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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 text (for guidance) may be replaced/deleted.
* In case of a Change Notification, please only fill in the applicable sections.

# Short Product Description relevant for Moist Heat Sterilization

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

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| **Short description incl. picture of the device** - in case of changes, as far as relevant |
| Description of the device as far as relevant for sterilization (pictures for clearer understanding):  *To be added*  *Product Schematic and/or Photo of product*  Variants under assessment:  *To be added*  *Product variants (e.g. Same product in different Sterile Barrier System (SBS), multiple products in same SBS)*  *Description of the Sterile Barrier System specifications used at sterilization*  **Product families -** *if applied*  *Please explain the rationale for sterilization product families* |

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| **Has this product previously been assessed by TÜV SÜD Product Service?** |
| *If yes, please provide 10-digit order no. usually starting with 071xxxxxxx, or equivalent traceable information* |

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| **Manufacturing facility and certification status of the applicable sterilization sites / facilities** | |
| *Manufacturing site to be named* | *Please provide the applicable QMS Certificate 13485 of the used sterilization site* |
| *Sterilization site to be named* | *Please provide the applicable QMS Certificate 13485 of the used sterilization site* |

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| **External laboratories (if used for sterilization validation and routine and certification status of the laboratory)** | |
| *Name of the laboratory* | *Please name the test done by the laboratory (e.g. microbiology BI testing, sterility testing, bioburden). Please provide the applicable 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). Please provide the applicable Accreditation Certificate (e.g. ISO 17025 or GLP)* |

# Production related Information

## Equipment Specification

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

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| **Equipment including Identifier (e.g. int. ID/ serial number)** | **Site** | **Applicable cycle operated by the equipment for the device in question** | **Type of cycle** | **Usable chamber volume in m3** | **All sensors / measurement devices (internal + external sensors, dataloggers for validation) are calibrated (statement sufficient)** |
| *e.g. Preconditioning (if applicable)* | *Inhouse or external source* | *Please name the cycle ID / version / revision* |  |  | Yes  No |
| *e.g. Sterilizer A10* | *Inhouse or external source* | *Please name the cycle ID / version / revision* | *e.g. (saturated steam, gravity displacement)* |  | Yes  No |
| *e.g. Autoclave 1* | *inhouse* | *e.g. program 3rev1* | *saturated steam* | *5,4* | Yes  No |
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| *Is equipment equivalency claimed?* | Yes, - justification is documented in *[x]*  No  *Please name the equipment that is equivalent* |

## If Applicable: Cleaning of Product in Manufacturing before Sterilization

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

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| **Cleaning process description** | |
| Are parameters that are specific for the medical device defined, such as specific load configuration, positioning, connection, accessories, process chemicals, pressures or temperature limit(s)? | yes documented in *[X,p.y]*   no *please justify:*  Please describe the cleaning cycle: |
| Were cleaning studies performed at validation of the used equipment to approve the respective cleaning process step is able to deliver appropriate performance? | yes documented in *[X,p.y]*   no *please justify:* |
| Are process residuals within limits?  (Endotoxins, particles, org. inorganic contaminations, detergent residues with adequate risk related to the device and body contact) | yes documented in *[X,p.y]*   no *please justify:* |
| Are preventive maintenance (e.g. exchange of cleaning media and or equipment) operations defined including frequencies. | yes documented in *[X,p.y]*   no *please justify:* |

## If Applicable: Disinfection of Product in Manufacturing before Sterilization

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

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| **Disinfection process description** | |
| Are parameters that are specific for the medical device defined, such as specific load configuration, positioning, connection, accessories, process chemicals, pressures or temperature limit(s)? | yes documented in *[X,p.y]*   no *please justify:*  Please describe the disinfection cycle: |
| Were disinfection studies performed at validation of the used equipment to approve the respective disinfection process step is able to deliver appropriate performance? | yes documented in *[X,p.y]*   no *please justify:* |
| Are process residuals within limits?  (Endotoxins, particles, org. inorganic contaminations, disinfectant residues with adequate risk related to the device and body contact) | yes documented in *[X,p.y]*   no *please justify:* |
| Are preventive maintenance (e.g. exchange of disinfection media and or equipment) operations defined including frequencies. | yes documented in *[X,p.y]*   no *please justify:* |

## If Applicable: Clean Room Control / Validation

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

*This section is applicable to be filled in case of first evaluation of the clean room or in case of changes occurred to the clean room (e.g. new clean room, modification of the cleanroom and changes to the setup of the points listed in the table below).*

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| Cleanroom | *Please identify the cleanroom where the manufacturing takes place* |
| Are action and alert limits set appropriately for the subsequent product bioburden in cleanroom processes? | yes documented in *[X,p.y]*   no *please justify:*  Acceptance criteria:  Airborne particles [*size*]: particles/m3  Airborne microbiological contamination: cfu/m3  Surface microbiological contamination: cfu/m2  Product bioburden: cfu *(type – spores, fungi, anaerobe, bacteria)* |
| Monitoring points are defined for the above mentioned measurements | yes documented in *[X,p.y]*   no *please justify* |
| Was IQ, OQ, PQ of the cleanroom successfully established? | yes documented in *[X,p.y]*   no *please justify:* |
| Is all measuring equipment in a calibrated state? | yes documented in *[X,p.y]*   no *please justify:* |
| Are utilities and media under surveillance | yes documented in *[X,p.y]*   no *please justify:*  *Please specify what media and related acceptance criteria are defined.*  *e.g. for water, compressed air…* |
| Are environmental parameters defined | yes documented in *[X,p.y]*   no *please justify:*  Please specify where applicable:  Temperature:  Humidity:  Pressure gradient:  Air change rates: |

