



Client Checklist Ethylene Oxide Sterilization

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

- [X, p.] 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. 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 note 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 Ethylene Oxide Sterilization

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

Note: Please replace italic text with respective information

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, material, Intended Use / Intended Purpose according to IFU (inclusive 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, multiple products in same SBS)

Description of the Sterile Barrier System specifications used at sterilization



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Has this product previously been assessed by TÜV SÜD Product Service?

If yes, please provide order no. usually starting with 07xxxxxxx, 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 final packaging site
Sterilization site to be named	Please provide the applicable QMS Certificate 13485 of the used sterilization site

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 sterilization validation 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, EO 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, EO residuals). Please provide the applicable QMS accreditation certificate (e.g. ISO 17025 or GLP)



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2. Production related information

2.1 Equipment Specification

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

Explanation: The intention of this section is intended for traceability of equipment used to sterilise device (family) under assessment related to a specific certificate as well as to enable conclusions regarding used sensors and BIs.

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 m ³	All sensors / measurement devices (internal + external sensors, dataloggers for validation) are calibrated (statement sufficient)
<i>e.g. Preconditioning (if applicable)</i>	<i>Inhouse or external source</i>	<i>Please name the cycle and version/ revision of cycle</i>			<input type="checkbox"/> Yes <input type="checkbox"/> No
<i>e.g. Sterilizer A10</i>	<i>Inhouse or external source</i>	<i>Please name the cycle and version/ revision of cycle</i>	<i>e.g. (overpressure, underpressure)</i>		<input type="checkbox"/> Yes <input type="checkbox"/> No
<i>e.g. Venting Tunnel</i>	<i>Inhouse or external source</i>	<i>e.g. program #3 rev11</i>			<input type="checkbox"/> Yes <input type="checkbox"/> No



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2.2 If Applicable: Cleaning of Product in Manufacturing before Sterilization

Note 1: Final cleaning is in scope of this section, which means cleaning before final packaging into sterile barrier system and sterilization. In consequence intermediate cleaning steps are not in scope of the sterilization assessment. Final cleaning could be performed via manual or automated cleaning processes.

Cleaning means reduction of manufacturing residues from the product i.e. grease, lubricants, particles, etc. An appropriate cleaning process is the basis for successful disinfection and sterilization, refer to section 2.3 Disinfection.

Note 2: Please replace italic text with respective information. Please add additional lines if required.

Explanation: The consistent pre-sterilization condition of a medical device after the manufacturing process ensures reproducible outcome of the sterilization process to achieve SAL<10⁻⁶. Therefore, cleaning and subsequent disinfection steps may be used to achieve this consistent pre-sterilization condition, e.g. to eliminate process residues. In case device cleaning is executed as a process step, please consider the section below.

General process information Final Cleaning	
Are the products undergoing Final Cleaning before sterile barrier packaging and sterilization?	<div><input type="checkbox"/> Yes [X,p,y] <input type="checkbox"/> No [X,p,y], if no, please mark N.A. in the table of section 2.2.</div> <div>Description of Final Cleaning Process: <i>Please add a short description of the final cleaning process</i></div> <div>Final Cleaning process specification and procedure: <i>Please add all references to the cleaning process procedure and specifications including the parameters of the cleaning process. Documented in [X,p,y]</i></div>
Cleaning site	<div><i>Please specify the site at which the Final Cleaning Process is located [X,p,y]</i></div> <div><input type="checkbox"/> N.A.</div>



