If reprocessing is carried out by **other parties**, it is advisable to specify the operator's and contractor's rights and obligations as well as the modalities for delivering, returning and reprocessing the medical devices in a written contract. The contractor shall provide evidence of a quality management system which guarantees adherence to the requirements mentioned in this document and must be licensed pursuant to Sections 10 and 25 of the Medical Devices Act (MPG). For the certification of the reprocessing of 'Critical C' medical devices, see also 1.4 and Table 1 (QM).

1.2 Prerequisites for Reprocessing

The prerequisite for reprocessing is that the **product compatibility of the reprocessing methods to be used** (guarantee of the medical device's functional and safety-relevant properties after reprocessing) and their **efficacy** must have been proven within the context of a product/product-group specific test and validation (see also 1.2.2, MPG, MPBetreibV, basic requirements pursuant to 93/42/EEC; QM; DIN EN ISO 17664).

Before purchasing medical devices, it is expedient for the medical devices operator to become informed not only of the medical and functional requirements but also of the relevant reprocessing information available from the medical device manufacturers (pursuant to DIN EN ISO 17664) so as to be able to consider the feasibility of reprocessing and the means and equipment necessary to this end (process chemicals, washer-disinfectors, steriliser etc), and to involve the persons in charge of reprocessing and procurement in the decision-making process (QM).

Before a decision on reprocessing is taken, **in addition to a critical feasibility study,** it must also be examined whether the entire process (also taking into account the **risk** associated with the reprocessing and use of the medical device, and the **cost and effort for validation and quality assurance) is economically and ecologically** reasonable. For 'critical C' medical devices, the results of this examination are to be documented (QM).

With regard to the spatial requirements for medical devices reprocessing units, see Annex 5 "Overview of requirements for medical devices reprocessing units" as well as the recommendation "*Anforderungen an die Hygiene bei der Reinigung und Desinfektion von Flächen* (Hygiene requirements for cleaning and disinfecting surfaces)" [32].

1.2.1 Risk Assessment and Classification of Medical Devices before Reprocessing

The person in charge of reprocessing must lay down in writing, for each medical device (if appropriate, for the medical device group):

- **whether, if appropriate how often** and
- with which methods it is to be reprocessed (QM, see Table 1).

The **operator** is responsible for **correctly classifying** the medical devices and for **determining the type and implementation of reprocessing**. The manufacturer's instructions must be followed (MPG; MPBetreibV; see also DIN EN ISO 17664). With a view to the necessary expertise, it is advisable for the person in charge of hygiene and the **person directly responsible for reprocessing** to be included in the process of classifying and determining the type of reprocessing (QM).

In case of doubt regarding classification, the medical device must be assigned to the higher (more critical) risk level (QM). The **suitability** (compliance with the medical device's properties

that are of relevance in terms of functionality and safety) and **efficacy** of the chosen reprocessing method must have been demonstrated previously in tests that are appropriate to the medical device and its risk assessment (MPG, MPBetreibV; DIN EN ISO 17664).

In the course of the **evaluation and selection of the reprocessing methods** which is required due to the need to classify each medical device or group of medical devices:

- the **constructional properties, material characteristics and functional properties** of the medical device, as well as the manufacturer's instructions (see also DIN EN ISO 17664) and
- the **nature of the previous and subsequent use** of the medical device

must be considered as they can affect the efficacy and suitability of methods [2, 5, 7-9, 11, 13-19, 21-23, 28, 30, 33-36].

Considerations regarding the **quantity and type** of **pathogens** likely to be present on the used medical device and their **resistance** to the reprocessing methods used are decisive for observing the **efficacy limits of the methods envisaged for use** ([2, 4, 7-9, 11-13, 15-25, 35].

Table 1. Risk Assessment and Classification of Medical Devices before Reprocessing

Classification	**Medical device**	**Prepara -tion**	**Cleaning and Disinfection**	**Special labelling**	**Sterilisa-tion**	**Critical processing steps, Special requirements**
.Non-critical	e.g. ECG electrodes		X			
Semi-critical A) no special requirements for reprocessing	e.g. speculum	(X)	X		(X)	Disinfection (activity spectrum bactericidal (incl. mycobacteria), fungicidal and virucidal)
B) with stricter requirements for reprocessing	e.g.: flexible endoscope (gastroscope)	X[1]	X		(X[2])	Additionally: see the relevant special Annex No. 8 "Hygiene requirements for the reprocessing of flexible endoscopes and endoscopic accessories"; preferably mechanical/automated washing and disinfection
.Critical A) no special requirements for reprocessing	e.g.: retractors	(X)	X		X	Preferably mechanical/automated washing and disinfection (see text No. 1.3) Generally **Sterilisation with moist heat**
B) with stricter requirements for reprocessing	e.g.: MIS trocar	X[1]	X	(X)	X	Additionally: - Evidence of recognised training completed by the person in charge of reprocessing[4]

Classification	Medical device	Prepara-tion	Cleaning and Disinfection	Special labelling	Sterilisa-tion	Critical processing steps, Special requirements
						- Generally mechanical/automated washing / thermal disinfection in washer/disinfectors[5] (see text No. 1.3) Sterilisation with moist heat
C) with particularly high requirements for reprocessing	e.g.: ERCP catheters	X[1]	X	X	X[3]	Suitable sterilisation[3] Additionally: Certification of the quality management system (DIN EN ISO 13485) in conjunction with the recommendation "Hygiene requirements for the reprocessing of medical devices" by a body notified by the competent authority, Risk analysis DIN EN ISO 14971 (see text 1.4)

1 Pre-cleaning also immediately after use
2 If appropriate in the case of endoscopes used in sterile body sites
3 So far, non-thermal sterilisation methods have not consistently proven effective for prion inactivation. This is relevant for medical devices of this group that are intended to come into contact with exposed lymphatic tissue or neural tissue (see also Annex 7).
4 See Annex 6 Staff expertise
5 In all cases, ensuring standardised and reproducible cleaning of evidence-based effectiveness (including internal surfaces)

(X) Optional step

The **risks** posed by reprocessed medical devices are determined:

a) by undesired effects that can arise from

- the previous use,
- previous reprocessing and
- transportation and storage,

as well as

b) from the nature of subsequent use.

