Note:

[Doc. X, page y] in this document: indicates a document to be named including page number - submitted for evidence.

Please replace *grey and italic text* with respective information.

In the following checklist the term (re-)processing means the reprocessing of used medical devices after clinical use or the initial processing of medical device without clinical use.

For most current version of Client Checklist please check [Biological safety checklists | TÜV SÜD (tuvsud.com)](https://www.tuvsud.com/en/industries/healthcare-and-medical-devices/sterilisation-practices-control-and-validation/biological-safety-checklists).

# Quality management system relating to (re-) Processing:

Note: Please replace *italic text* with respective information.

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| **Procedures relating to (re-)processing** | |
| 1.1  Procedure describing the interface to change management: | *Decision rules on significance of device or IFU changes, product adoption strategy including decision criteria for new validation and review of product families.*  documented in procedure *[X,p.y]* |
| A list of all changes relating to (re-)processing of devices covered by the (re-)processing instructions is provided: | *List of all changes since certificate extension or initial certification relating to (re-)processing with decision if (in-)significant, description of the respective change, reference to validation documentation and short summary of validation results, if applicable. Changes may be regarding product adoption of new devices, cleaning/disinfection agents with time/concentration/temperature, cleaning adapters and processing aids, sterile packaging, washer-disinfector or sterilization program, storage, and transport.*   yes documented in *[X,p.y]*   n/a (initial certification) |
| 1.2  Development procedure including new development of reusable/initially to be processed devices and of the related Instructions for use:  Please provide the development procedure describing the approach for | * development of new devices:   *Product adoption strategy including decision criteria for new validation documented in procedure* *[X,p.y]*   * the validation of instruction for use:   *The respective procedure is expected to address reprocessing acceptance criteria (cleaning, disinfection, sterilization, life-cycle data including biocompatibility and functionality testing and verification of readability of direct markings), justified limits and test soil selection with scientific rationales based on the risk assessment (refer also to EN ISO 17664 clause 5).*  documented in procedure *[X,p.y]*   * if applicable: grouping strategy of product family:   *Grouping strategy and worst-case product selection for validation of cleaning, disinfection, sterilization, and lifetime studies including biocompatibility and functional testing*  documented in procedure *[X,p.y]*   * risk management considering aspects of (re-)processing and/or (initial) processing:   *At least the relevant points to processing according to EN ISO 17664, clause 5 are expected.*  documented in *[X,p.y]*   * national (re-)processing requirements of EU member states:   *Provisions for systematic search for and handling of national reprocessing requirements and guidance of EU member states, where the devices are placed on the market.*  documented in procedure *[X,p.y]*   * requirements in relation to qualification of personnel regarding the assessment of (re-)processing/biocompatibility data:   *Trainings, CV related to EN ISO 17664 of involved decision maker of e.g., grouping of devices, instructions for (re-)processing, product adoption, evidence for qualification related to EN ISO 10993-1, …*  documented in procedure *[X,p.y]* |
| 1.3  Procedure focussing on Post Market Surveillance covering specifically reusable or (initially) processed devices in relation to processing? | yes documented in procedure *[X,p.y]* |

# Short product description relevant for (re-) processing:

Note: Please replace *italic text* with respective information

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| **2.1 Short description incl. picture of the device** - in case of changes, as far as relevant | |
| Description of the device as far as relevant for (re-)processing  *Product drawings and/or picture of product. Including worst case position(s) that is/are supposed to be a challenge to the (re-) processing process including details of the product’s challenging dimensions.* | |
| Product family of the device and selected worst-case products - if applied:  *Please explain the rationale for building the (re-)processing product family. Why is the representative worst-case applied for this product covering the family members and the respective device under review (with regard to cleaning, disinfection, sterilization, biocompatibility and functionality).*  *(For guidance see e.g., DIN EN ISO 17664-1:2021, Annex C.3, RDS 007)*  *Product drawings and/or picture of selected worst-case product(s) including worst-case position(s) that is/are supposed to be a challenge to the (re-) processing process and relevant for biocompatibility as well as functional testing.* | |
| The device under assessment is: | reusable/reprocessed after patient contact   single-use and initially processed in the hospital before use |
| Intended to be: | sterilized by steam   sterilized by plasma   sterilized by: *please describe*  not sterilized: *Please provide a justification* |
| Contact to Central Nervous System (CNS) per intended use: | yes   no  *Refer to high-risk tissue for (v)CJD transmission in Bundesgesundheitsbl. 2012 • 55:1244–1310 Annex 7* |