## Cycle Specification

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

*Please add additional lines if required.*

|  |  |
| --- | --- |
| Type of moist heat media: | *Air steam mixture, prevac cycle, hot water, hot water sprinkling, submersion* |
| Load configuration | Dedicated load  *1 product only / product configuration is fixed in number and location within chamber*    Mixed load  *different products allowed*  Please add information on min/max load variation, if applicable: |

**Please paste a copy of the cycle specification used at routine sterilization:**

|  |
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| *Please paste here* |

## Basic Validation Development Data

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

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| Validation method | Overkill    BI and bioburden    Bioburden    USP / Pharm. Eur. 121°C 15 min cycle    F0: *Please submit the calculation details and start and end temperature of the count and the qualification of the F0 calculation*    Other: *Please specify and add rationale for not using a standardized method* |
| Revalidation criteria | By what events a new validation is triggered - *is documented in [X]*  *Please provide the review interval of data, and interval of time till repeat MPQ / PPQ studies are performed. When was the last MPQ, PPQ study executed?*  *What are further criteria that trigger a revalidation study (e.g. Product changes…)?*    Validation protocol for the actual sterilization cycle including acceptance criteria - *is documented in [X]* |

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| Functional verification test: Was product tested for conformity after sterilization? | Yes, *please add number of sterilization cycle used at verification*  No, *please justify*: |

## MPQ

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| **Validation MPQ** | |
| Biological indicators (if applicable) | Specification of BI used is provided and documented in *[x]*  *Placement scheme and number of BIs or spore suspension, BI certificate* |
| IPCD/EPCD (if applicable): | Drawings or pictures including place of inoculation position is provided in the submission *[documented in X]* |
| Data on the relationship of the resistance between EPCD, IPCD, worst-case Products, natural Bioburden are provided *documented in [X]* |
| Bioburden | *Please specify the bioburden levels/limits e.g. in respect to bacteria, yeast/molds and anaerobic bacteria (as applicable)*  *Please provide the bioburden trending data as a summary of the last year, if not available at least for the validation LOT* |
| Is endotoxin testing applicable for the device under assessment? | no   yes *Please specify the method and related results. The data is documented in [X].* |

## PPQ Physical Performance Qualification

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

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| Please specify the validation load configuration: | *Please specify the load used during validation at PPQ and MPQ:*  *Min and max configuration, scheme of total load, number of BIs, number of sensors, scheme of position of BIs, T and rH sensors* |
| Please specify which product was used in the load: | The product is the same as in section 1   yes [X,p.y]    no *– Please provide a description and justification* |

**Please paste copy of the cycle specification used at validation of sterilization**

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| *Please paste here. Cycle record summaries are documented in [X]* |

**Please assure that the following phases and cycle setpoints and tolerances are part of the overall validation requirements.**

Please be aware that the below parameters are not exhaustive to cover the cycle and load types, but are often omitted.

|  |  |  |
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| **Phase** | **Target values and tolerances** | **Comments if needed** |
| vacuum | *to be added* |  |
|  | *how many vacuum pulls* |  |
| steam injection condition/time | *to be added* |  |
|  | *how many steam pulses* |  |
| plateau phase | *to be added* |  |
| cooldown | *to be added* |  |
| drying time | *to be added* |  |

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| The achievement of all cycle specification data and parameters above is verified during validation: | Yes, documented in *[X]*  *(best provided in a table showing setpoint/tolerances against measured data)*  No, *please justify:* |

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| Please indicate if and what heat distribution and heat penetration data was collected in relation to the product load in question | Yes. Heat distribution and heat penetration to detect cold and hot spot in the load was executed and is documented in *[X].*  No. Heat distribution and heat penetration investigation in the load was not executed.  Justification:  *Please name the applied product load used at this study* |
| Placement scheme and rationale of thermal probes amount provided? (for PPQ as well if applicable for MPQ) | Yes, documented in *[x]*  No, *please justify:* |
| The derived “worst case” (cold/hot -spot) measurements for cycle control are done in a defined documented position and are justified by measured data | Yes, the rationale is documented in *[x].*  The position is:  *(please name the position in the chamber/load)*  No, *please justify:* |

# Routine Processing

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

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| **Routine Processing** | | |
| Routine release | BI release    Parametric release  *Placement of reference sensor(s)* | |
| Routine cycle control and regulation is achieved by: | Chamber fixed internal sensors only  Product integrated sensors (e.g. simulated product with integrated sensor) | |
| Placement scheme and number of BIs, BI certificate provided? | Release criteria *[documented in X]:*  *e.g. comparison of validation plot to routine plot, BI negative, pressure on plateau OK, dwell time OK, pulses achieved, F0 achieved, Bowie Dick Test, pre-heat, vacuum test* | |
| Bioburden Levels/Limits (Alert, Action): | Alert level/limit:  Action level/limit: | |
| Placement scheme and rationale of thermal probes amount provided? | Yes, documented in *[x]*  No, *please justify:* | |
| Bowie Dick test (steam penetration test) | | Yes: *frequency to be added*  No |
| Vacuum test | | Yes: *frequency to be added*  No |

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| **Release by client:** |  |  |  |
|  | Date | Signature | 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.*