



Client Checklist Instructions for Reprocessing

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://tuvsud.com).

How to fill this Checklist:

- Initial Submission and TD sampling reviews:

This checklist should be used for initial conformity assessments and surveillance sampling of Technical Documentation as well as renewals, as applicable.

- Substantial changes:

It should also be used in case of notified substantial changes, which require a (re-)assessment of the Technical Documentation (TD), Module “Sterilization”.

However, in case of substantial changes not all parts of this checklist may be applicable. Some questions are related specifically to substantial changes. If not applicable nor relevant, respective sections can be left blank or parts can be deleted, if self-explanatory. If unsure if the respective section may be applied, please include a justification why this information is not of relevance for the change assessment. In cases, in which the information is only partly relevant, the corresponding section should be filled in as far as relevant for the change (e.g., description of changed manufacturing steps only).

- To distinguish between the given text and your information more easily, it is recommended to use a different text colour for filling in the requested information. The italic text providing information and guidance on what is requested in the section can be replaced by the respective information. **For the purpose of clarity, it is recommended to delete the guidance of the template italic text prior to submission.**
- In case of an information request to specifically include specific information, please include at least a brief summary of the requested information.
- For a swift assessment process, it is very helpful to directly reference to the specific evidence document and page number / section (where evidence is required and can be provided). **This is indicated by [X] in this checklist.**
- All documents referenced in this checklist shall be submitted and available for review. Please ensure that the document ID number / document title is consistent with the information given in the checklist. This includes also complete test or study protocols and reports to be submitted.
- Please note that we can only accept documents in English or German language.

Signature: Please sign the completed checklist. This is important, so that we are able to use information as provided in this checklist. Please submit a signed PDF as well as the corresponding word document to be able to extract the information.



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Disclaimer on the examples provided in the Checklist:

The below examples are hypothetical. The described medical devices, manufacturers, suppliers, sterilisers, etc. are fictitious. No identification of a real-life medical device or manufacturer is intended or should be inferred. Please consider that the given examples were related to the specific section and are not always linked to each other.

1. QUALITY MANAGEMENT SYSTEM RELATING TO (RE-) PROCESSING

Explanation: The intention of this section is to give an overview of the quality management system and the related procedure for (Re-)processing and initial processing of medical devices. The number of different medical devices and designs makes it necessary to have structured operating practise in place to cover all processed devices under one certificate.

Note: Please replace *italic text* with respective information

| Procedures relating to (re-)processing | |
|---|--|
| <div>1.1 Procedure describing the interface to change management:</div> <div>A list of all changes relating to (re-) processing of devices covered by the (re-)processing instructions is provided:</div> | <div>Decision rules on significance of device or IFU changes, product adoption strategy including decision criteria for new validation and review of product families.</div> <div>Documented in procedure</div> <div>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.</div> <div><input type="checkbox"/> Yes, documented in</div> <div><input type="checkbox"/> N/A (initial certification)</div> |



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| | |
| <p>1.2 <u>Development procedure including new development of reusable/initially to be processed devices and of the related Instructions for use:</u></p> <p>Please provide the development procedure describing the approach for</p> | <ul style="list-style-type: none"> • Development of new devices: <i>Product adoption strategy including decision criteria for new validation documented in procedure [X,p,y]</i> • The validation of instruction for use: <i>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).</i> Documented in procedure • If applicable: grouping strategy of product family: <i>Grouping strategy and worst-case product selection for validation of cleaning, disinfection, sterilization, and lifetime studies including biocompatibility and functional testing</i> Documented in procedure • Risk management considering aspects of (re-)processing and/or (initial) processing: <i>At least the relevant points to processing according to EN ISO 17664, clause 5 are expected.</i> Documented in |



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| | <ul style="list-style-type: none">• National (re-)processing requirements of EU member states: <i>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.</i> Documented in procedure• Requirements in relation to qualification of personnel regarding the assessment of (re-)processing/biocompatibility data: <i>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, ...</i> Documented in procedure |
| <u>1.3</u> <u>Procedure focussing on Post Market Surveillance covering specifically reusable or (initially) processed devices in relation to processing?</u> | <input type="checkbox"/> Yes, documented in procedure |



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2. SHORT PRODUCT DESCRIPTION RELEVANT FOR (RE-) PROCESSING

Explanation: The intention of this section is to give a description of the medical device displaying relevant design characteristics for (re-)processing including worst-case positions.