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| **2.2 Applicable national requirements** | |
| In which EU member states are the devices placed on the market:  All member states   If not, please list the respective member states: | |
| Has an evaluation regarding specific national requirements and guidance in the applicable EU member states been performed? | yes   no  Doc.-No.: |
| If there are national requirements, have potential differences to instructions for (re-)processing in the IFU and validation thereof been evaluated? | yes  no  Doc.-No.: |

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| **2.3 Risk management file/ risk analysis relating to (re-)processing** | |
| Risk management file/ risk analysis of the sampled device relating to (re-)processing (at least relevant points of EN ISO 17664, clause 5): | *Only the relevant parts relating to (re-)processing shall be extracted from the risk analysis or referenced.*  documented in *[X,p.y]* |

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| **2.4 Post market surveillance of devices covered by device under assessment (re-)processing instructions** | |
| Average number of processing over lifetime of sampled device: | *Please specify* |
| Expected lifetime of the device: | *Please specify*  *Note: Wear and tear should also be considered based on related risks for functionality and biocompatibility and marking readability* |
| Device is on the market since: | *Please specify* |
| Number of devices placed on the market: | *Please specify* |
| Number of complaints related to (re-)processing | *Please specify* |
| Post market surveillance data isolated to (re-)processingof the device: | documented in *[X,p.y]* |
| * Are there open corrective actions: | no   yes *[X, p.y] please describe in detail:* |
| or |  |
| * current incidents relating to (re-)processing | no   yes *[X, p.y] please describe in detail:* |

# Information on external laboratories

Note: Please replace *italic text* with respective information.

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| **External Laboratories** | |
| *Name of the laboratory* | *Please name the test laboratory with performed tests (e.g., cleaning, disinfection, sterilization validation, cytotoxicity, and TOC testing for lifetime studies). Please provide the applicable quality management certificate (e.g., ISO/IEC 17025 or GLP) with relevant scope (Annex of the certificate) at the timepoint when the test was performed.* |
| *Name of the laboratory* | *Please name the test laboratory with performed tests (e.g., cleaning, disinfection, sterilization validation, cytotoxicity, and TOC testing for lifetime studies). Please provide the applicable quality management certificate (e.g., ISO/IEC 17025 or GLP) with relevant scope (Annex of the certificate) at the timepoint when the test was performed.* |
| *…* | *…* |

# Information to be provided by the medical device manufacturer for (Re-)processing the medical device

Note: Please replace *italic text* with respective information

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| **Instructions for use** | |
| Please provide the current version of the IFU or detailed instructions for (re-)processing | *Including detailed step by step description of the processing with the required accessories (e.g. brushes, connectors, baskets) and equipment (like washer disinfector or sterilizer - with reference to international standard, if applicable), cleaning detergents and disinfectants, process parameters and limits (e.g. temperature, concentration, water quality, pressure), detailed (dis-)assembly instructions, required sterile barrier system, sterilization process (if applicable), , visual inspection criteria and maintenance, transport and storage after (re-)processing, IFU revision number and date, if applicable lubricant suitable for sterilization with evidence on biocompatibility - refer to ISO 17664 clause 6.*  *Additionally, international (e.g. WHO Infection Control Guidelines for TSE) and national guidance documents (e.g. KRINKO BfArM, Bonnes Pratiques de Pharmacie Hospitalière (arr. 22 juin 2001 - Good Pharmaceutical Practices at hospital) as well as commonly available process and equipment in the EU shall be considered.*  documented in IFU *[X,p.y]* |
| Is the device accompanied by a printed version of the IFU? | yes   no, *please justify and consider implementing regulation (EU) 2021/2226 [X;p.y]* |
| *Please paste (re-)processing process parameters here for (pre-)cleaning, disinfection, packaging, and sterilization (if applicable):* | |
| If applicable - Is an end of lifetime indicator document available? | *Criteria for the user that indicate end of life of the device for inspection or functional testing.*   yes, *please provide [X; p.y]*  no |
| If further information relating to (re-)processing is provided e.g., web-based instructions for maintenance, please provide the respective description. | documented in *[X,p.y]* |