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Cleaning process identifier	<p>Please provide identification of the cleaning process in form of name and/or program number [X,p,y]</p> <p><input type="checkbox"/> N.A.</p>
Cleaning equipment - if applicable	<p>Please specify which cleaning equipment is used for the cleaning of product in scope with equipment name and device identifier [X,p,y]</p> <p><input type="checkbox"/> N.A.</p>
Cleaning detergent - if applicable	<p>Please specify the cleaning detergent [X,p,y]</p> <p><input type="checkbox"/> N.A.</p>
Final Cleaning before Disinfection	
Is the product disinfected after Final Cleaning?	<p><input type="checkbox"/> Yes <input type="checkbox"/> N.A. [X,p,y], please mark sections below in this chapter as N.A.</p>
Are cleaning process validations/studies available providing evidence for efficient reduction of the manufacturing residuals?	<p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N.A.</p> <p>Defined residuals to be reduced/removed: <i>It shall be specified which residues could obstruct the subsequent disinfection process and are therefore intended to be reduced by final cleaning. Appropriate cleaning process is the basis for successful disinfection.</i></p> <p>Verification of successful reduction of defined manufacturing residues: <i>Please add evidence for successful reduction of defined residues by validation, monitoring, and/or cleaning batch records. Documented in [X,p,y].</i></p>

2.3 If Applicable: Disinfection of Product in Manufacturing before Sterilization

Note 2: Please replace italic text with respective information. Please add additional lines if required.

Explanation: The consistent pre-sterilization condition of a medical device after the manufacturing process ensures reproducible outcome of the sterilization process to achieve $SAL < 10^{-6}$. Therefore, cleaning and subsequent disinfection steps may be used to achieve this consistent pre-sterilization condition, e.g. to eliminate process residues. In case device disinfection is executed as a process step, please consider the section below.

General process information Disinfection	
	<input type="checkbox"/> N.A. [Section 2.3 can be omitted]
Disinfection process description and specification	<p>Description of Disinfection Process: <i>Please add a short description of the disinfection process</i></p> <p>Disinfection process specification and procedure: <i>Please add reference to disinfection process procedure and specification including parameters of the disinfection process, specific load configurations, and supplies. Documented in [X,p,y]</i></p>
Disinfection site	<i>Please specify the site at which disinfection process is located [X,p,y]</i>
Disinfection process identifier	<i>Please provide an identification of the disinfection process in form of name and/or program number [X,p,y]</i>



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Disinfectant- if applicable	<i>Please specify the disinfectant [X,p,y]</i>
Disinfection equipment- if applicable	<i>Please specify the disinfection equipment in use for disinfecting product in scope with equipment name and device identifier [X,p,y]</i>
Disinfection with defined efficiency for bioburden reduction	
Are the products disinfected to achieve a defined efficiency for bioburden reduction, e.g. log reduction or A0 value?	<input type="checkbox"/> Yes [X,p,y] <input type="checkbox"/> No
Are disinfection process validations/ studies available providing evidence for efficient reduction of the microbiological contamination to a specified level?	<input type="checkbox"/> Yes [X,p,y] <input type="checkbox"/> No <i>Please provide documented evidence for efficient reduction of microbiological contamination of the disinfection process. Efficient reduction of bioburden could be shown by achieving specified log-reduction or A0 value.</i>



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2.4 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).

Explanation: The information to be provided are based on the requirements as laid down in ISO 14644 standard series, EN 17141 and connected regulatory guidance documents.

This section is to be filled only on the following occasions:

- NEW cleanroom

Please fill in all sections below or provide a rationale when a section may not be applicable in the individual case.

- CHANGE to an existing cleanroom:

In case of a change to an existing cleanroom environment, please only address the respective sections below that apply to the actual change to the cleanroom, so that it becomes clear what the extent of the change is. Since the cleanroom itself has been assessed in the past, it is additionally helpful to provide the information to the original cleanroom approval decision by the order no (e.g. 0713....)