Risks can arise, for example, from

- **residues from previous use** (e.g. blood, blood constituents, secretions, excretions and other parts of the body, medicinal products),
- **residues from previous reprocessing** (e.g. **detergents, disinfectants, sterilising products and other agents**, including their reaction products);
- **changes in physical, chemical or functional properties** of the medical device or
- **changes in material condition** (e.g. accelerated material wear, embrittlement and altered surface properties, changes at contact points and joints, e.g. from adhesive bonding, welding, pressing) [5, 14, 37].

Regarding the **nature of subsequent use** and the resulting risk, medical devices can be classified into:

Non-critical medical devices:
Medical devices which only come into contact with intact skin.

Semi-critical medical devices:
Medical devices which come into contact with mucous membranes or pathologically altered skin.

Critical medical devices:
Medical devices for the use of **blood, blood products or other sterile medicinal products/sterile medical devices**, and medical devices that are intended to penetrate the **skin or mucous membranes** and thus come into contact with blood, internal tissues or organs, including wounds (see Table 1) [9, 19, 25].

The **constructional and material-related details** of the product design could necessitate stricter reprocessing requirements. Consequently, it is necessary to specify this classification [6, 9, 10, 19, 28-30, 37].

Semi-critical and critical medical devices can be further divided into those which can be reprocessed **without special requirements (Group A)** or those **needing stricter requirements (Group B).**

Moreover, a specific group of critical medical devices is subject to particularly strict reprocessing requirements (Group C) (see 1.4 and Table 1).

Medical devices that are subject to stricter reprocessing requirements are medical devices for which:

- **cleaning effectiveness** cannot be directly assessed by means of an inspection (e.g. due to long, narrow, especially terminal lumina, hollow spaces with only one opening (no flushing

but only dilution possible), complex, rough and hard to access surfaces which makes them difficult to clean);

- **reprocessing effects (including transportation)** that affect the safe use or functional safety of the **medical device and its material properties** cannot be excluded (e.g. bend-sensitive medical devices; sensitive surfaces; electronic components / active medical devices) so that, as a result, it requires greater cost and effort to conduct their technical-functional examination,

or

- the **manufacturer has limited the number of uses or reprocessing cycles** to a certain number.

Within the group of critical medical devices, those subject to stricter reprocessing requirements ('critical B') must be further divided into:

- **thermostable** medical devices (i.e. devices that can undergo steam sterilisation at 134°C) 'Critical B' and
- **thermolabile** medical devices (i.e. those that cannot undergo steam sterilisation) 'critical C'.

Owing to the **process-specific** efficacy limits and/or the prerequisites for non-thermal sterilisation methods, **critical** medical devices that cannot undergo steam sterilisation and belong to this group must be classified as **medical devices with especially strict reprocessing requirements (= critical C**; see Table 1) [5, 9-11, 14, 17, 24, 25, 28].

The special reprocessing requirements resulting from this classification (risk assessment) are also outlined in Table 1 so as to give an overview.

Owing to

- the particularly strict requirements for cleaning performance that can only be consistently guaranteed by process engineering,
- the limitations of the sterilisation methods used and
- the need for specific requirements that are to be guaranteed regularly in order to ensure the effectiveness of non-thermal sterilisation methods,

the reprocessing of critical medical devices with especially strict reprocessing requirements ('Critical C', see Table 1) is subject to an external quality control. The latter has to be proven by means of the **certification that the quality management system** is able to guarantee the adherence to these requirements at all times (see also 1.4 and Table 1; QM) [38, 39]
The external certification requirement does not apply if the manufacturer of the medical device has provided concrete information on the use of another specified sterilisation procedure and the use of this procedure has been validated on site with a view to its efficacy.

When carrying out the risk assessment of medical devices for reprocessing, the **critical processing steps** (critical control points) and the corresponding results as well as the **potential hazards** need to be defined (QM). This results in measures for **risk minimisation** and assessment or, if the risks are deemed to be uncontrollable or inacceptable, the decision to forego reprocessing.

In this context, it must also be considered that **effective cleaning** can be rendered impossible by **special uses** (e.g. the use of oily or viscous substances). Particular difficulties arise if medical devices containing hollow spaces are cleaned after they have been used in solid tissue (e.g. drills and screws after use on bones) [40].

Medical devices that are technically difficult to reprocess and the reprocessing of which brings with it a high **risk of injury**, should be given particular attention. If some cases if necessary, as with injection cannulae, reprocessing should be dispensed with (TRBA 250).

Owing to their particular hazard potential, medical devices used for administering **cytostatic or radiopharmaceutical medicines** should also be **barred from reprocessing** (Medicinal Products Act (AMG), Hazardous Substances Ordinance (GefStoffV), Radiation Protection Ordinance (StrlSchV).

Regarding the reprocessing of medical devices that have been used or are intended for use in persons with confirmed or suspected Creutzfeldt-Jacob-Disease (**CJD**) or its variant (**vCJD**), the requirements mentioned in the respective Annex to this Recommendation (Annex 7) shall be adhered to. **Dry heat, ethanol, peracetic acid, formaldehyde and glutaraldehyde have a fixating but not inactivating effect** on TSE pathogens. Of the available sterilisation methods, it was possible to prove a limited effect for vapour sterilisation (134°C, 5-18 minutes) and for certain H_2O_2-based methods [11, 12, 16, 17, 21, 22].

The results of the classification and risk assessment shall be documented (see e.g. Table 1, QM).