# Validation of instructions for (RE-)processing of the medical device

Note: Please replace *italic text* with respective information

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| **5.1 Cleaning efficacy testing** | |
| Evidence of automated cleaning validation |  |
| Cleaning efficacy of device under assessment was performed: | *Note: The study shall include acceptance criteria, recovery factor (if applicable), type and method of application of artificial contamination considering the intended use. Contamination positions should reflect the most-difficult-to-clean positions of the device. Artificial soil for testing and its application to the device should reflect the type of contamination expected during use of the device (e.g., bone meal for drills).*   yes documented in *[X,p.y]*  no *please justify:* |
| Was the washer disinfector program terminated after cleaning process prior to thermal disinfection? | yes documented in *[X,p.y]*  no *please justify:* |
| Rationale in case of equivalence approach (device under assessment vs tested device): | *Comparison of the devices in a comprehensible way.*  *Please address all relevant device features, at least materials, surface characteristics, critical geometric features (e.g., lumens, gaps) and shielding effects (e.g., by washing trays).*  documented in *[X,p.y]* |

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| If applicable: Evidence of manual cleaning validation |  |
| Cleaning efficacy of device under assessment was performed: | *Note: The study shall include acceptance criteria, recovery factor (if applicable), type and method of application of artificial contamination considering the intended use. Contamination positions should reflect the most-difficult-to-clean positions of the device. Artificial soil for testing and its application to the device should reflect the type of contamination expected during use of the device (e.g., bone meal for drills).*   yes documented in *[X,p.y]*  no *please justify:* |
| Rationale in case of equivalence approach (device under assessment vs tested device): | *Comparison of the devices in a comprehensible way.*  *Please address all relevant device features, at least materials, surface characteristics, critical geometric features (e.g., lumens, gaps) and shielding effects (e.g., by washing trays).*  documented in *[X,p.y]* |
| The automated and/or manual cleaning efficacy studies above are reflecting the identical process as described in the instructions for use: | *Note: Worst-case parameters should be considered in validation (e.g., lowest temperature, shortest contact/processing time, lowest cleaning agent concentration).*  *Differences in cleaning parameters (e.g., temperature, holding time, type, and concentration of cleaning agent) and their effect on cleaning efficiency should be addressed.*   yes documented in *[X,p.y]*  no *please justify:* |

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| **5.2 Disinfection efficacy testing** | |
| Evidence of automated disinfection validation |  |
| Disinfection efficacy of device under assessment | yes documented in *[X,p.y]*  no *please justify:* |
| Applied method of disinfection: | *Note: Inoculation/sensor positions should reflect the most-difficult-to-reach positions for the disinfectant. The resistance of the selected test organism(s) against the disinfection process to be validated and relevance for the expected contamination during the intended use of the device should be considered.*   thermal disinfection/A0:  thermocouples with justification on sensor position documented in *[X,p.y]*  test organism(s) and inoculation position(s) with justification documented in *[X,p.y]* |
|  | *Note: Inoculation positions should reflect the most-difficult-to-reach positions for the disinfectant. The resistance of the selected test organism(s) against the disinfection process to be validated and relevance for the expected contamination during the intended use of the device should be considered.*   chemical disinfection:  test organism(s) and inoculation position(s) with justification documented in *[X,p.y]* |
| Rationale in case of equivalence approach (device under assessment vs tested device) | *Comparison of the devices in a comprehensible way.*  *Please address all relevant device features, at least materials, surface characteristics, critical geometric features (e.g., lumens, gaps) and shielding effects (e.g., by washing trays).*  documented in *[X,p.y]* |

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| if applicable: Evidence of manual disinfection validation |  |
| Disinfection efficacy of device under assessment | yes documented in *[X,p.y]*  no *please justify:* |
|  | *Note: Inoculation positions should reflect the most-difficult-to-reach positions for the disinfectant. The resistance of the selected test organism(s) against the disinfection process to be validated and relevance for the expected contamination during the intended use of the device should be considered.*   chemical disinfection:  test organism(s) and inoculation position(s) was used with justification documented in *[X,p.y]* |
| Rationale in case of equivalence approach (device under assessment vs tested device): | *Comparison of the devices in a comprehensible way.*  *Please address all relevant device features, at least materials, surface characteristics, critical geometric features (e.g., lumens, gaps) and shielding effects (e.g., by washing trays).*  documented in *[X,p.y]* |
| The automated and/or manual disinfection efficacy studies above are reflecting the identical process as described in the instructions for use: | *Note: Worst-case parameters should be considered in validation (e.g., lowest temperature, shortest contact/processing time, lowest concentration of disinfectant).*  *Differences in disinfection parameters (e.g., temperature, holding time, type and concentration of disinfectant) and their effect on disinfection efficiency should be addressed.*   yes documented in *[X,p.y]*  no *please justify:* |