For product families it must be understandable in which relation the chosen worst-case device for validation is reflecting the medical device under assessment.

The requested information helps to decide if the selected worst-case product(s) are applicable and cover the device under assessment regarding cleaning, disinfection, sterilization, biocompatibility, and functionality.

Apart from comprehensibility of challenging design characteristics for (re-)processing the section aims at traceability for future submissions of design changes.

Note: Please replace *italic text* with respective information

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.



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| Has this product family already been assessed by TÜV SÜD Product Service? <input type="checkbox"/> Yes <i>Please list any previous TÜV SÜD Product Service project no. # related to the product family in scope of the current product assessment.</i> <i>Do the devices share:</i> <ul style="list-style-type: none"> • the identical instruction for processing (Rev. XX) • the same worst-case devices for: <ul style="list-style-type: none"> • cleaning, • disinfection, • sterilization, • functional and, • biocompatibility testing. | |
| <input type="checkbox"/> No | |
| The device under assessment is: | <input type="checkbox"/> reusable/reprocessed after patient contact <input type="checkbox"/> single-use and initially processed in the hospital before use |
| Intended to be: | <input type="checkbox"/> sterilized by steam <input type="checkbox"/> sterilized by plasma <input type="checkbox"/> sterilized by: <i>Please describe</i> <input type="checkbox"/> not sterilized: <i>Please provide a justification</i> |
| Contact to Central Nervous System (CNS) per intended use: | <input type="checkbox"/> Yes <input type="checkbox"/> No <i>Refer to high-risk tissue for (v)CJD transmission in Bundesgesundheitsbl. 2012 • 55:1244–1310 Annex 7</i> |

Explanation: The intention of this section is to get information regarding evidence that the information provided in the instruction for (re-)processing is appropriate to the national requirements and guidance applicable to the EU Member State(s) in which the device has been placed on the market.

| 2.2 Applicable national requirements | |
|--|---|
| In which EU member states are the devices placed on the market: All member states <input type="checkbox"/> 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? | <input type="checkbox"/> Yes <input type="checkbox"/> No Doc.-No.: |
| If there are national requirements, have potential differences to instructions for (re-)processing in the IFU and validation thereof been evaluated? | <input type="checkbox"/> Yes <input type="checkbox"/> No Doc.-No.: |



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Explanation: The intention of the section is to get information regarding evidence that (re-)processing is considered in the risk analysis of the medical device and that test design in validation studies as well as in lifecycle testing is based on this risk assessment, e.g. test soil selection, acceptance criteria, water quality, life cycle, and limitation on number of reuses etc.

| 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): | <p><i>Only the relevant parts relating to (re-)processing shall be extracted from the risk analysis or referenced.</i></p> <p>Documented in</p> |

Explanation: This section should give an overview of the quality, performance, and safety of a device throughout its entire lifetime and monitoring of preventive and corrective actions related to (re-)

| 2.4 Post market surveillance of devices covered by device under assessment (re-)processing instructions | |
|---|--|
| Average number of processing over lifetime of sampled device: | <i>Please specify</i> |
| Expected lifetime of the device: | <p><i>Please specify</i></p> <p><i>Note: Wear and tear should also be considered based on related risks for functionality and biocompatibility and marking readability</i></p> |
| Device is on the market since: | <i>Please specify</i> |
| Number of devices placed on the market: | <i>Please specify</i> |
| Number of complaints related to (re-)processing | <i>Please specify</i> |
| Post market surveillance data isolated to (re-)processing of the device: • Are there open corrective actions: or • Current incidents relating to (re-)processing | <p>Documented in</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <i>[X,p,y] please describe in detail:</i></p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <i>[X,p,y] please describe in detail:</i></p> |



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3. INFORMATION ON EXTERNAL LABORATORIES

Explanation: This section is intended to provide evidence that validated test methods were used at the time point when the test was performed.