Is this the first evaluation of the clean room or have changes occurred to the cleanroom? (e.g. new clean room, modification of the cleanroom and changes to the setup of the points listed in the table below)	<input type="checkbox"/> Yes, documented in <input type="checkbox"/> No, please mark N.A. in the table below for section 2.4.
Cleanroom	Please identify the cleanroom(s) where the manufacturing takes place, including ISO classification



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<p>Are action and alert levels/limits set appropriately for the subsequent product bioburden in cleanroom processes?</p>	<p><input type="checkbox"/> Yes, documented in [X,p,y] <input type="checkbox"/> N.A. <input type="checkbox"/> No, please justify:</p> <p>Acceptance criteria for "in operation" condition: Airborne particles [size]: particles/m³ Airborne microbiological contamination: cfu/m³ (and/or settle plates)</p> <p>Surface microbiological contamination: cfu/m² Product bioburden (action limit): cfu (type – spores, fungi, anaerobe, bacteria) The bioburden shall be known to a degree to make decision on resistance</p>
<p>Monitoring points are defined for the above-mentioned measurements</p>	<p><input type="checkbox"/> Yes, documented in [X,p,y] <input type="checkbox"/> N.A. <input type="checkbox"/> No, please justify:</p>
<p>Was IQ, OQ, PQ of the cleanroom successfully established?</p>	<p><input type="checkbox"/> Yes, documented in [X,p,y] <input type="checkbox"/> N.A. <input type="checkbox"/> No, please justify:</p>
<p>Is all measuring equipment in a calibrated state?</p>	<p><input type="checkbox"/> Yes, documented in [X,p,y] <input type="checkbox"/> N.A. <input type="checkbox"/> No, please justify:</p>
<p>Are utilities and media under surveillance?</p>	<p><input type="checkbox"/> Yes, documented in [X,p,y] <input type="checkbox"/> N.A. <input type="checkbox"/> No, please justify:</p> <p>Please specify what media and related acceptance criteria are defined. e.g. for water, compressed air...</p>
<p>Are environmental parameters defined?</p>	<p><input type="checkbox"/> Yes, documented in [X,p,y]</p> <p><input type="checkbox"/> N.A. <input type="checkbox"/> No, please justify:</p> <p>Please Specify where applicable: Temperature: Humidity:</p>



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<p>Are environmental parameters defined?</p>	<p>Pressure gradient: Air change rates:</p>
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2.5 Cycle Specification

Note: Please replace 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 routine sterilization:

Explanation: The intention of this section is to understand that all parameters relevant for the control of the cycle are listed below covering all requirements of EN ISO 11135 series.

<p><i>Please paste here</i></p>



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Is resterilization allowed?	<div><input type="checkbox"/> Yes. <i>Please name the amount of re-sterilizations allowed</i></div> <div><input type="checkbox"/> No</div>
Was product functionality verified after maximum amount of allowed sterilization cycles?	<div><input type="checkbox"/> Yes, documented in [X]</div> <div><input type="checkbox"/> No, <i>please justify:</i></div>



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2.6 Basic Validation Development Data

Note: Please replace italic text with respective information.

Explanation: This section addresses the basic validation data including the validation approach, the revalidation criteria and what the maximum number of allowed sterilization cycles for the device under assessment is.

Validation Method	<input type="checkbox"/> overkill half cycle approach (EN ISO 11135 Annex B 1.2.a) <input type="checkbox"/> overkill cycle calculation approach (EN ISO 11135 Annex B 1.2b) <input type="checkbox"/> BI and bioburden (EN ISO 11135 Annex A 1.3 b,c) <input type="checkbox"/> Bioburden (EN ISO 11135 Annex A 1.3 a) <input type="checkbox"/> Product adoption to an existing cycle – please fill box below <p><i>Please assure that the adoption rationale and MPQ/PPQ validation data are submitted for the predicate device. This data is documented in [X]</i></p> <input type="checkbox"/> Other: <i>Please specify and add rationale for not using a standardized method</i>
<p>Only for product adoption or cycle equivalence:</p> <input type="checkbox"/> N/A	<p>Please provide the approved TÜV SÜD assessed predicate (EN ISO 11135, Annex D.12.5) project number: _____</p> <p>Was a product adoption process followed and documented (e.g. based on AAMI TIR 28 or ISO 11135, D.12.5)?</p> <input type="checkbox"/> Yes, documented in [X]