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| **5.3 If applicable: Drying (if drying steps are necessary in addition to drying step in washer-disinfector)** | |
| Verification of drying step for device under assessment is | documented in *[X,p.y]*  *Media quality, accessories, process parameters* |
| Rationale in case of equivalence approach (device under assessment vs tested device): | documented in *[X,p.y]* |
| The studies above are reflecting the identical process as described in the instructions for use: | yes documented in *[X,p.y]*  no *please justify:* |

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| **5.4 Sterilization efficacy testing – if steam sterilization is applicable** | |
| Evidence for the sterilization of the device under assessment | *Note: Test report including BI certificate according to ISO 11138, description of the inoculation position (e.g., picture), detailed description of the sterile barrier system, and Spore Log Reduction (SLR) determination. Contamination of the device before sterilization.SLR ≠ SAL*  documented in *[X,p.y]* |
| Rationale in case of equivalence approach (device under assessment vs tested device): | documented *in [X,p.y]*  *For representative devices please address device features, at least materials, surface characteristics, weight, geometric features (e.g., lumens, gaps)* |
| What type of sterilization is applied?  Refer to EN ISO 17665-1/ EN 13060 and EN 285 | Moist Heat Sterilization (134°C, 3-18 min, fractional pre-vacuum) documented in *[X,p.y]*   Different Moist Heat process (deviating from above) with justification documented in *[X,p.y], please describe sterilization parameters:* |
| Evaluation of a sterilization process: | documented including justification in *[X,p.y]* |
| * based on biological indicator | yes   n/a |
|  | test organism used: *please describe applied CFU/device and/or position.* |
|  | bio-indicator certificate meeting requirements of EN ISO 11138-3 provided in: *[X,p.y]* |
|  | Have all BIs been inactivated (result: no growth)?   yes   no *please justify:* |
| Sterilization parameters (T, p, t) have been met? | yes documented in *[X,p.y]*  no *please justify:* |
| Packaging according to EN ISO 11607-1? | yes documented in *[X,p.y]*  no *please justify:*  *Please refer to packaging system used for sterilizability study and provide data sheet for packaging material.* |
| The studies above are reflecting the identical process as described in the instructions for use including the sterile packaging: | yes documented in *[X,p.y]*  no *please justify:* |

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| **5.5 Testing in internal laboratory – if tests of conformity documentation have been performed in internal test laboratory** | |
| Internal laboratory has been used for conformity testing mentioned in section 5. | yes, *please fill this table*   no |
| Tests performed in internal laboratory | Testing of Cleaning efficacy   Testing of Disinfection efficacy   Testing of Sterilization efficacy   Life cycle testing   ….  *If more than one box is checked, please copy, and fill below boxes for each performed test* |
| Have validated test methods been applied? | yes *[X,p.y]*  *Validation protocol justifies sample size of test items, sample preparation, acceptance criteria. Please provide test method validation plan and report*  *Note: Test method validation should demonstrate adequate sensitivity and specificity as well as traceability of the results. The validated state at the time of test conduction should be demonstrated*. |
| Is a summarizing qualification report available of used test equipment?  Refer to EN ISO 17665-1/ EN 13060 and EN 285 | *Note: Qualification report should demonstrate successful IQ, and OQ, as well as regular maintenance and calibration of the equipment at the time of test conduction. For equipment with measuring function, calibration and traceability to international standards should be demonstrated for the time of test conduction.*   yes *[X,p.y]* |

# Impact of (re-)processing on the medical device lifetime

Note: Please replace *italic text* with respective information

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| **6.1 Lifetime data - impact of (re-)processing** | |
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| How is the information in the IFU provided when the device should no longer be used? | signs of material degradation *[X, p.y] (Further referred as unlimited lifecycle)*   the maximum number of allowable reuses[X, p.y])  Note:  Limitation of maximum number of reprocessing cycles needs to be considered for medical devices with critical elements such as e.g., multiple components, movable parts, dismantlable devices, cavities, holes, plastics, corrosion sensitive, porous surfaces, and greater mechanical stress changes, which may affect product safety.  More than two observation time points are considered necessary to establish biocompatibility and functional safety with unlimited lifetime. |
| Rationale for lifecycle simulation approach: | documented *in [X,p.y]*  *Please add a short summary*  *For representative reprocessing procedures, please address differences in processing parameters, at least temperature, time, detergent type and concentration, mechanical impact (brushing)*  *If more than one reprocessing procedure is allowed per IFU, please provide a justification based on evidence that worst – case path was chosen for the simulation.* |