Note: Please replace *italic text* with respective information

| External Laboratories | |
|-------------------------------|--|
| <i>Name of the laboratory</i> | <i>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.</i> |
| <i>Name of the laboratory</i> | <i>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.</i> |

4. INFORMATION TO BE PROVIDED BY THE MEDICAL DEVICE MANUFACTURER FOR (RE-) PROCESSING THE MEDICAL DEVICE

Note: Please replace *italic text* with respective information

| Instructions for use | |
|--|---|
| <p>Please provide the current version of the IFU or detailed instructions for (re-) processing</p> | <p><i>Including detailed step by step description of the processing with the required accessories (e.g. brushes, connectors, baskets) and equipment (like washer disinfectant 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.</i></p> <p>Documented in IFU</p> |
| <p>Is the device accompanied by a printed version of the IFU?</p> | <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No <i>Please justify and consider implementing regulation (EU) 2021/2226 [X;py]</i></p> |
| <p><i>Please paste (re-)processing process parameters here for (pre-)cleaning, disinfection, packaging, and sterilization (if applicable):</i></p> | |



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| <p>If applicable - Is an end of lifetime indicator document available?</p> | <p>Criteria for the user that indicate end of life of the device for inspection or functional testing.</p> <p><input type="checkbox"/> Yes Please provide [X; p.y]</p> <p><input type="checkbox"/> No</p> |
| <p>If further information relating to (re-) processing is provided e.g., web-based instructions for maintenance, please provide the respective description.</p> | <p>Documented in</p> |



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5. VALIDATION OF INSTRUCTIONS FOR (RE-)PROCESSING OF THE MEDICAL DEVICE

Explanation: This section addresses the cleaning validation substantiating the efficacy of the cleaning process for the medical device under assessment in relation to the (re-)processing instructions in the IFU. If the device under assessment is represented by a worst-case device in the validation study, it must be comprehensible based on which criteria the test data have been transferred.

Note: Please replace *italic text* with respective information

| 5.1 Cleaning efficacy testing | |
|---|---|
| <u>Evidence of automated cleaning validation</u> Cleaning efficacy of device under assessment was performed: | <p><i>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).</i></p> <p><input type="checkbox"/> Yes, documented in</p> <p><input type="checkbox"/> No, <i>please justify:</i></p> |
| Was the washer disinfectant program terminated after cleaning process prior to thermal disinfection? | <p><input type="checkbox"/> Yes, documented in [X,p,y]</p> <p><input type="checkbox"/> No, <i>please justify:</i></p> |
| Rationale in case of equivalence approach (device under assessment vs tested device): | <p><i>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).</i></p> <p>Documented in</p> |
| | |
| <u>If applicable: Evidence of manual cleaning validation</u> Cleaning efficacy of device under assessment was performed: | <p><i>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).</i></p> <p><input type="checkbox"/> Yes, documented in</p> <p><input type="checkbox"/> No, <i>please justify:</i></p> |



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| <p>Rationale in case of equivalence approach (device under assessment vs tested device):</p> | <p>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</p> |
| <p><u>The automated and/or manual cleaning efficacy studies above are reflecting the identical process as described in the instructions for use:</u></p> | <p>Note: Worst-case parameters should be considered in validation (e.g., lowest temperature, shortest contact/processing time, lowest cleaning agent concentration).</p> <p><input type="checkbox"/> Yes, documented in [X,p,y] <input type="checkbox"/> No, please justify:</p> |

Explanation: This section addresses the disinfection validation substantiating the efficacy of the disinfection process for the medical device under assessment in relation to the (re-)processing instructions in the IFU. If the device under assessment is represented by a worst-case device in the validation study, it must be comprehensible based on which criteria the test data have been transferred.

| 5.2 Disinfection efficacy testing | |
|---|---|
| <p><u>Evidence of automated disinfection validation</u></p> <p>Disinfection efficacy of device under assessment</p> | <p><input type="checkbox"/> Yes, documented in <input type="checkbox"/> No, please justify:</p> |
| <p>Applied method of disinfection:</p> | <p>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.</p> <p><input type="checkbox"/> Thermal disinfection/A0: <input type="checkbox"/> Thermocouples with justification on sensor position documented in <input type="checkbox"/> Test organism(s) and inoculation position(s) with justification documented in [X,p,y]</p> <p>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.</p> <p><input type="checkbox"/> Chemical disinfection: Test organism(s) and inoculation position(s) with justification documented in [X,p,y]</p> |



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| <p>Rationale in case of equivalence approach (device under assessment vs tested device):</p> | <p>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).</p> <p>Documented in</p> |
| <p><u>If applicable: Evidence of manual disinfection validation</u></p> <p>Disinfection efficacy of device under assessment</p> | <p><input type="checkbox"/> Yes, documented in</p> <p><input type="checkbox"/> No, please justify:</p> <p><i>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.</i></p> <p><input type="checkbox"/> Chemical disinfection: Test organism(s) and inoculation position(s) with justification documented in</p> |
| <p>Rationale in case of equivalence approach (device under assessment vs tested device):</p> | <p>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).</p> <p>Documented in</p> |
| <p><u>The automated and/or manual disinfection efficacy studies above are reflecting the identical process as described in the instructions for use:</u></p> | <p><i>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.</i></p> <p><input type="checkbox"/> Yes, documented in [X,p.y]</p> <p><input type="checkbox"/> No, please justify:</p> |



