This checklist is **ONLY** intended for use with *re-processable medical devices* applying H2O2 sterilization. Please use the other respective checklists for H2O2 terminally sterilized devices ([MED\_T\_09.81](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=208226)) or using other / non-standard sterilization methods ([MED\_T\_09.80](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=208224)). Please request a current copy from your TÜV SÜD Product Service primary contact.

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| **Application ID (as it appears in the application form / change notification form)** |
|  |

* *[X]* in this document: indicates a document to be named including page number - submitted for evidence. Grey guidance text may be replaced/deleted.
* In case of a Change Notification, please only fill in the applicable sections

# Short Product Description relevant for H2O2 Gas Plasma Sterilization

*Note: Please replace grey italic text below with respective information*

|  |
| --- |
| **Short description incl. picture of the device** - in case of changes, as applicable |
| Description of the device as far as relevant for sterilization (pictures for clearer understanding):*To be included**Product Schematic and / or Photo of product, size, material, Intended Use / Intended Purpose according to IFU (total application duration, body contact, implantable, patient group), Packaging description, Picture*Variants under assessment: *To be added**Product variants (e.g. Same product in different SBS, Different products or product variants in same SBS)**Description of the Sterile Barrier System Specifications used at sterilization.** *What is the representative / worst-case SBS for the product under assessment?*
 |

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| **Manufacturing facility and Certification status of the applicable sterilization sites / facilities** |
| *(Product) Manufacturing site(s) to be named* | *Please provide the applicable QMS Certificate 13485 of all applicable manufacturing site(s), if not already listed on the certificate.* |
| *Sterilization site / Validation contractor to be named where the sterilization study was executed* | *Please provide the applicable QMS Certificate 13485 of the used sterilization site**In case of identical laboratory subcontractor (e.g. residual analysis, microbial testing) please additionally provide ISO 17025 certificate including respective scope.* |
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| **External laboratories if used for sterilization validation and certification status of the laboratory** |
| *Name of the laboratory* | *Please name the test done by these laboratory (e.g. Microbiology BI testing, Sterility testing, Bioburden, Residuals). Please provide the applicable QMS Accreditation Certificate (e.g. ISO 17025 or GLP)*  |
| *Name of the laboratory* | *Please name the test done by the laboratory (e.g. Microbiology BI testing, Sterility testing, Bioburden, Residuals). Please provide the applicable QMS Accreditation Certificate (e.g. ISO 17025 or GLP)* |
|  |  |

# Production related Information

## Used Hardware Specifications

*Note: Please replace grey italic text below with respective information. Please add additional lines if required.*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Equipment including Identifier (e.g. int. ID/ serial number & software revision)** | **Site / Location** | **Applicable cycle operated by the equipment for the device in question** | **Typical load configuration** | **Usable chamber volume in m3** | **All sensors / measurement devices (internal + external sensors, dataloggers for validation) are calibrated** |
| *e.g. Super H2O2 Plasma* | *Inhouse or external source* | *Please name the cycle and Version/ Revision of cycle / Software revision**e.g. FAST & CLEAN**please list ALL cycles that can be used together with the product and are listed in the IFU.* | *e.g. Flexible Endoscope / Central Sterilization mixed load* | *5,4* | [ ]  Yes[ ]  No |
|  |  |  |  |  |  |

*Notes:*

* *Sensor calibration and equipment maintenance need to cover all critical sensors, e.g. optical / spectral detector for H2O2 as in-process monitor.*
* *Sterilizer equipment used for the validation must be CE certified by a European Notified Body and equipment must be available on the European Market.*

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| **Sterilizing agent definition** |
| *Clear identifier, e.g.**H2O2 prefilled cartridge* | *Further details on the sterilizing agent presentation: Half-Dose cartridge, Booster, 3rd party cartridge, fill volume, sample picture, REF Code or order code from supplier, other unique identifier, certificate of conformity or certificate of analysis**In case during validation the H2O2 is manually injected (e.g. by syringe) into the process chamber, please provide above data for the separately sourced H2O2 bottle and how the H2O2 is considered to be equal / comparable to the routine H2O2 in cartridges.**Above information may be used as guidance and not each individual point may be available for the individual submission.* |
|  |  |

