*[X]* in this document:indicates a document to be named including page number - submitted for evidence

For multiple packaging variants multiple checklists may be applied to increase the transparency of the data. Redundant data can be omitted in this case focussing to the differences.

# Short product description relevant for sterile packaging validation

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

|  |
| --- |
| **Short description incl. picture of the device** - in case of changes, as far as relevant |
| Description of the device as far as relevant for packaging (pictures for clearer understanding):  *To be added*  *Product schematic and / or photo of product, size, please provide a scheme or picture of packed product in its final sterile barrier (including sizes), packaging material, intended use / intended purpose according to IFU instructions for use), packaging description, picture*  Variants under assessment:  *To be added*  *Product variants (e.g. same product in different SBS (Sterile Barrier System), multiple products in same SBS)*  *Description of the SBS specifications*  Was this product previously assessed by TÜV SÜD?   Yes, *please list, if any previous TÜV approval exist related to the packaging in the scope of the actual product assessment to ensure that there are no open items.*   No |

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| **Packaging type** | **Amount of units in the next lower packaging type** | **Used packaging**  **material** | **Supplier** | **Material number** | **Supplier certificate** |
| sterile barrier system, SBS   Pouch   Blister   Other:  *Please specify*  ­­­­­­­­­­­­­­Documented in *[X]* | - | Top web:  *Please specify the material*  Bottom web:  *Please specify the material*  Dimension:  *Please specify length X width (X height) in e.g. mm* | Preformed barrier supplier:  *Please name the supplier*   Material Supplier:  *Please name the supplier* | *Please specify the internal material number*  What is the specification of the seal width and seal strength:  *Please specify*  Data is documented in *[X]* | The certificate(s) of the supplier(s) of the packaging material (incl. biocompatibility data for the material in contact with the device) is/are documented in *[X]* |
| protective packaging1   Pouch   Blister   Other:  *Please specify*  Documented in *[X]* | *Please specify how many sterile barrier packed products are in the protective packaging* | Top web:  *Please specify the material*  Bottom web:  *Please specify the material*  Dimension:  *Please specify length X width (X height) in e.g. mm* | Preformed barrier supplier:  *Please name the supplier*   Material Supplier:  *Please name the supplier* | *Please specify the internal material number*  Data is documented in *[X]* | The certificate(s) of the supplier(s) of the packaging material (incl. biocompatibility data for the material in contact with the device) is/are documented in *[X]* |
| protective packaging 2  Shelf box  Documented in *[X]* | *Please specify how many secondary barrier packed products are in the shelf box* | *Please specify the material*  Dimension:  *Please specify length X width (X height) in e.g. mm* | *Please name the supplier* | *Please specify the internal material number* |  |
| protective packaging 3  Transportation Package  Documented in *[X]* | *Please specify how many shelf boxes packed products are in the transport package* | *Please specify the material*  Dimension:  *Please specify length X width (X height) in e.g. mm* | *Please name the supplier* | *Please specify the internal material number* |  |
| … |  | *…* | *….* | *….* |  |

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| **Manufacturing facility and certification status of the applicable packaging sites / facilities** | | |
| *Manufacturing site to be named (device) including sterile packaging* | *Please provide the applicable QMS certificate ISO 13485 of the used packaging site* | |
| *Manufacturing site to be named (device) including sterile packaging* | *Please provide the applicable QMS certificate ISO 13485 of the used packaging site* | |
| *…* | *…* |  |

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| **External laboratories if used for packaging validation and certification status of the laboratory** | |
| *Name of the laboratory* | *Please name the test done by the laboratory (e.g. testing of seal strength, integrity, transport simulation, ageing, microbial barrier properties, visual control …). Please provide the applicable QMS accreditation certificate (e.g. ISO 17025 or GLP) including annex indicating the accreditation scope.* |
| *Name of the laboratory* | *Please name the test done by the laboratory (e.g. testing of seal strength, integrity, transport simulation, ageing, microbial barrier properties, visual control …). Please provide the applicable QMS accreditation certificate (e.g. ISO 17025 or GLP) including annex indicating the accreditation scope.* |
| *…* | *…* |