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In this section further information regarding drying verification can be specified.

| 5.3 If applicable: Drying (if drying steps are necessary in addition to drying step in washer-disinfector) | |
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| Verification of drying step for device under assessment is | Documented in [X,p,y] <i>Media quality, accessories, process parameters</i> |
| 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: | <input type="checkbox"/> Yes, documented in [X,p,y] <input type="checkbox"/> No, <i>please justify:</i> |

Explanation: This section addresses the sterilization validation substantiating the efficacy of the sterilization process for the medical device under assessment in relation to the (re-)processing instructions in the IFU. If the device under assessment is represented by a worst-case device in the validation study, it must be comprehensible based on which criteria the test data have been transferred.

| 5.4 Sterilization efficacy testing – if steam sterilization is applicable | |
|---|--|
| <u>Evidence for the sterilization of the device under assessment</u> Rationale in case of equivalence approach (device under assessment vs tested device): | <p><i>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.</i> <i>Contamination of the device before sterilization. SLR ≠ SAL</i></p> <p>Documented in</p> <p>Documented in</p> <p><i>For representative devices please address device features, at least materials, surface characteristics, weight, geometric features (e.g., lumens, gaps)</i></p> |
| What type of sterilization is applied? Refer to EN ISO 17665-1/ EN 13060 and EN 285 | <input type="checkbox"/> Moist Heat Sterilization (134°C, 3-18 min, fractional pre-vacuum) documented in <input type="checkbox"/> Different Moist Heat process (deviating from above) with justification documented in [X,p,y], <i>please describe sterilization parameters:</i> |
| <u>Evaluation of a sterilization process:</u> • based on biological indicator | <p>Documented including justification in</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> N/A</p> |



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| | <p>Test organism used: <i>Please describe applied CFU/device and/or position.</i></p> <p>Bio-indicator certificate meeting requirements of EN ISO 11138-3 provided in:</p> <p>Have all BIs been inactivated (result: no growth)?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No, <i>please justify:</i></p> |
| <p>Sterilization parameters (T, p, t) have been met?</p> <p>Packaging according to EN ISO 11607-1?</p> | <p><input type="checkbox"/> Yes, documented in</p> <p><input type="checkbox"/> No, <i>please justify:</i></p> <p><input type="checkbox"/> Yes, documented in</p> <p><input type="checkbox"/> No, <i>please justify:</i></p> <p><i>Please refer to packaging system used for sterilizability study and provide data sheet for packaging material.</i></p> |
| <p>The studies above are reflecting the identical process as described in the instructions for use including the sterile packaging:</p> | <p><input type="checkbox"/> Yes, documented in [X,p,y]</p> <p><input type="checkbox"/> No, <i>please justify:</i></p> |

Explanation: In case the testing laboratory is NOT ISO/IEC 17025 accredited / GLP certified, please reference individual documents / chapters and submit corresponding objective evidence for review to verify that the test method is validated and the test results therefore can be considered as valid test data (e.g. equipment qualification protocol, equipment qualification report, test method validation protocol, test method validation report as well as work instruction for sample preparation, analytical method, test instruction, and data analysis effective at the time of testing, etc.). The objective evidence shall cover relevant test methods valid at the time the corresponding analytical method was carried out. Note that a separate assessment of the test method validation documentation might apply.

| 5.5 Testing in internal laboratory – if tests of conformity documentation have been performed in internal test laboratory | |
|---|---|
| <p>Internal laboratory has been used for conformity testing mentioned in section 5.</p> | <p><input type="checkbox"/> Yes, <i>please fill this table</i></p> <p><input type="checkbox"/> No</p> |