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	<div><input type="checkbox"/> No</div> <div>Have aspects of effects on packaging integrity, product functionality and residuals been assessed?</div> <div><input type="checkbox"/> Yes, documented in [X]</div> <div><input type="checkbox"/> No</div>



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	<p>Was a reduced validation performed based on chamber / process equivalence?</p> <p><input type="checkbox"/> Yes, documented in [X]</p> <p><input type="checkbox"/> No</p>
Revalidation criteria	<p><input type="checkbox"/> By what events is a new validation is triggered - is documented in [X]</p> <p><i>Please provide the review interval of data, and interval of time till repeat MPQ / PPQ studies.</i></p> <p><i>When was the last MPQ, PPQ study executed?</i></p> <p><i>What are further criteria that to trigger a revalidation study (e.g. product changes...)?</i></p> <p><input type="checkbox"/> Validation protocol for the actual sterilization cycle including acceptance criteria - is documented in [X]</p>

2.7 MPQ

Explanation: The MPQ is performed to demonstrate the sterilization process is capable to achieve a SAL 10^{-6} and to inactivate the individual respective product bioburden on the medical device and if applicable the biological indicator. If biological indicators and / or PCDs are used the relative resistance in relation to natural bioburden is verified. This is also called the “resistance hierarchy”. This is usually established by running the sterilization in a sublethal-cycle, where it is intentionally expected to detect survivors. A second aspect relates to the grouping of products and their grouping criteria (e.g. similar materials, similar manufacturing, similar product bioburden). A significant aspect relates to the microbiological practice itself and considers the recovery method and its efficacy, which is used to determine the product bioburden as well as a proper establishment of the test of sterility method validation.

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



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

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



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MPQ Processing - Microbial Performance Qualification	
Biological indicators (if applicable)	<div><input type="checkbox"/> Specification of Biological Indicators (BI) used is provided. <i>This data is documented in [X]</i> <i>Placement scheme and number of BIs or spore suspension, BI certificate</i></div> <div><input type="checkbox"/> Parametric release <i>Placement of reference sensor(s)</i></div>



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BI results including culture conditions and time between end of cycle and BI testing	<input type="checkbox"/> Sublethal cycle for BI resistance was performed – if no <i>please justify</i> <input type="checkbox"/> BI results including culture conditions and time between end of cycle and BI testing is documented in [X]
IPCD/EPCD (if applicable):	<input type="checkbox"/> Drawings or pictures including place of inoculation position is provided in the submission <i>including rational for the position and type taking into account: challenge to bioburden, physical conditions in load and diffusion pathways. This data is documented in [X]</i>
	<input type="checkbox"/> Data on the relationship of the resistance between EPCD, IPCD, worst-case Products, natural Bioburden are provided. <i>This data is documented in [X]</i>
Bioburden	<i>Please specify the bioburden level/limits e.g. in respect to bacteria, yeast/molds and anaerobic bacteria (were these investigations at least part of the initial assessment of bioburden)</i>



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	<p><i>Please provide the bioburden trending data as a summary of the last year, if not available at least for the validation LOT.</i></p> <p><i>Please specify further for the environmental controlled manufacturing area the control limits for airborne bioburden and particles.</i></p>
<p>Is endotoxin testing applicable for the device under assessment?</p>	<p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes [X,p,y]. Please specify the method and related results. The data is documented in [X]. (e.g. in case of direct contact to blood, CNS / CSF, eye or other systemic exposure)</p>

2.8 PPQ Physical Performance Qualification

Explanation: The intention of this section is to give a description of the load in relation to its composition (Materials, density, etc.), size (load volume) and/or limitation where the load is positioned in the sterilization chamber and exposed to the sterilization cycle. It must be understandable in which relation this validation load is reflecting the routine sterilization load from worst case perspective.

