



## Client Checklist Sterile Packaging

<b>Application ID (as it appears in the application form / change notification form)</b>

- [X] in this document indicates a document to be named including page number – submitted for evidence. Grey text (for guidance) may be replaced/deleted.
- 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.
- In case of a Change Notification, please only fill in the applicable sections. Please provide the latest full validation review / originating sterilization review project number (usually starting with 07xxxxx)
- 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).

- One product/product family, or product adoption, or process equivalence per checklist:
- 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 text of the template *italic text* prior to submission.**
- All documents referenced in this checklist shall be submitted and available for review. Please ensure that the document ID number / document title are consistent with the information given in the checklist. This includes also complete test or study protocols and reports to be submitted.
- Please ensure that we can only accept documents in English or German language.



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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. Short product description relevant for sterile packaging validation

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

Explanation: The intention of this section is to give a description of the medical device displaying relevant design characteristics for packaging and for traceability of device (family) under assessment related to a specific certificate.

#### 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*



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Has this product previously been assessed by TÜV SÜD Product Service?	
<input type="checkbox"/> Yes	Please provide 10-digit order no. usually starting with 071xxxxxx (or equivalent traceable information) related to the packaging in scope of the actual product assessment.
<input type="checkbox"/> No	

Manufacturing facility and certification status of the applicable sterilization sites / facilities	
Manufacturing site to be named (device) including sterile packaging	<p>Please provide the applicable QMS certificate ISO 13485 of the used packaging site</p> <p>The respective data is documented in [X]</p>
Manufacturing site to be named (device) including sterile packaging	<p>Please provide the applicable QMS certificate ISO 13485 of the used packaging site</p> <p>The respective data is documented in [X]</p>

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

External laboratories if used for packaging validation and certification status of the laboratory	
Name of the laboratory	<p>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.</p> <p>The respective data is documented in [X]</p>
Name of the laboratory	<p>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.</p> <p>The respective data is documented in [X]</p>



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### 2. Production related information

#### 2.1 General Packaging Design and Validation Approach

Explanation: Many different packaging designs with different functions are available on the market. In some instances, it is not always possible to clearly distinguish between the SBS and the protective packaging, or between the device and the packaging. The purpose of this section is to give an overview regarding the key characteristics of the SBS design, the validation strategy as well as regarding labelling and instructions for use (IFU) associated with the SBS. In addition, different methods for testing a specific packaging or material characteristic exists which may not be comparably appropriate for evaluating the specific characteristic. Therefore, a rationale for the selection of the applied tests on the packaging system is needed to follow the appropriateness of the test method.

Is a risk management process applicable to packaging systems and packaging processes established, implemented, documented and maintained?	<input type="checkbox"/> Yes    The respective data is documented in [X]  <input type="checkbox"/> No <i>Please provide a rationale how packaging related risks are kept under control</i>
Was a preformed SBS used?	<input type="checkbox"/> Yes <i>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.</i>  The respective data is documented in [X]  <input type="checkbox"/> No
Please indicate what side of the SBS is sealed in the sealing process under review.	<i>Please describe on what side the SBS is sealed during the sealing process, e.g. bottom seam not intended to be opened.</i>  The respective data is documented in [X]
What minimum seal strength did you specify?	<i>Please specify the minimum seal strength necessary to open the packaging.</i>  The respective data is documented in [X]



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By what means is the aseptic presentation of the product ensured?	<p><i>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.</i></p> <p>The respective data is documented in [X]</p>
By what means is the SBS indicated?	<p><i>Please specify – by what means can the SBS be distinguished from the protective packaging.</i></p> <p>The respective data is documented in [X]</p>
Does the instruction for use (IFU) include direction to inspect the SBS for breaches of packaging integrity prior to aseptic presentation?	<p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No <i>Please provide a justification</i></p> <p>The respective data is documented in [X]</p>
How is biocompatibility of the packaging material ensured?	<p><i>Please specify – what type of test method (standard) or reference was used</i></p> <p>The respective data is documented in [X]</p>
By what data are the microbial barrier properties of the SBS materials (top and bottom web) assured?	<p><i>Please specify – what type of test method (standard) or reference was used</i></p> <p>The respective data is documented in [X]</p>



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<p>What is the rationale for the applied test methods and how were validated test methods ensured?</p>	<p><i>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?</i></p>
<p>What is the rationale for the number of samples taken for each of the tests?</p>	<p><i>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 <math>10^{-6}</math></i></p> <p>The respective data is documented in [X]</p>
<p>In case for the testing strategy a worst case representative packaging was used please indicate this for the topics:</p>	<p><input type="checkbox"/> Yes, for sealing</p> <p><input type="checkbox"/> Yes, for forming</p> <p><input type="checkbox"/> Yes, for labeling</p>



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	<input type="checkbox"/> yes for packaging performance testing (shipping/transport validation)  <input type="checkbox"/> yes for packaging stability testing (ageing/shelf life testing)  <input type="checkbox"/> No
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### 2.2 Material Specification

Explanation: For terminally sterilized medical devices it is essential to clearly define the packaging system, which is the combination of the sterile barrier system (SBS) and the protective packaging.