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| **Accessories & Components as part of the validation and intended routine (IFU) processing** |
| *Please list all accessories and components that are to be used in preparation and/or inside the sterilization chamber for the validation activities and also for intended routine sterilization. These shall be listed in the IFU so that the end-user is able to follow the validated (routine) process.** *ExtraDeep Instrument Tray*
* *CompatibleTRAY Instrument Tray*
* *SuperFoil Sterilization Wrap*
* *Ultra PRECISE Chemical indicator Tape*
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| **Biological Indicator (BI) / Process Challenging Device (PCD) description** |
| *Minimum expected level of information:** *Detailed description of the BI (carrier material, dimensions, microorganism, population, D-Value (H2O2), survival/kill window, dose/response characteristics, adherence to EN ISO 11138-1, Certificate of Analysis, Certificate of Compliance)In case it is deviated from the standard microorganism Geobacillus stearothermophilus, a full investigation study (including scientific data) needs to be provided to demonstrate equal or higher resistance.If the biological indicator is not sourced from a certified supplier (e.g. manufactured by internal microbiology lab), then a full design documentation of the BI manufacturing process needs to be added to the documentation or separately covered by an (supplier) audit of this manufacturing process.*
* *Detailed description of the PCD (picture / drawing, placement of BI inside PCD, inoculation with spore suspension)*
* *Is the used ePCD available in the market to the commercial end-user? If not, how is the correlation between the publicly available ePCD (for routine release) to the custom ePCD within this validation achieved?*
 |

## Cycle Specification

*Note: Please replace grey italic text below with respective information for inhouse and/or outsourced processes.*

**Please paste copy of the cycle specification used for *routine* sterilization (IFU):**

|  |
| --- |
| *Please paste or reference [X] cycle specification here**In case different parameters are used for the validation cycle please detail the differences including a rationale for doing so (see also section 2.4. for validation cycle specifications)**In case only pre-defined sterilization programs / cycles can be selected by the end-user, please provide a rationale and reference to the cycle descriptions in the equipment manufacturer’s manual.* |

## Basic Validation Data

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

|  |  |
| --- | --- |
| Validation Method | *Please specify which approach is used for the sterilization validation:*[ ]   Overkill half cycle / partial cycle approach (EN ISO 14937 Annex D / Approach 3)[ ]   BI and (simulated) bioburden (EN ISO 14937 Annex C / Approach 2)[ ]   (Simulated) Bioburden (EN ISO14937 Annex B / Approach 1)[ ]   Other: *Please specify and add rationale for not using a standardized approach* |

## MPQ

*Note: Please replace grey italic text with respective information for inhouse and outsourced processes. Please add additional lines if required.*

**Please paste copy of the cycle specification used at *validation* of sterilization MPQ (e.g. half-cycle / partial cycle):**

|  |
| --- |
| *Please paste here. Cycle record summaries are documented in [X]**If identical to routine cycle as described / referenced in section 2.2, please specify.* |

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| **MPQ Processing - Microbial Performance Qualification** |
| Worst-case sterilizer conditions met? | *Please explain, how the worst-case sterilizer process limits have been challenged (e.g. using H2O2 cartridge at end-of-shelf-life, highest tolerable process pressure, lowest plasma power). Please only consider parameters, that are changeable by the equipment end-user. If pre-defined cycle programs & parameters are unchangeable by the end-user only maximum possible load configuration is considered relevant.**This ensures that the sterilizer equipment, operating at the lower process limits, is still capable of achieving an SAL<10-6 in the chosen cycle for the device-under-test.* |
| Placement scheme of BI and/or PCD within the load and in/on the actual device | *Please provide detailed information where the BI / spore inoculation / PCD placement in or on the medical device is done, including a rationale (e.g. longest lumen, difficult to reach crevice, high absorbent material, high surface roughness, materials that catalytically dissociate H2O2 on the surface, etc.)**Additionally, please provide the placement of BI/PCD within the chamber load to resemble representative routine conditions (load release).* |
| BI results including culture conditions and time between end of cycle and BI testing | [ ]  BI results including culture conditions and time between end of cycle and start of BI incubation is documented in *[X]* |
| Confirm resistance hierarchy from least resistant (natural product bioburden) < IPCD <= ePCD (most resistant) | [ ]   sublethal / reduced cycle for BI resistance was performed and is documented in [X][ ]  Data on the relationship of the resistance between ePCD, iPCD / worst-case product and natural bioburden is provided and is documented in [X].*Since natural product bioburden can only be simulated for re-usable devices, this is usually achieved e.g., by direct inoculation. In case another method is used please describe and justify in detail.**A link to a publicly available ePCD needs to be established, to confirm that inoculation of the device (iPCD) is at least comparable or higher in resistance than a commercially available ePCD for H2O2 processes that may be used e.g. by healthcare facilities.* |
| Material-dependent microbial resistance | *Please state how material-dependent microbial resistance is covered during the validation activity? It is well-known, that different material surfaces exhibit large variability in microbial inactivation time. Please consider the following** *What would be the worst-case material (slowest to achieve inactivation) with respect to the sterilizing agent?*
* *Is this material covered / included by the validation activity?*
* *How is the material covered (e.g. direct inoculation on the actual device, BI using this material as carrier material, representative worst-case inoculated dummy material, etc.)*
* *Has this been pre-established by the equipment manufacturer in an internal study that could be referenced / audited?*
 |

## PPQ Physical Performance Qualification

*Note: Please replace grey italic text below with respective information for inhouse and outsourced processes. Please add additional lines if required.*

|  |  |
| --- | --- |
| Please specify the validation load configuration: | Please specify the load used during validation at PPQ and MPQ:*Please consider min and max configuration in case of widely varying load configurations, such as re-processable devices and instruments in a healthcare setting, provide scheme of total load), number of BIs, number of Sensors (T and rH), scheme of position of BIs, total load volume, density, amount of adsorptive material. The data is documented in [X]* |
| Please specify which product(s) was/were used in the load: | The product is the same as in section 1[ ]  yes [ ]  no *– Please provide a description and justification*  |

*Note:*

* Please include additional information on how the used load / dummy load is representative for the expected routine load configuration.