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

<p>Please specify the validation load configuration:</p>	<p>Please specify the load used during validation at PPQ and MPQ:</p> <p><i>Please consider min and max configuration in case of widely varying load configurations, 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 (EO and water) (EN ISO 11135 9.4). The data is documented in [X]</i></p>
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Please specify which product was used in the load:	<p>The product is the same as in section 1</p> <p><input type="checkbox"/> Yes [X,p,y]</p> <p><input type="checkbox"/> No - <i>Please provide a description and justification</i></p>

Please paste copy of the cycle specification used at validation of sterilization PPQ:

Please paste here covering all of section 11135 9.5.4 The data is documented in [X]



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

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

Phase	Acceptance criteria: values and tolerance	Results measured acc. 11135 9.5.4	Comments if needed
Preconditioning	<i>Min/Max load temperature and humidity at end of preconditioning</i>	<i>To be added</i>	<i>To be added if any</i>
Conditioning	<i>Min/Max load temperature and humidity at end of preconditioning</i>	<i>To be added</i>	<i>To be added if any</i>
Sterilization/ Exposure phase	<i>Load temperature</i>	<i>To be added</i>	<i>To be added if any</i>
The achievement of all cycle specification data and parameters above is verified during validation covering all of EN ISO 11135 9.5.4	<input type="checkbox"/> Yes, documented in [X] <i>(best provided in a table showing setpoint/ tolerances against measured data)</i> <input type="checkbox"/> No - <i>Please justify</i>		<i>To be added if any</i>



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3. EO/ECH Residuals

Explanation: This section requires information to understand the toxicological effects of the sterilizing agent EtO on the product itself. Residues may be the sterilizing agent itself and also chemically reacted components of the product materials. Therefore, it is important to not only investigate for EtO as a chemical residual, but also for ECH (Ethylene chlorohydrate) and potentially EG (Ethyleneglycol), if these chemicals may have been formed in the sterilization process. The allowable limits are described as part of the latest ISO 10993-7. When the device under assessment is also to be used in a paediatric setting, the limits need to be scaled down to the applicable body mass of the target patient group.

Note: Please replace italic text 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)	<input type="checkbox"/> Yes, documented in [X]	<input type="checkbox"/> No - <i>Please justify</i>	<i>To be added if any</i>
Are the applicable Allowable limits for EO/ECH for the product in question considering the patient population provided	<input type="checkbox"/> Yes, documented in [X]	<input type="checkbox"/> No - <i>Please justify</i>	<i>To be added if any</i>
Results and test method provided	<input type="checkbox"/> Yes, documented in [X]	<input type="checkbox"/> No - <i>Please justify</i>	<i>To be added if any</i>
Has there been confirmatory testing of the degassing kinetics (at least 3 runs total)	<input type="checkbox"/> Yes, documented in [X]	<input type="checkbox"/> No - <i>Please justify</i>	<i>To be added if any</i>



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4. Routine Processing

Explanation: This section summarizes the release criteria used during routine sterilization. The information in this section relate in main focus to the determined and established routine parameters of the EO sterilization to ensure a reproducible SAL < 10⁻⁶.

Routine Processing	
Please provide the EO-gas specification	Please name the supplier of the EO gas and EO gas specification
Routine release	<input type="checkbox"/> BI and physical parameters <i>Placement scheme and number of BIs, BI certificate or spore suspension</i>
	<input type="checkbox"/> Parametric release <i>Placement of reference sensor(s)</i>
	Release criteria documented in [X] <i>e.g. comparison of validation plot to routine plot, BI negative</i>
Placement scheme and number of BIs, BI certificate provided?	<input type="checkbox"/> Yes, documented in [X] <input type="checkbox"/> No - Please justify:
Routine cycle control and regulation is achieved by	<input type="checkbox"/> Chamber fixated sensors only <input type="checkbox"/> Product integrated sensors (e.g. simulated product with integrated sensor)



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Load configuration	<input type="checkbox"/> Dedicated load
	<i>Product configuration is fixed in number and location within chamber</i>
	<input type="checkbox"/> Mixed load
	<i>different products allowed</i>
Please add information on min/max load variation, if applicable:	

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.