It must be understandable which minimum packaging is specified as SBS that prevents ingress of microorganisms and allows for aseptic presentation of the product. Additionally, the protective packaging needs to be described to enable an understanding by which components a damage to the SBS and its content is prevented until point of use.

The intention of this section is the traceability of the packaging materials and packaging system configuration of the device (family) under assessment related to a specific certificate.

Packaging type	Amount of units in the next lower packaging type	Used packaging material	Supplier	Material number	Supplier certificate
Sterile barrier system (SBS) <input type="checkbox"/> Pouch <input type="checkbox"/> Blister <input type="checkbox"/> Other: <i>Please specify</i>  Documented in [X]	-	Top web: <i>Please specify the material</i>  Bottom web: <i>Please specify the material</i>  Dimension: <i>Please specify length X width (X height) in e.g. mm</i>	<input type="checkbox"/> Preformed barrier supplier: <i>Please name the supplier</i>  <input type="checkbox"/> Material supplier: <i>Please name the supplier</i>	<i>Please specify the internal material number</i>  What is the specification of the seal width and seal strength: <i>Please specify</i>  Data is documented in [X]	The certificat(s) of the supplier(s) of the packaging material is documented in [X]



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Protective packaging 1 <input type="checkbox"/> Pouch <input type="checkbox"/> Blister <input type="checkbox"/> Other  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	<input type="checkbox"/> Preformed barrier supplier: Please name the supplier  <input type="checkbox"/> Material supplier: Please name the supplier	Please specify the internal material number  Data is documented in [X]	The certificat(s) of the supplier(s) of the packaging material is 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 Transpotation 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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### 2.3 Equipment Specification

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

Explanation: The SBS design dictates the packaging processes to produce the SBS. The intention of this section is the traceability of equipment and critical process parameters used for sterile packaging of the device (family) under assessment related to a specific certificate.

FORMING 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)
<i>Please indicate the type of packaging machine (Manufacturer, including the technology used – positive forming, negative forming, ...) including number of cavities for forming</i>  Documented in [X]	<i>Please specify</i>	Please name all relevant parameters  <i>Forming Temperature: Please specify</i> <i>Forming Time: Please specify</i> <i>Cooling Time: Please specify</i> <i>Pressure: Please specify</i> <i>Other:</i>  Documented in [X]	Please name all relevant parameters  <i>Forming Temperature: Please specify</i> <i>Forming Time: Please specify</i> <i>Cooling Time: Please specify</i> <i>Pressure: Please specify</i> <i>Other:</i>  Documented in [X]	<input type="checkbox"/> Inhouse <input type="checkbox"/> External supplier: <i>Please name</i>  Equipment was validated at place of production:  <input type="checkbox"/> Yes <input type="checkbox"/> No <i>Please provide a rationale</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<i>Please specify</i>	Please name all relevant parameters  <i>Forming Temperature: Please specify</i> <i>Forming Time: Please specify</i> <i>Cooling Time: Please specify</i> <i>Pressure: Please specify</i> <i>Other:</i>  Documented in [X]	Please name all relevant parameters  <i>Forming Temperature: Please specify</i> <i>Forming Time: Please specify</i> <i>Cooling Time: Please specify</i> <i>Pressure: Please specify</i> <i>Other:</i>  Documented in [X]	<input type="checkbox"/> Inhouse <input type="checkbox"/> External supplier: <i>Please name</i>  Equipment was validated at place of production:  <input type="checkbox"/> Yes <input type="checkbox"/> No <i>Please provide a rationale</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No
...	...	...	...	...	...



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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)
<p>Please indicate the type of packaging machine (Manufacturer, including the technology used – positive forming, negative forming, ...) including number of cavities for forming</p> <p>Documented in [X]</p>	<p>Please specify</p>	<p>Please name all relevant parameters</p> <p>Sealing Temperature: Please specify Sealing Time: Please specify Cooling Time: Please specify Pressure: Please specify Other:</p> <p>Documented in [X]</p>	<p>Please name all relevant parameters</p> <p>Sealing Temperature: Please specify Sealing Time: Please specify Cooling Time: Please specify Pressure: Please specify Other:</p> <p>Documented in [X]</p>	<p><input type="checkbox"/> Inhouse <input type="checkbox"/> External supplier: Please name</p> <p>Equipment was validated at place of production: <input type="checkbox"/> Yes <input type="checkbox"/> No Please provide a rationale</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>Please indicate the type of packaging machine (Manufacturer, including the technology used – positive forming, negative forming, ...) including number of cavities for forming</p> <p>Documented in [X]</p>	<p>Please specify</p>	<p>Please name all relevant parameters</p> <p>Sealing Temperature: Please specify Sealing Time: Please specify Cooling Time: Please specify Pressure: Please specify Other:</p> <p>Documented in [X]</p>	<p>Please name all relevant parameters</p> <p>Sealing Temperature: Please specify Sealing Time: Please specify Cooling Time: Please specify Pressure: Please specify Other:</p> <p>Documented in [X]</p>	<p><input type="checkbox"/> Inhouse <input type="checkbox"/> External supplier: Please name</p> <p>Equipment was validated at place of production: <input type="checkbox"/> Yes <input type="checkbox"/> No Please provide a rationale</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
...	...	...	...	...	...