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|---|--|
| <p>Tests performed in internal laboratory</p> | <p><input type="checkbox"/> Testing of Cleaning efficacy</p> <p><input type="checkbox"/> Testing of Disinfection efficacy</p> <p><input type="checkbox"/> Testing of Sterilization efficacy</p> <p><input type="checkbox"/> Life cycle testing</p> <p><input type="checkbox"/> ...</p> <p><i>If more than one box is checked, please copy, and fill below boxes for each performed test.</i></p> |
| <p>Have validated test methods been applied?</p> | <p><input type="checkbox"/> Yes</p> <p><i>Validation protocol justifies sample size of test items, sample preparation, acceptance criteria. Please provide test method validation plan and report.</i></p> <p><i>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.</i></p> |
| <p><u>Is a summarizing qualification report available of used test equipment?</u></p> <p>Refer to EN ISO 17665-1/ EN ISO 13060 and EN 285</p> | <p><i>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.</i></p> <p><input type="checkbox"/> Yes</p> |



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6. IMPACT OF (RE-)PROCESSING ON THE MEDICAL DEVICE LIFETIME

Note: Please replace *italic text* with respective information
Explanation: This section shall provide a rationale why the performed lifecycle simulation testing is appropriated and cover the entire lifetime.

| 6.1 Lifetime data - impact of (re-)processing | |
|--|--|
| How is the information in the IFU provided when the device should no longer be used? | <div><input type="checkbox"/> signs of material degradation [X, p.y] (Further referred as unlimited lifecycle)</div> <div><input type="checkbox"/> the maximum number of allowable reuses</div> <p><i>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.</i></p> <p><i>More than two observation time points are considered necessary to establish biocompatibility and functional safety with unlimited lifetime.</i></p> |
| Rationale for lifecycle simulation approach: | <p>Documented in</p> <p><i>Please add a short summary</i></p> <p><i>For representative reprocessing procedures, please address differences in processing parameters, at least temperature, time, detergent type and concentration, mechanical impact (brushing).</i></p> <p><i>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.</i></p> |

Explanation: This section is to provide evidence that the device fulfils the requirements for quality, performance, and safety throughout its entire lifetime.

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Explanation: This section is to provide evidence that the device fulfils the requirements for biological safety throughout its entire lifetime.

| 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? | <div><input type="checkbox"/> Yes, documented in</div> <div><i>Please add a short summary</i> <i>Please add a short summary</i> <i>Evaluation includes both degradation of material(s) and accumulation of processing aids.</i> <i>It should be demonstrated that the biocompatibility of the device is not expected to be impaired by the described (re-)processing procedure.</i> <i>The maximum allowed/expected number of full (re-)processing cycles (cleaning/ disinfection/sterilization) during the device's life cycle should be considered.</i> <i>The risk of material degradation and accumulation of processing agent residues has to be considered.</i></div> |
| Rationale in case of equivalence approach (device under assessment vs tested device): | <div>Documented in</div> <div><i>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).</i></div> |



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| <p>Has the risk of endotoxins been addressed in relation to respective body contact?</p> | <p>Is required water quality defined in IFU for final rinse step(s):</p> <p><input type="checkbox"/> Yes, documented in</p> <p><i>Please specify the water quality below</i></p> <p>Is a risk assessment of an appropriate water quality available in the risk management file?</p> <p><input type="checkbox"/> Yes, documented in</p> <p><i>Please paste justification on risk acceptance below.</i></p> <p><i>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.</i></p> |
|--|--|



Client Checklist Instructions for Reprocessing

7. RISK OF PRION TRANSMISSION OF (V)CJD THROUGH MEDICAL DEVICE

This section is only applicable for medical with contact to the central nerve system per intended use.

Note: Please replace *italic text* with respective information

| 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? | <p><i>Risk analysis including literature research regarding current state of the art for decontamination procedures.</i></p> <p><i>Risk assessment and mitigation measures following considerations in Annex 7 KRINKO/BfArM 2012 guidance.</i></p> <p><i>please describe [X; p.y]</i></p> |
| Does the IFU contain a statement to follow country specific requirements? | <input type="checkbox"/> Yes, documented in |
| Does the IFU contain at least two partially prion inactivating/ decontaminating steps? | <p><i>Appropriate measures to prevent drying or fixation of contamination.</i></p> <p><i>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)</i></p> <input type="checkbox"/> Yes, documented in <input type="checkbox"/> No, <i>please justify:</i> |
| In vitro and in vivo (literature) studies to substantiate efficacy of described detergent and sterilization step are provided: | <input type="checkbox"/> Yes, documented in |



Client Checklist Instructions for Reprocessing

Regulatory
release by client:

*Please sign the document so
the provided rationales and
data herein can be officially
used by the reviewer*

xxxx-xx-xx

Date

Signature

Name

Name of Legal Manufacturer