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| **6.2 Functional testing** | |
| Was product functionality substantiated over lifetime? | *Performed tests including acceptance criteria and results, literature data, market data, end of life indicators, inspection criteria in IFU, …*   yes documented in *[X,p.y]* *Please add a short summary*  *It should be demonstrated that functionality of the device is not expected to be impaired by the described (re-)processing procedure. The maximum allowed/expected number of full (re-)processing cycles (cleaning/disinfection/sterilization) during the device’s life cycle should be considered.* |
| Rationale in case of equivalence approach (device under assessment vs tested device): | documented in *[X,p.y]* |
| Was device labelling substantiated for readability (e.g., REF number and UDI) over lifetime: | yes documented in *[X,p.y]* *Please add a short summary* |
| Rationale in case of equivalence approach (device under assessment vs tested device): | documented in *[X,p.y]*  *For representative devices please address device features, at least materials, surface characteristics, geometric features (hinges, lumens)*  *For representative (re-)processing procedures, please address differences in processing parameters, at least temperature, time, detergent type and concentration, mechanical impact (brushing)* |

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| **6.3 Biocompatibility** | |
| Have the effects of (re-)processing on biocompatibility been evaluated, considering the service life / lifetime of the device, and have the associated risks been classified as acceptable? | yes documented in *[X,p.y] Please add a short summary*  *Evaluation includes both degradation of material(s) and accumulation of processing aids.*  *It should be demonstrated that the biocompatibility of the device is not expected to be impaired by the described (re-)processing procedure.*  *The maximum allowed/expected number of full (re-)processing cycles (cleaning/disinfection/sterilization) during the device’s life cycle should be considered.*  *The risk of material degradation and accumulation of processing agent residues has to be considered.* |
| Rationale in case of equivalence approach (device under assessment vs tested device): | documented in *[X,p.y]*  *For representative devices please address device features, at least materials, surface characteristics, geometric features (e.g., lumens, gaps)*  *For representative (re-)processing procedures, please address processing parameters, at least temperature, time, detergent type and concentration, mechanical impact (brushing)* |
| Has the risk of endotoxins been addressed in relation to respective body contact? | Is required water quality defined in IFU for final rinse step(s):   yes documented in *[X,p.y] Please specify the water quality below*  Is a risk assessment of an appropriate water quality available in the risk management file?   yes documented in *[X,p.y] Please paste justification on risk acceptance below*  *Please consider that for sterile implantable medical devices that contact non-intact tissue during use or medical devices that have direct or indirect intravascular, intralymphatic, intrathecal, and/or intraocular contact shall have an evaluation performed for bacterial endotoxins.* |
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# Risk of prion transmission of (v)CJD through medical device

Note: Please replace *italic text* with respective information.

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| **Prion decontamination, if applicable** | |
| If prion contamination during intended use is a risk, was the contamination after use considered in the risk management in relation to the decontamination steps? | *Risk analysis including literature research regarding current state of the art for decontamination procedures.*  *Risk assessment and mitigation measures following considerations in Annex 7 KRINKO/BfArM 2012 guidance.*  *please describe [X; p.y]* |
| Does the IFU contain a statement to follow country specific requirements? | yes documented in *[X,p.y]* |
| Does the IFU contain at least two partially prion inactivating/decontaminating steps? | *Appropriate measures to prevent drying or fixation of contamination.*  *Description of two at least partially prion inactivating or decontaminating procedures (cleaning agent with proven efficacy in in vitro and in vivo studies and sterilization with proven efficacy against prions (e.g., list of ANSM)*   yes documented in *[X,p.y]*  no *please justify:* |
| In vitro and in vivo (literature) studies to substantiate efficacy of described detergent and sterilization step are provided: | yes documented in *[X,p.y]* |

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| **Regulatory release by client:** | ­­ |  |  |
|  | Date | Signature | Name |
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|  |  |  | Name of Legal Manufacturer |