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### 2.4 Packaging Process Validation

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

Explanation: The objective of this section is to gather the conducted packaging process validation activities to receive objective evidence that the packaging process is capable to constantly produce SBSs which fulfill all predefined requirements.

Description of the packaging process	<p><i>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.</i></p> <p>The respective data is documented in [X]</p>
<b>Operational Qualification (OQ)</b>	
Were the upper and lower process parameters challenged?	<p><input type="checkbox"/> Yes, upper and lower process parameters were challenged for:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Forming</li> <li><input type="checkbox"/> Sealing</li> <li><input type="checkbox"/> Other closure modes</li> </ul> <p><input type="checkbox"/> No, <i>please provide a rationale how is ensured that the equipment produces compliant outputs at the limits of the operating window.</i></p> <p>The respective data is documented in [X]</p>
Does the SBS meet the specifications of the required quality properties?	<p><input type="checkbox"/> Yes, the SBS fulfill the specified quality properties after</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Forming /assembly</li> <li><input type="checkbox"/> Sealing</li> <li><input type="checkbox"/> Other closure modes</li> </ul> <p><input type="checkbox"/> No, <i>please provide a rationale how the normative quality properties of SBS are ensured at the limits of the operating window.</i></p> <p>The respective data is documented in [X]</p>
How many samples were tested?	<p><i>Please state how many samples were tested for which quality property, each at upper and lower process parameters</i></p>



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	The respective data is documented in [X]
<b>Performance Qualification (PQ)</b>	
Was the actual product under review used in PQ?	<input type="checkbox"/> Yes, the product was used. <input type="checkbox"/> A simulated product was used <i>Please specify and provide a rationale why the product is representative</i>  <input type="checkbox"/> No, <i>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.</i> The respective data is documented in [X]
Were 3 production runs (nominal parameters) applied?	<input type="checkbox"/> Yes, documented in [X] <input type="checkbox"/> No, <i>please provide a rationale how variability within a run and reproducibility between different runs are assessed.</i> A statistical sound rationale for sample size is documented in [X]
Does the process produce SBS which consistently meet predetermined requirements?	<input type="checkbox"/> Yes, the SBS meet predetermined requirements after: <input type="checkbox"/> Forming/assembly <input type="checkbox"/> Sealing <input type="checkbox"/> Other closure modes <input type="checkbox"/> No, <i>please provide a rationale how is ensured that the process will constantly produce SBS which fulfil all predetermined requirements.</i> The respective data is documented in [X]
How many samples were tested?	<i>Please state how many samples were tested per run for which quality property.</i>   The respective data is documented in [X]





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Was integrity of the whole SBS tested after transport simulation?	<input type="checkbox"/> Yes <input type="checkbox"/> No <i>Please a rationale how SBS integrity after transport simulation is ensured.</i> The respective data is documented in [X]
How was the integrity and readability of the labelling system after hazards of handling and transportation demonstrated?	<i>Please specify – what type of test method (standard) or reference was used</i>  The respective data and test results is documented in [X]

### 2.6 Packaging Stability Testing

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

Explanation: When considering a product's life cycle, long-term packaging stability has to be established. Stability testing, conducted by means of accelerated aging studies, are considered adequate proof of a 'claimed' expiry date until data from real-time studies are available. The claimed maximum storage conditions, especially the storage temperature, impacts the calculation of the accelerated ageing time. Therefore it needs to be explained how the claimed product shelf life and storage conditions, are covered by the accelerated ageing study. In order to finally conclude that packaging stability study passed, SBS integrity (seals + substrate) and labelling integrity need to be shown for the claimed product shelf-life under the claimed storage conditions.

How are the claimed maximum storage conditions covered by the calculation of the accelerated aging time?	<i>Please specify the ageing conditions and respective ageing calculation in case of accelerated ageing</i>  The respective data is documented in [X]
Was integrity of the whole SBS tested after ageing?	<input type="checkbox"/> Yes <input type="checkbox"/> No <i>Please provide a rationale how SBS integrity after shelf life is ensured.</i> The respective data is documented in [X]



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<p>How was the integrity and readability of the labelling system until point of use demonstrated?</p>	<p><i>Please specify – what type of test method (standard) or reference was used</i></p> <p>The respective data is documented in [X]</p>
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Release by client:

_____	_____	_____
Date	Signature	Name
_____		
Name of Legal Manufacturer		

Revision 0: Initial creation  
Revision 1: Re-structure of sections, addition of risk-management and IFU directions in section 2.1, addition of OQ and update of PQ in section 2.4, addition of labelling integrity in section 2.5, brand refresh.