technology risks

Instruments

- Shortcomings in the cleaning results achieved for complex medical devices
- Missing documents, e.g. reprocessing instructions not available in the national language
- Deviation of inhouse processes from the manufacturer's instructions
- Improper reprocessing of loan instruments

Unclean side

- Dosing pump failure
- Mix up of chemical products
- Nozzles of washer-disinfector (WD) rotary arms blocked
- No WD mechanical action because of blocked rotary arms
- Inadequate precleaning
- Incorrect WD loading

Packing area risks

- Re-contamination of medical devices because of cleaning solution in overturned containers
- Incorrect release processes
- Incomplete trays returned by the clients
- Residual contamination of medical devices
- Delivery of defective or corroded medical devices
- Use of unsuitable work materials, packaging materials or care products
- Re-contamination because of microorganisms or oil residues in the medical compressed air
- Missing container filters or seals
- Incorrect packaging techniques
- Defective soft packaging
- Untight sealing seams

Sterilization

- Routine checks not carried out
- Incorrect loading
- Lack of certainty regarding the sterilization process outcome (use worst-case load for verification purposes)
- The medical device/tray to be sterilized is not suitable for the process
- Incorrect process release
- Incorrect product release
- Damage to sterile supplies because of transport mistakes
- Damage to sterile supplies because of mistakes in the storage area

Personnel

- Employee performance reviews
- Team meetings
- Complaints, error management
- Corporate communication (consistent communication)
- Cooperation partners
- Coordination between various departments

2. Analysis and assessment of the potential risk

Analysis and assessment of the risks is based on the extent of the potential impact and is assessed by means of the following factors, on a scale from 1-10 in each case:

- the probability of occurrence (A)
- the significance (B)
- the probability of detection (E)

At the end, the results are multiplied together giving the risk priority number (RPN), which can be used to calculate the potential risk. The RPN is used to try ranking the risks.

RPN = A x B x E

Probability of occurrence of the risk* = Factor A			
Probability	**Description**	**Frequency**	**Factor A value**
Unlikely	It is unlikely that the risk* will occur.	0	1
Very low	The risk* may occur rarely.	1/5,000	2
		1/2,000	3
Low	The risk* may occur occasionally.	1/1,000	4
		1/500	5
Moderate	The risk* does occur but it is under statistical control.	1/200	6
		1/100	7
High	The risk*occurs time and again.	1/50	8
		1/20	9
Very high	The risk*occurs very often.	1/10	10

Significance of the risk* = Factor B		
Probability	**Description**	**Factor B value**
Minor risk*	Barely noticeable	1
	Minor impact	2 - 3
Major risk*	Moderate impact	4 - 6
	Major impact	7 - 8
Critical risk*	Very major impact	9
	Damage/hazard	10

Probability of detection of the risk* = Factor E	
Description	**Factor E value**
The risk* is noticed in the next process at the latest	1
Apparent	2 - 4
Easily detected	5 - 7
Not easily detected	8 - 9
Hidden risk *, is not noticed, only becomes apparent after a long time	10

Transfer the values calculated to the sample table “Template worksheet risk management CSSD”, Current state column.

Template worksheet risk management CSSD

Risk management | **Date** xx.xx.xxxx | **Process** | **Compiled by** Mr/Ms XXXXX

Potential risks				Current state						Improved state					
Risk	Date	Process	Impact	Causes	Control measures	Probability of occurrence	Significance/ damage	Probability of detection	RPZ	Measures	Responsibility for implementation	Control measure	Probability of occurrence	Significance/ damage	Probability of detection	RPZ
Mix-up of chemical products	xx.xx.xxxx	Automated cleaning and disinfection process	Inadequate cleaning results, changes to the medical device surface, damage to machine, machine failure	Lack of attention, inadequate knowledge	Staff member checks when connecting the chemical product to the machine that the correct product is used	6	10	8	480	Labelling of tubes/lances with the correct chemical product designation	Management	Documentation spot checks	2	10	2	40
										Regular staff training						
										4-eye principle						
										Checklist						

No risk	Risk	Unacceptable risk
0 - 50	50 - 100	≥ 100

The **RISK MANAGEMENT** process must be continuously developed.

3. Introduction of suitable measures for risk management

Using suitable measures, one can reduce or prevent risks. The measures must be implemented on time and, if necessary, documented in an action plan. That helps to monitor the measures and, as applicable, adapt them during the project.

The aim is to tailor medical device reprocessing to the operational and legal requirements as well as to continuously develop **RISK MANAGEMENT**. Processes must be continuously checked for new risks to ensure counter measures can be taken in order to mitigate, or even prevent, negative impacts/damage.

A sample table that can be used for assessment of an institution's own risk is featured in an annex to this Recommendation.

Measures must be taken if the RPN indicates a risk or an unacceptable risk.

There is no need for action if the assessment carried out does not indicate a risk.