**Please assure that the following phases and process values and tolerances are part of the overall validation requirement.**

*Please be aware that the below parameter-list is not exhaustive to cover the cycle and load types but are often omitted causing deficiencies and are therefore specifically requested.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Phase** | **Acceptance criteria: values and tolerance** | **Results measured and within tolerances****EN ISO 14937:2009 item 9.4.4** | **Comments if needed** |
| Total Cycle time | *Min / Max running time* | *(best provided in a table showing setpoint/tolerances against measured data)* |  |
| Chamber wall temperature | *Min / Max. temperature* | *See above* |  |
| Diffusion time | *Min / Max diffusion time of the sterilizing agent* | *See above* |  |
| Plasma time | *Min / Max. plasma running time* | *See above* |  |
| Plasma pressure | *Min / Max. allowed pressure during the plasma phase* | *See above* |  |
| Plasma power | *Min / Max. allowed plasma power* | *See above* |  |
| No. of injections per cycle | *Exact number of H2O2 injections into the chamber* | *See above* |  |
| Estimated H2O2 concentration within the sterilizer chamber at dwell phase | *~ xxx   mg/liter* | *See above* |  |
| Total H2O2 Injection volume for all injections within one full cycle | *~ 5 x 10 g / ml* | *See above* |  |

*Note:*

* Please provide above table for each cycle that is to be considered for reprocessing and is specified within the IFU. In this case, please copy above table and fill out the fields for each individual cycle.

# H2O2 Residuals after maximum number of reprocessing cycles(EN ISO 10993-17)

*Note: Please replace grey italic text below with respective information for inhouse and outsourced processes. Please add additional lines if required.*

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  | **Comments** |
| Is a rationale provided for selection of representative sample(s) | [ ]  Yes, documented in *[X]* | [ ]  No, *please justify*: | *To be added if any*  |
| Are the applicable allowable limits for H2O2 residuals specified and confirmed for the product in question considering the patient population provided (e.g. paediatric application implies lower body mass)e.g. by TCL, TI, TTC,  | [ ]  Yes, documented in *[x]* | [ ]  No, *please justify:* | *To be added if any*  |
| Results and Test method provided and validated?*Method qualification can be supported by ISO 17025 certificate of an accredited laboratory.* | [ ]  Yes, documented in *[x]* | [ ]  No, *please justify:* | *To be added if any*  |

# Additional Reprocessing-related topics

*Note: Please replace grey italic text below with respective information for inhouse and/or outsourced processes. Some information may be redundant to the reprocessing assessment. In this case please also provide the Checklist “Reprocessing” and reference to the respective sections therein.*

|  |  |
| --- | --- |
|  |  |
| List of all allowed terminal sterilization methods as stated in the IFU | *Including also the cycle specifier, e.g. MegaPlas , cycle “Overkill”* |
| Maximum allowable number of reuses / number of reprocessing cycles | *Please provide a reference [X] to the investigation document, confirming the maximum number of re-uses / re-sterilization cycles before product functionality, biocompatibility, H2O2 residual accumulation or other safety and performance topics can longer be ensured.* |
| Do the re-processing instruction in the IFU contain detailed information on how to prepare the device and load to adequately sterilize using H2O2 gas plasma? | *Please reference the respective section in the IFU [X] for further review.* |
| Was product functionality verified at the end-of-service-life after maximum number of re-processing cycles | *Please reference here [X] the respective report, describing the executed tests and test results.* |
| **Biocompatibility endpoint at the end of service life** | *Please reference [X] the biological test report to exclude accumulative effect of the sterilizing agent or other residues.* |
| Have the effects of reprocessing (particularly the sterilization as described in IFU) on biocompatibility been evaluated, taking into account 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  |
| Rationale in case of equivalence approach (Why is the candidate sterilizer equivalent to the claimed sterilizer in the IFU?) | documented in *[X,p.y]*   |

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| **Release by client:** |
|  |  |  |  |  |
| **Date** |   |  Signature |  | Full Name |
|  |  |  |  |  |
|  |   |   |  | Name of Legal Manufacturer |

*Note as to the signature’s relevance: If this document is officially signed, the provided rationales and data herein can be officially used by the reviewer. Otherwise, only the referenced documents can be used as evidence.*