1.2.2 Manufacturer's instructions

The marketability of a medical device classified as reusable by the manufacturer also involves the latter's obligation to issue instructions for reprocessing including cleaning, disinfection, rinsing, drying, if appropriate packaging and sterilisation, transport and proper storage, as well as information on risks involved in reprocessing, if appropriate (see footnote [2] and DIN EN ISO 17664) (MPG, MPV). This must already be taken into account when purchasing medical devices.

Deviations from the manufacturer's reprocessing instructions must be justified and documented and it must be ensured that the reprocessed medical device's

- operability and thus ability to fulfill its intended purpose, as well as
- its safety in use are fully guaranteed (see also 1.2.1). In consultation with the infection control personnel, procedures must be tested and validated for suitability and efficacy, using methods that are appropriate to the medical device and its risk assessment and classification [39].

Where necessary, in the case of incomplete and/or implausible information in the manufacturer's directions for use, the completion, further elaboration and/or correction of the information must be demanded. In the individual case, it will be necessary to examine whether an incident pursuant to section 2, no. 1 of the Medical Devices Safety Plan Ordinance (MPSV) and, consequently, a notification to the Federal Institute for Drugs and Medical Devices (BfArM) is necessary, pursuant to section 3, subsection 2 of the Medical Devices Safety Plan Ordinance (MPSV).

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[2] *Excerpt from COUNCIL DIRECTIVE 93/42/EEC concerning medical devices, Annex I, Section II, 13.6: Where appropriate, the instructions for use must contain the following particulars:*
h) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be re-sterilized, and any restriction on the number of reuses. Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section I.
If the medical device bears an indication that it is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. If in accordance with Section 13.1 no instructions for use are needed, the information must be made available to the user upon request;

1.3 Validating Reprocessing Methods/Procedures

Pursuant to Section 4 of the Ordinance on Operators of Medical Devices (MPBetreibV), medical devices that are intended for use in an almost sterile or sterile state must be reprocessed using **appropriate, validated methods** in such a way that the **success** of these methods is **traceable and guaranteed** and the **safety and health** of patients, users and third parties are not endangered (MPBetreibV). In validating the reprocessing methods, the parameters that are necessary for proving that the specific process (individual reprocessing steps, e.g. in cleaning, disinfecting and sterilising medical devices) has been completed in a way which guarantees the fulfilment of the corresponding specifications are also defined (see also Annex 1).

In the foregoing context, these are:

- those **parameters of the medical device** (suitability of the method for the medical device in terms of operability and safety) that must be **guaranteed in order to fulfill the demands of technical-functional safety** and
- the parameters for **guaranteeing effective cleaning, disinfection and sterilisation (cleanliness/low microbial contamination) and sterilisation (sterility) including the maintenance of low microbial contamination or sterility up to the time of use.**

Validation is to be appropriate for the medical device, its risk assessment and classification, and be carried out in accordance with **accepted engineering practice,** (see for example Annex B) taking account of **state-of-the-art science and technology.** The extent of the tests required for validation can be reduced or adapted in keeping with the technical or site-related requirements, if evidence of suitable information from the manufacturer is presented (DIN EN ISO 17664).

Helpful information for the validation of cleaning and disinfection methods and/or sterilisation methods can be found in Annex No. 3. Commissioning and operation of washers/disinfectors (WD) for the reprocessing of medical devices (checklist) and No. 4: Commissioning and operation of small-scale sterilisers for the reprocessing of medical devices (checklist).

If no **batches of uniform medical devices** can be created, testing must be done within the context of validating the processes necessary for the reprocessing of medical devices that are intended for use in an almost sterile or sterile state using **representative medical devices (test models**, where appropriate). The criteria for selecting test models have to be substantiated and documented.

Full validation of **sterilisation methods** is possible provided that they are used for medical devices that are residue-free after cleaning. This has been addressed in relevant technical rules (see harmonised standards in Annex B).

With regard to **cleaning and disinfection methods,** mechanical/automated methods lend themselves particularly to validation and should be preferred. **Manual cleaning and disinfection methods that are used, for instance, to pre-clean medical devices or for medical devices that cannot be mechanically cleaned/disinfected (Group B), or used based on a risk analysis**, must always be carried out in a validated manner according to **documented standard operating procedures** and using methods and processes tested for efficacy and adapted to the individual medical device (i.e. suitable and compatible with materials) (Medical Devices Act, basic requirements and DIN EN ISO 17664).
The standard operating procedures shall explicitly specify the critical processing steps. These should be taken into account within the framework of periodic testing, in order to provide evidence of the efficacy of the individual measures.

The disadvantages of manual reprocessing consist, above all, in the problem of reproducibility and standardisation, as well as in personnel protection.
In any case, standardised and reproducible cleaning with evidence-based effectiveness (for Group B including internal surfaces) must be ensured.

The contents of the standard operating procedures shall address the following prerequisites:

- The procedure has been specified in sufficient detail.
- The specification includes, in particular, a precise description of all steps as well as the technical aids they involve.
- The description of the procedures is to contain – with reference to the technical aids to be used – clearly defined minimum requirements (including admissible tolerances) for the intensities to be used, rinsing and treatment durations, rinsing volumes, number of rinsing steps, etc.
- In the validation process, 'worst-case' aspects are to be used with regard to the conditions specified in the description.

In the case of **mechanical/automated cleaning and disinfection methods**, process engineering can ensure that the **parameters**, e.g. water volumes, water pressure, temperature, dosage of detergents and disinfectants and contact times, which are necessary to achieve **quantifiable cleaning and disinfection results,** are adhered to. The machines' monitoring, control and alarm systems are the prerequisite for ensuring successful cleaning and disinfection and thus reprocessing. Owing to the great importance of cleaning and disinfection results and product-specific determinants, only devices that have successfully undergone type examination can be recommended [29, 41]. It should be noted that the cleaning performance of mechanical/automated methods varies [29, 42] and that performance also depends on careful loading and the use of product-specific connectors (see e.g. errors in connecting hollow instruments or unwanted screening effects). Proper operation is facilitated by corresponding detailed directions from the manufacturer. The training/construction of the operating personnel is therefore essential for the operation of washers/disinfectors as well (MPBetreibV; QM) (see also Annex 3: Commissioning and operation of washers/disinfectors (WD) for the reprocessing of medical devices (checklist)).