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| **General packaging design** | |
| Please indicate how the products are shipped | *Please specify the transport packaging like pallet, shipper. Please declare the typical transportation route: e.g. Air, Truck, Ship…* |
| Was a preformed SBS used? | Yes, *please specify on how these pre-formed SBS assure their specification on seal strength, seal width and integrity? Please specify – what type of test method (standard) or reference was used. Preformed SBS may be tray/blister, pouches or any partially assembled packaging that will be filled and finally sealed/closed.*  The respective data is documented in *[X]*  No |
| Please indicate what side of the packaging is sealed in the packaging process under review. | *Please describe on what side the SBS is sealed during the sealing process, e.g. bottom seam not intended to be opened.*  The respective data is documented in *[X]* |
| What minimum seal strength did you specify? | *Please specify the minimum seal strength necessary to open the packaging*  The respective data is documented in *[X]* |
| By what means is the aseptic presentation of the product ensured? | *Please specify how it is assured that the above mentioned seal strength is adequate – what type of test method (standard) or reference was used. Please also specify what usability study data or what studies were performed to show aseptic presentation and the aspect of identification of breached SBS by inspection immediately before aseptic presentation.*  The respective data is documented in *[X]* |
| By what means is the SBS indicated? | *Please specify – by what means can the SBS be distinguished from the protective packaging.*  The respective data is documented in *[X]* |
| How is biocompatibility of the packaging material ensured? | *Please specify – what type of test method (standard) or reference was used*  The respective data is documented in *[X]* |
| By what data are the microbial barrier properties in case of a porous SBS material assured? | *Please specify – what type of test method (standard) or reference was used*  The respective data is documented in *[X]* |
| What is the rationale for the applied test methods and how were validated test methods ensured? | *Please specify the applicable test methods (standard) and intentions what is to be shown by the chosen test methods. How is it assured that these applied test methods are in validated state?* |
| What is the rationale for the number of samples taken for each of the tests? | *Please provide the statistical approach by which it is assured that the whole process (including OQ, PQ) is covered by the samples taken – considering to keep the Sterility Assurance Level of 10-6*  The respective data is documented in *[X]* |
| In case for the testing strategy a worst case representative packaging was used please indicate this for the topics: | yes for sealing   yes for forming   yes for labeling   yes for packaging performance testing (shipping/transport validation)   yes for packaging stability testing (ageing/shelf life testing)   no |

# Production related Information

## Equipment Specification

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

In case of changes, as far as relevant.

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| --- | --- | --- | --- | --- | --- |
| **FORMING equipment** | **Equipment no./ID and tool ID** | **Process parameters**  **(routine settings)**  **Setpoint and tolerances** | **Process boundaries tested at OQ** | **Site** | **Equipment calibrated (statement sufficient)** |
| *Please indicate the type of packaging machine (Manufacturer, including the technology used – positive forming, negative forming, …) including number of cavities for forming*  Documented in *[X]* | *Please specify* | Please name all relevant parameters  *Forming Temperature: Please specify Forming Time: Please specify  Cooling Time: Please specify  Pressure: Please specify*  *Other:*  *Documented in [X]* | Please name all relevant parameters  *Forming Temperature: Please specify Forming Time: Please specify  Cooling Time: Please specify  Pressure: Please specify*  *Other:*  *Documented in [X]* | Inhouse  External supplier: *Please name*  Equipment was validated at place of production:  Yes  No, *please provide a rational* | Yes  No |
| *Please specify* | Please name all relevant parameters  *Forming Temperature: Please specify Forming Time: Please specify  Cooling Time: Please specify  Pressure: Please specify*  *Other:*  *Documented in [X]* | Please name all relevant parameters  *Forming Temperature: Please specify Forming Time: Please specify  Cooling Time: Please specify  Pressure: Please specify*  *Other:*  *Documented in [X]* | Inhouse  External supplier: *Please name*  Equipment was validated at place of production:  Yes  No, *please provide a rational* | Yes  No |
| … | *….* | … | … |  |  |
| **SEALING equipment for SBS** | **Equipment no./ID and tool ID** | **Process parameters**  **(routine settings)**  **Setpoint and tolerances** | **Process boundaries tested at OQ** | **Site** | **Equipment calibrated (statement sufficient)** |
| *Please indicate the type of packaging machine (Manufacturer, including the technology used – impulse heat sealer, ultrasound…) including number of cavities for sealing*  Documented in *[X]* | *Please specify* | Please name all relevant parameters  *Sealing Temperature: Please specify Sealing Time: Please specify  Cooling Time: Please specify  Pressure: Please specify*  *Other:*  *Documented in [X]* | Please name all relevant parameters  *Sealing Temperature: Please specify Sealing Time: Please specify  Cooling Time: Please specify  Pressure: Please specify*  *Other:*  *Documented in [X]* | Inhouse  External supplier: *Please name*  Equipment was validated at place of production:  Yes  No, *please provide a rational* | Yes  No |
|  | *Please specify* | Please name all relevant parameters  *Sealing Temperature: Please specify Sealing Time: Please specify  Cooling Time: Please specify  Pressure: Please specify*  *Other:*  *Documented in [X]* | Please name all relevant parameters  *Sealing Temperature: Please specify Sealing Time: Please specify  Cooling Time: Please specify  Pressure: Please specify*  *Other:*  *Documented in [X]* | Inhouse  External supplier: *Please name*  Equipment was validated at place of production:  Yes  No, *please provide a rational* | Yes  No |
| … | *….* | … | … |  |  |