1.4 Assuring the Quality of the Reprocessing Methods Used

Consistently ensuring reprocessing quality requires expertise [26, 27] and should be guaranteed by means of a quality management system and relevant training in line with this Recommendation (see Annex 6 Expertise; MPBetreibV; QM).

Also for the sake of standardisation and reproducibility, the individual steps involved in the reprocessing methods to be performed according to the medical devices' classification must be specified in **standard operating procedures and operating instructions**, detailing the **tests** required in each case (QM/MPBetreibV).

The quality management system for **reprocessing medical devices with particularly strict reprocessing requirements** ('Critical C', see Table 1) should be **certified** by a **body notified** by the competent authority pursuant to DIN EN 13485 in conjunction with the Hygiene Requirements for the Reprocessing of Medical Devices (QM). Explicit reference is made to risk management based on DIN EN ISO 14971 (see also Annex No. 2 on section 2.2.3. Technical-functional safety testing).

Test and validation reports prepared by laboratories accredited for the relevant methods by the competent authority (see above) can be taken into account for the validation of reprocessing methods within the context of certification.

The external certification requirement does not apply if the manufacturer of the medical device has provided concrete information on the use of another specified sterilisation procedure and the use of this procedure has been validated on site with a view to its efficacy.

Reprocessing quality is guaranteed, depending on the cleaning, disinfection and sterilisation method used, by means of:

a) **validation (consisting of installation, operational and performance qualification)**
b) **periodic routine tests (e.g. daily)**
c) **batch-related routine tests**
d) **metrological monitoring and testing of processing parameters**
e) maintenance, calibration, if appropriate adjustment, repair and
f) **periodic process qualification (renewed performance test)**
g) **event-driven process qualification (performance testing for specific reasons)**

(QM, see also Annex B Standards, as well as the particulars in Annex 3. Commissioning and operation of washers/disinfectors (WD) for the reprocessing of medical devices (checklist) and Annex 4: Commissioning and operation of small-scale sterilisers for the reprocessing of medical devices (checklist)).

The parameters to be checked can be seen from the instructions for use and the validation protocols/plans.

Periodic process qualifications are to confirm that:

- no undesired changes in processes have occurred over time and prove that
- the parameters specified in the validation protocol/plan are being adhered to (QM). They can, for example, be co-ordinated with the maintenance of the devices used for reprocessing, in order to avoid additional downtimes.

2. Undertaking Reprocessing

2.1 Reprocessing of Unused Medical Devices

These medical devices include:

- **medical devices that have been delivered in an unsterile state but must be used in a sterile state** and which have to be reprocessed before use according to the manufacturer's instructions;

- sterilised medical devices the **packaging of which has been damaged** or opened without the medical device having been used or

- medical devices the **sterile shelf life of which has expired** within the period of time in which safe use of the medical device is possible (expiry date),

without them being used in the meantime, if their design lends itself to reprocessing.

If contamination of or damage to the medical device is ruled out, reprocessing may be limited to repackaging and re-sterilisation, provided that the technical-functional safety of the device is not compromised in the process. In this process, the manufacturer's instructions must be taken into consideration.

The following steps are necessary:

- where appropriate, unpack and **test technical-functional safety** (see also 2.2.3),
- **repack** (see 2.2.4),
- use a suitable **sterilisation method** (see 2.2.5) that, aside from sterilisation, guarantees that the medical device's function is preserved without restriction,
- **labelling** (see. 2.2 .6]),
- **documentation of reprocessing** (see 2.2.8),
- **release** for use (see 2.2.7).

If contamination **cannot** be excluded and, if appropriate, also where medical devices are delivered in an unsterile state but must be used in a sterile state, these medical devices must also be reprocessed as if they had been used pursuant to Point 2.2, in keeping with the manufacturer's instructions (MPG; MPBetreibV).

2.2 Reprocessing of Used Medical Devices

The following steps are necessary when reprocessing used medical devices:

- proper **preparation (e.g. pre-treatment, collection, pre-cleaning** and, where appropriate, **disassembling) (see 2.2.1)** of used medical devices and their safe **transport** to the reprocessing site in a closed container to avoid damage;
- **cleaning, if necessary intermediate rinsing, disinfection, rinsing and drying** (see 2.2.2);
- **check for cleanliness and integrity of surfaces** (e.g. corrosion, material condition) and, where applicable, identification for the purpose of deciding whether to repeat the reprocessing;
- **maintenance and repair;**
- **technical-functional safety testing** (see 2.2.3);

and, if required,

- **labelling** (see 2.2.6);

- **packaging** (see 2.2.4);

- **and sterilisation (**see 2.25).

Reprocessing is concluded with the documented **release** of the medical device for further use or storage (see 2.2.6 and 2.2.7) (QM).

2.2.1 Preparation of Reprocessing, (Pre-treatment, Collection, Pre-cleaning, if appropriate, Disassembling, Temporary Storage and Transport)

The chain of required measures must be optimised as any weakness in a single step (e.g. cleaning) might compromise the overall result. Inadequate results can be the consequence of flaws in any of the individual reprocessing steps, such as the use of unsuitable detergents and disinfectants, faulty use, contaminated disinfection or rinsing liquids, insufficient drying and improper storage [2, 5, 7, 9, 11, 13-17, 19, 22, 23, 28-30]. Therefore, **preparation** (pre-treatment and collection) is normally necessary to ensure that medical devices are reprocessed properly (see also Table 1). In order to avoid compromising the hygienic safety and operability of the reprocessed medical device, particularly when cleaning and disinfection are delayed, the pre-cleaning that is necessary in these cases and, where appropriate, **temporary storage** must meet the following requirements:

- **Gross debris** must be removed from the medical device promptly after use. As far as possible, blood and tissue must be prevented from drying and sticking to the device. This is achieved by specifying adequate methods and procedures (e.g. wiping off outer debris and flushing working channels immediately after use, specifying disposal times), especially to ensure that cleaning performance is not adversely affected (drying and sticking of infectious agents in protective colloids) [11, 13, 23].

- The **pre-cleaning** agents and methods must be adapted to the subsequent reprocessing procedure, especially to preclude adverse effects on subsequent steps (e.g. avoiding fixating methods, such as the use of heat or aldehydes before cleaning; exemptions might be necessary in specific situations for the purpose of infection prevention) [9, 12, 13, 19, 21].

- Chemical, mechanical and physical damage to medical devices due to pre-cleaning, **transportation** or perhaps necessary **temporary storage** (e.g. resulting in the crystallisation of liquid residues) must be ruled out by specifying suitable operational procedures. Corresponding risks (e.g. kinking) are to be taking into account in tests for cleanliness and technical-functional safety (QM).

- Occupational health and safety is to be guaranteed during all preparation stages (collection, pre-cleaning, temporary storage and transportation), e.g. by providing suitable protective clothing, safety goggles, suitable gloves and ensuring good indoor air quality (TRBA 250).

2.2.2 Cleaning, Disinfection, Rinsing and Drying

Only clean medical devices can be sterilised in a reliably effective manner. Cleaning is therefore of paramount importance in the overall reprocessing procedure [9, 11-13, 19, 21, 23, 28, 30].

With respect to **cleaning, disinfection, rinsing and drying**, it is necessary to distinguish between manual and mechanical/automated methods, whereby mechanical/automated methods should be preferred, especially since they are easier to standardise and reproduce and for reasons of occupational health and safety (see also 1.3) [23, 27, 41].

The use of manual processes, given the availability of mechanical/automated processes, presupposes that evidence of the equivalence of the efficacy of manual and mechanical/automated processes has been furnished.

In the case of manual cleaning and disinfection involving possible risks of injury and infection, a non-fixating disinfection of proven efficacy must be performed while observing further **occupational health and safety measures** (e.g. protective clothing, safety goggles, suitable gloves and good indoor air quality) (TRBA 250).

Cleaning, disinfection, rinsing and drying methods must comply with the following requirements.

- In principle, **all external and internal surfaces** must be **accessible** to the detergents and disinfectants used (opening of valves/taps, hinged instruments, avoiding of screening effects, correct connection of hollow instruments). Where appropriate, complex medical devices must be disassembled according to the manufacturer's instructions [9, 10, 19].

Cleaning:

- An **effective cleaning method** must be used which avoids persistent cross-contamination, i.e. cross-contamination relevant to the safe use of the released medical device. The aim of the measures is residue-free cleaning (see above for the cleanliness warning value) to prevent the subsequent disinfection and sterilisation stages from being adversely affected, for example, by blood, secretion or tissue residues [9, 11, 13, 19, 21, 23, 30].

- As in the case of **pre-cleaning,** the procedure **used for (main) cleaning** must be such as to **prevent the fixation** of residues (e.g. tissue residues, blood) to the medical device as this would adversely affect cleaning, disinfection and sterilisation performance (Cat. IB) [2, 8, 9, 14].

- **Alkaline cleaning** is usually very effective at dissolving protein and fat residues and may even have an antimicrobial effect. On the other hand, it might cause adverse material changes. When purchasing medical devices, it is therefore advisable to opt for devices that are also suitable for alkaline cleaning. What is decisive is the **proven cleaning performance** of an agent or method (such as DIN EN ISO **15883**). Also with a view to the problem of unidentified carriers of pathological prion proteins, the aspect of cleaning has a prominent role to play since, on the one hand, the efficacy of inactivation procedures is considerably compromised by prior thermal drying or the use of protein-fixing disinfectants, on the other, a suitable cleaning procedure can lead to a considerable reduction in the burden of prion proteins [8, 16, 22, 44].

- The use of **ultrasound** can increase cleaning performance under certain conditions (see the manufacturer's instructions for validated methods). When using ultrasound, the dosage instructions for the ultrasound-tested detergent/disinfectant in combination with the specified exposure time must be adhered to, in keeping with the manufacturer's instructions. The detergents used are to prevent the reattachment of dissolved material (minimising cross-contamination). Ultrasound is not appropriate for all medical devices (caution is advised, for example, in the case of adhesive bonds or lenses) or is not always effective, especially as a result of insufficient sound transmission in the case of soft or air-filled medical devices. In case of doubt, the manufacturer (of the medical devices to be reprocessed) should be consulted. Special diligence needs to be exercised when loading ultrasonic baths since improper loading can result in poor results (e.g. due to acoustic shadows). For the bath to be fully effective, all components of the medical device must be completely wet by liquid (inside and outside). The ultrasonic transmitter is subject to wear and tear, which causes a reduction in performance. Since ultrasound can raise the temperature of the bath, and this might have negative effects on the medical devices or on the cleaning performance, the operating

temperature is to be controlled by the device [45]. It is advisable to cover ultrasonic baths for reasons of industrial safety (see TRBA 250).

- As the cleaning solution becomes contaminated by organic matter and chemical residues it is to be freshly prepared at least once every working day, and changed promptly in the event of visible contamination, so as to **avoid microbial propagation**, persistent **cross-contamination** and adverse effects on the cleaning results. For the same reasons, and to avoid biofilm formation, the cleaning basin is to undergo thorough mechanical/automated cleaning and disinfection on each working day (QM) [46].

Intermediate rinsing:

- In reprocessing medical devices, it is either obligatory to perform rinsing between cleaning and disinfection to prevent organic material and chemical residues from the previous cleaning from adversely affecting the efficacy of the disinfection, or the manufacturer of the process chemicals can provide proof of sufficient disinfection even without rinsing.