## Packaging Process Validation

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

In case of changes, as far as relevant.

|  |  |
| --- | --- |
| Validation related procedures | Procedure to be part of the submission:  ☐  How new product will be added to a packaging process- *is documented in [X]*  ☐  When a new validation has to be done and what stages of validation has to address what type of measurements - *is documented in [X]*  ☐  How new equipment/process will be qualified/validated - *is documented in [X]*  ☐ What significant changes related to packaging and sterile packaging process will be notified to the Notified body - *is documented in [X]*  ☐ Validation protocol for the actual packaging process including acceptance criteria - *is documented in [X]* |

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| Description of the packaging process | *Please describe the sequence how the packaging is processed till the SBS is complete. E.g. what machines seals what packaging to establish the primary sterile barrier – how is the secondary barrier (if applicable) formed and sealed.*  The respective data is documented in *[X]* |
| **Process Validation PQ** | |
| Was the actual product under review used in PQ | Yes, the product was used  A simulated product was used, *please specify and provide a rational why the product is representative*  No, *please justify why no product was used at PQ – how is it assured that there is no interaction between product and SBS influencing the result.*  The respective data is documented in *[X]* |
| Were 3 production runs (nominal parameters) applied? | yes, documented in [X]   No, *please provide a rationale*  A statistical sound rationale for sample size is documented in [X] |

## Packaging System Performance Testing

Note: Please replace italic text with respective information.

In case of changes, as far as relevant.

|  |  |
| --- | --- |
| How are routine transport routes covered by the method of the performed transport simulation? | *Please specify the applicable distribution cycle at transport simulation and it`s relation to the real transport pathway of the product.*  The respective data is documented in *[X]* |
| How is it justified that worst-case SBS was tested in transport validation? | *Please specify the worst-case conditions for sealing and forming as well as sterilization applied. Please also describe if a worst-case representative product was simulated in the packaging.*  The respective data is documented in *[X]* |
| Was integrity of the whole SBS tested after transport simulation? | Yes  No, *please provide a rationale how SBS integrity after transport simulation is ensured.*  The respective data is documented in *[X]* |

## Packaging Stability Testing

Note: Please replace italic text. Please add additional lines if required.

In case of changes, as far as relevant.

|  |  |
| --- | --- |
| How are the claimed maximum storage conditions covered by the calculation of the accelerated aging time? | *Please specify the ageing conditions and respective ageing calculation in case of accelerated ageing*  The respective data is documented in *[X]* |
| Was integrity of the whole SBS tested after ageing? | yes   No, *please provide a rationale how SBS integrity after shelf life is ensured.*  The respective data is documented in *[X]* |
| How was the integrity and readability of the labelling system until point of use demonstrated? | *Please specify – what type of test method (standard) or reference was used*  The respective data and test results is documented in *[X]* |

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