Disinfection:

- The disinfectants used in the final disinfection of semi-critical medical devices must demonstrably be **bactericidal** (including mycobacteria), **fungicidal and virucidal**. The Robert Koch Institute's working group on virucidal activity has published a statement on claims regarding the efficacy of disinfectants (*Arbeitskreis Viruzidie beim RKI [47] 2004*). In this statement, two fields of action are defined – disinfectants with a limited spectrum of virucidal activity (effective against enveloped viruses) and disinfectants with virucidal activity (effective against enveloped and non-enveloped viruses). The working group on virucidal activity recommended the testing method of the German Association for the Control of Virus Diseases (DVV) and the RKI which comprises a suspension test. This testing method was systematically revised in 2005 and supplemented in 2008 and should therefore only be used in the current version (Version 2005: also suitable for use with the exception of the chemo-thermal procedures; see the DVV's website for information) for tests and declarations. This means, in practice, that for a declaration of virucidal efficacy, expert opinions pursuant to the DVV/RKI guideline must include polio virus, adenovirus and SV40.

  For *C. difficile*, decontamination using a combination of thorough pre-cleaning and cleaning, as well as instrument disinfection based on glutaraldehyde and peracetic acid, has been found to be effective [48, 49].

- The cleaned and disinfected medical device may not pose any risk of infection when it comes into contact with skin or mucous membranes. **Thermal methods** in washer-disinfectors should be preferred over chemical and chemo-thermal disinfection methods on account of their more reliable efficacy (less residual soiling) [9, 19, 23, 24, 41]. Disinfectants on the list of the Association for Applied Hygiene (VAH) are intended for the manual disinfection of medical devices but not for mechanical/automated disinfection. The efficacy of cleaning/disinfection equipment must therefore be proven by means of expert reports based on mechanical/automated reprocessing conditions (see Annex 3: Commissioning and operation of washers/disinfectors (WD) for the reprocessing of medical devices (checklist)).

- As is the case during **pre-cleaning and cleaning, during disinfection**, process control must **prevent the fixation** of residues (e.g. blood, secretions, tissue residues) on the medical device as this would adversely affect cleaning, disinfection and sterilisation performance rates [9, 11, 13, 19, 21, 23, 30].

- Since aldehyde, alcohol, peracetic acid and temperatures > 55°C have fixative properties, cleaning performance in the previous cleaning step must ensure that no relevant protein fixation can occur here [12, 13, 16, 21, 22].
- Effective cleaning and disinfection presupposes compliance with instructions for use, especially as regards **concentrations** and **contact times** [9, 18, 19, 24, 29]. This must be taken into account when **organising the operating cycles** (QM).

Rinsing and drying:

- The build-up of **reaction products and the presence of residues** from used detergents and disinfectants or other process chemicals in quantities that might have adverse health effects (e.g. chemical irritations or allergic reactions) must be avoided. Cleaning and disinfectant solutions must therefore be removed by **intensive renewed rinsing**, down to the limit that the manufacturer deems to be tolerable. The effect of this step depends on the time, temperature and water volume used. Information on tolerable residues, if necessary from the manufacturer, is to be given for all process chemicals, such as neutralisation agents or drying agents, left on the medical device as a result of the procedure. If necessary, the examination procedures used by the process chemicals' manufacturer are to be made available. In the case of eye surgeries, complications at the patient's eye (for example ocular burns) because of alkaline detergent residues must be excluded. Therefore, a standardised and appropriate rinsing with suitable water between uses is of major importance when reprocessing medical devices used in ophthalmology. When washing and disinfecting ophthalmologic devices in a washer-disinfector, a suitable programme should be used to ensure the success of the rinsing operation and to prevent potential burns to the patient's eye due to alkaline detergent residues. In the course of the process validation it must be proven that the alkalinity has been removed.

- The necessary requirements, in terms of microbiological and chemical properties, for water intended for use in the reprocessing of medical devices are to be defined for each specific process. This applies, in particular, to the water used for the **final rinse**.

  General requirements:
  - In terms of microbiology, the water shall have at least potable water quality [15, 27]. Regarding the subsequent propagation of typical water bacteria (e.g. pseudomonads, legionellae and atypical mycobacteria), please refer to the Recommendations for the reprocessing of flexible endoscopes (Annex 8).

  Requirements for final rinse water:
  - Absence of potentially pathogenic microorganisms

  - Demineralised water is recommended in order to avoid crystallisation on the medical device [9]. In this context, account should be taken of the potential for bacterial contamination depending on the water treatment process used [50-55].

  Microbiologically clean water for final rinsing can be produced by suitable water filters. It might be necessary to use water of a higher quality (e.g. purified water (Aqua purificata) or water for injection (Aqua ad iniectabilia) [56]) for certain medical devices (especially those with higher or particularly strict reprocessing requirements) owing to the material properties of the medical device or because of the need to ensure the absence of endotoxins or particles in the case of long and narrow lumina.

- Final rinsing and drying must be performed under conditions that **rule out the re-contamination of disinfected medical devices.** The use of medical compressed air [56] for drying is therefore recommended, as it is fast-acting and effective.

Visual check:

- Only clean medical devices can be safely sterilised [9, 11-13, 19, 21, 23, 28, 30] [9, 11-13, 19, 21, 23, 28, 30] (for the warning value see the footnote under 2.2.2). It is therefore necessary to verify the cleaning effect. After cleaning/disinfection, **no contaminants** (e.g. encrustation, deposits) may be visible on any components of the medical device during visual checks (normal vision or vision corrected to normal) (QM). If need be (e.g. in case of critical medical devices with particularly strict reprocessing requirements = 'Critical C'), optical magnifying aids or appropriate other (e.g. chemical or physical) methods will be required to evaluate cleaning performance.

- If cleaning success cannot be assessed by visual inspection (e.g. due to long, narrow lumina, hollow spaces, such as, for instance, in MIS instruments; 'Critical B and C' medical devices) cleaning must be ensured through process engineering (e.g. by validated, mechanical/automated cleaning methods) and, where applicable, parametric monitoring (see Table 1; Annex 3. Commissioning and operation of washers/disinfectors (WD) for the reprocessing of medical devices (checklist), QM). In this context, the difficulty of manual cleaning lies especially in providing proof of reproducible implementation (for example, thorough brush cleaning of endoscopes). Periodic testing of the cleaning performance, above and beyond the thorough implementation of the manual procedures pursuant to the standard operating instructions, is therefore advisable.

2.2.3 Verifying Technical-Functional Safety (see also Annex No. 2 on Section 2.2.3 Technical-functional safety testing)

Guaranteeing the technical-functional safety of a reprocessed medical device is the responsibility of the operator. Simple, safety-relevant functional tests are to be carried out also by the user immediately before use (MPBetreibV).

Technical-functional tests should also be carried out after cleaning, disinfection, rinsing and drying have been completed but prior to sterilisation, especially when maintenance and repair work is being performed (MPBetreibV). The scope and nature of the tests depend on the medical device and are to be defined in the standard operating procedures (QM).

In this respect, no contamination with harmful substances (e.g. toxic care products) or particles (e.g. talc) which would outlast subsequent reprocessing steps may occur (MPBetreibV). Moreover, the care products used (e.g. paraffins according to the European pharmacopeia (Ph.Eur.) [56]) may not adversely affect sterilisation success [9]. For this purpose, the care product manufacturer may have to be consulted.

The tests for cleanliness, integrity and defined technical-functional properties serve to screen out medical devices from which visible residues cannot be removed, even after renewed-cleaning, or where technical-functional deficiencies cannot be remedied (QM). Where

deficiencies are observed, these are to be documented, their source investigated and eliminated.

Effects of the reprocessing procedure on material properties and technical-functional safety tend to be product-specific. They must therefore be verified on an individual basis, declared in the manufacturer's instructions for reprocessing, where appropriate indicating the tests or checks to be carried out after reprocessing, and must be taken into account by the operator in the standard operating procedures, for example, by specifying the target values to be achieved (see also 1.2.2 and 1.3) (MPG; MPBetreibV; QM).
Moreover, maintenance and repair must also be in line with the relevant manufacturer's directions (MPBetreibV).

2.2.4 Packaging

The packaging system normally consists of a sterile barrier system and, if appropriate, a protective wrapping and must be adapted to:

- the sterilisation method used (e.g. enabling sterilisation through suitable sterilant penetration) (see Point 2.2.5);
- the properties of the medical device that is disinfected or is to be sterilised, maintaining its operability (e.g. mechanical protection of sensitive components) as well as
- the intended storage and transportation (taking mechanical stress factors into account).

Air plays only a subordinate role in the re-contamination of cleaned and disinfected medical devices. Consequently, no special requirements are placed on the quality of the air in the packaging area.

The **packaging system** must enable sterilisation and guarantee sterility until use under proper storage conditions; where required, a **sterile goods shelf life** has to be specified (see also instructions of the sterile goods packaging manufacturer). Recontamination of the medical device after it has been reprocessed must be ruled out until it is used (also see Annex B Standards).
Imperviousness of the sealing seams must be proven, at least by means of simple tests in the course of the reprocessing process (see also Annex 4 page 4 "Batch-related Tests – Visual Inspection of Packaging"). This is without prejudice to the obligation to conduct tests immediately before use. The DIN 58953 standard series contains useful information on sterile supplies.

2.2.5 Sterilisation

Basically, sterilisation is conducted subsequent to the thorough cleaning and disinfection of medical devices that is required for reasons of occupational health and safety [9, 11, 13, 21, 23, 24, 28].

A method that is effective and has been validated and verified with a view to its suitability for the medical device must be used for sterilisation (see also Point 1.3) (MPBetreibV). The nature of the sterile goods, their packaging and loading configuration are important determinants of sterilisation success [10, 11, 33, 34, 57].

The use of steam sterilisation at 134 °C is to be preferred as the standard procedure owing to its minimal dependence on influencing factors [9, 24, 25]. Care must be taken to ensure that

the sterilant has access to all external and internal surfaces of the medical device within the sterile packaging (e.g. by thoroughly cleaning all lumina and opening valves or taps). Before any lubricants/sprays (grease, oils) are used, it must be ensured that they will not adversely affect the sterilisation success. These requirements must be taken into account when purchasing the medical devices and the relevant containers (QM).

Hot-air sterilisation (disinfection) can only be considered, according to the current state of technology, for semi-critical A (unpacked) or critical A products (in packaging that is suited to the procedure). Unlike other sterilisation procedures, in the case of hot-air sterilisation, the mass of the goods, their specific heat and specific thermal conductivity, packaging and especially the loading pattern are critical. As a result, the operator must validate the procedure, define and standardise the load (mass of the instruments) and the packaging and consistently document these as well as the observance of the necessary temperature-time relationships [34].

For the purpose of **conducting and monitoring sterilisation,** reference should be made to the corresponding standards (see Annex B Standards) as well as Annex 4: "Commissioning and operation of small-scale sterilisers for the reprocessing of medical devices".
Annex 4 provides an overview of the essential components of a validation.

Especially prior to using **low-temperature methods** and in the case of medical devices classified as 'Critical C', the **performance limits** of the methods employed are to be defined, documented and evaluated, taking account of the previous use of the medical device (QM, see also Table 1) [4, 9, 58].

Additionally, the **requirements stipulated by the Hazardous Substances Ordinance and relevant standards** might have to be taken into account (e.g. those for ethylenoxide, formaldehyde or hydrogen peroxide sterilisation) (e.g. TRGS 513).

2.2.6 Labelling

Packaged, reprocessed medical devices are to be accompanied by **information** that enable **safe use**, taking into consideration the level of training and knowledge of the user circle and the complexity of the medical device (MPG).

It must be possible at all times for the user to recognise:

- the **name of the medical device**; this must allow for use-relevant identification (e.g. model, size) if this is not immediately obvious;

- information on the labelling of released medical devices; as well as

- the **release decision** and, where applicable, process indicators;

as well as information that enables a decision to be taken on time-related aspects of safe use of the medical device, such as:

- date of sterilisation and the type of sterilisation method used (**batch number of the sterilisation, sterilisation date**);
- where appropriate, an **expiry date** understood as the manufacturer-indicated date until which safe use is proven to be possible;
- the **sterile goods shelf life**, if it is closer than the expiry date.

Where appropriate (e.g. in the case of medical devices belonging to the 'Critical C' group)

- Specifications for technical-functional testing and safety, **safety instructions, warnings** and other information, which is exclusively present on the original packaging and is relevant for safe use and traceability;
- the **name of the manufacturer** and, where appropriate, **batch or serial number;**

and, when **reprocessing is undertaken by other parties**, additionally

- the name and address of the reprocessing company.

If the manufacturer has specified the number of times a medical device may be reprocessed, the **number and type of completed reprocessing cycles** must also be stated (MPG, QM). This is not necessary in the case of medical devices that are intended for multiple use for which the manufacturer has not specified a maximum number of reprocessing cycles. Pertinent labels can also be attached directly to the medical device using electronic data processing if it is ensured that the number and type of reprocessing cycles performed on the respective medical device are readable when the decision is to be taken on a renewed reprocessing cycle. Such medical devices may only be released if the corresponding product-specific requirements have been complied with (MPG).

The results are to be documented in such a way that traceability to the specific batch (in the case of medical devices in the critical A and critical B groups) or to the specific reprocessed medical device (in the case of medical devices belonging to the critical C group) is guaranteed.

As regards the use of **symbols** for labelling, please refer to the appended standards (see DIN EN 980).

In determining the expiry date, meaning the date until which use is demonstrated to be safe, the possibility of material changes (also possibly caused by the reprocessing method/s) has to be taking into account; in determining the sterile goods shelf life, the type of packaging, transport and storage conditions also have to be factored in.

The user must also be able to identify completion of the process cycle in the case of medical devices the reprocessing cycle of which ends with disinfection (QM).

2.2.7 Release for Use

The reprocessing of medical devices ends with their documented release for use. This is authorised if the process parameters measured during the reprocessing cycle comply with those of the validation reports and includes:

- **implementing and documenting routine checks;**
- verifying and documenting the full and proper implementation of the process (batch-related routine checks and batch documentation);
- **checking the packaging for integrity and dryness;** and
- verifying the labelling (see 2.2.5) (QM).

For reasons of quality management, the persons authorised to approve releases must be specified in writing (QM).

Standard operating procedures must include

- the form in which **the release decision must be documented,**

and

- the **procedure to be followed for process deviations** (QM).

Care is to be taken to ensure the **safe removal** (rinsing and desorption) **of harmful substances** resulting from the reprocessing procedure (e.g. adherence to desorption times) (see Annex Standards, Technical Rules for Hazardous Substances (TRGS) 513). It is only subsequently that the release for use, which must be documented, can be authorised.

2.2.8 Batch documentation

The data on the process parameters measured during reprocessing and the release decision must be documented and reference must be made to the batch and the person authorising the release. They must document that the **reprocessing procedure used was completed according to the standard operating procedures and in compliance with the parameters laid down in the validation protocol** (QM).

Records of the reprocessing of medical devices must be kept for not less than five years. This is to be without prejudice to other legislation on retention periods (e.g. patient documentation). In this context, neither may the original content of an entry be obliterated nor alterations be made which render it impossible to tell if they were made during or after the original entry. Records may also be stored on image or data storage media. It must be ensured that they are accessible and readable during the retention period. The records and protocols must be submitted to the competent authorities on request (MPBetreibV).

3. Transportation and Storage

Transportation and storage may not adversely affect the properties of the reprocessed medical device. The instructions of the manufacturer of the medical device and of the packaging materials must be taken into account when storing reprocessed medical devices (MPBetreibV). Reprocessed medical devices that are used in a sterile state must always be packaged and must be stored in a dustproof, clean, dry and vermin-proof area at room temperature.
Storage periods depend on the quality of packaging materials, sealing seam integrity and storage conditions. Depending on these conditions, storage periods over the six month are conceivable.
Almost-sterile (semi-critical) medical devices must be stored under conditions that prevent recontamination during storage.

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Annex A: Laws, Ordinances, Directives

- Council Directive 90/385/EEC of 20 June 1990 relatingto implantable medical devices
- Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
- DIRECTIVE 2007/47/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market
- Medical Devices Act (MPG)
- Ordinance on Medical Devices (MPV)
- Ordinance on Installing, Operating and Using Medical Devices (Medical Devices Operator Ordinance (MPBetreibV)
- Medical Devices Safety Plan Ordinance (MPSV)

Occupational health and environmental protection:

- Biological Agents Regulation (Bio StoffV).
- Ordinance on Occupational Health Care (ArbMedVV)
- Chemicals Act (*Chemikaliengesetz*)
- Hazardous Substances Ordinance (*Gefahrstoffverordnung*)
- Radiation Protection Ordinance (*Strahlenschutzverordnung*)
- Waste Avoidance and Waste Management Act (*Abfallgesetz*)
- Technical Rules for Biological Agents (TRBA) 250
- Technical Rules for Hazardous Substances (TRGS) (300, 401, 440, 513, 525, 555; 900, 905)

Annex B: Standards

If the provisions of the standards referred to are complied with, accepted engineering practice is deemed to be fulfilled. This collection comprises the standards to be observed under aspects of hygiene from which the standards matching the planned reprocessing work must be selected in each case. For testing that serves to ensure technical-functional safety, additional standards may have to be observed, as appropriate.
The column "Sections of the Annex" cross-references the underlying standards and the corresponding sections of the Recommendation. The standards with particular **practical**