



Client Checklist Irradiation 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 Irradiation Sterilization

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

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.

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, 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 (Sterile Barrier System Specifications), Multiple products in same SBS)

Description of the Sterile Barrier System Specifications used at sterilization



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Product families – if applied
Please explain the rationale for sterilization product families

Has this product previously been assessed by TÜV SÜD Product Service?
<i>If yes, please provide 10-digit order no. usually starting with 07xxxxxxx, or equivalent traceable information</i>

Manufacturing facility and certification status of the applicable sterilization sites / facilities	
<i>Manufacturing site to be named (device) including sterile packaging</i>	<i>Please provide the applicable QMS Certificate 13485 of the used sterilization site</i>



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Manufacturing site to be named (device) if multiple site can produce/or parts thereof contributing to a different bioburden	Please provide the applicable QMS Certificate 13485 of the used sterilization site	
Sterilization site to be named for routine sterilization and dose	Please provide the applicable QMS Certificate 13485 of the used final packaging site	<input type="checkbox"/> Gamma <input type="checkbox"/> E-beam <input type="checkbox"/> X-ray
Sterilization site to be named for Dose Verification Experiment	Please provide the applicable QMS Certificate 13485 of the used final packaging site	<input type="checkbox"/> Gamma <input type="checkbox"/> E-beam <input type="checkbox"/> X-ray

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 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, endotoxin testing). 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, endotoxin testing). Please provide the applicable 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.

Equipment including Identifier (e.g. int. ID/ serial number)	Site	Applicable cycle operated by the equipment for the device in question	Type of irradiation technology	Irradiation source	Measurement equipment (e.g. timer, dosimeters...) calibrated (statement sufficient)
<i>e.g. Irradiator A10</i>	<i>Inhouse or external source</i>	<i>Please name the processing category</i>	<input type="checkbox"/> Gamma <input type="checkbox"/> E-beam <input type="checkbox"/> X-ray	<i>e.g. Co60 E-beam 6 MeV</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<i>e.g. Irradiator X16</i>	<i>Inhouse or external source</i>	<i>Please name the processing category</i>	<input type="checkbox"/> Gamma <input type="checkbox"/> E-beam <input type="checkbox"/> X-ray	<i>e.g. Co60 E-beam 6 MeV</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No

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.



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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?	<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. Description of Final Cleaning Process: <i>Please add a short description of the final cleaning process</i> 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>
Cleaning site	<i>Please specify the site at which the Final Cleaning Process is located [X,p,y]</i> <input type="checkbox"/> N.A.
Cleaning process identifier	<i>Please provide identification of the cleaning process in form of name and/or program number [X,p,y]</i> <input type="checkbox"/> N.A.
Cleaning equipment - if applicable	<i>Please specify which cleaning equipment is used for the cleaning of product in scope with equipment name and device identifier [X,p,y]</i> <input type="checkbox"/> N.A.



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Cleaning detergent - if applicable	Please specify the cleaning detergent [X,p,y] <input type="checkbox"/> N.A.
Final Cleaning before Disinfection	
Is the product disinfected after Final Cleaning?	<input type="checkbox"/> Yes <input type="checkbox"/> N.A. [X,p,y], please mark sections below in this chapter as N.A.
Are cleaning process validations/ studies available providing evidence for efficient reduction of the manufacturing residuals?	<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N.A. </div> <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 1: Disinfection means reduction of microbial load with a defined efficiency. Disinfection could be performed with chemical disinfection with disinfectant or physical disinfection like thermal treatment or rinsing with hot water.

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.



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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>
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>



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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>

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.



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- 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....)

<p>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)</p>	<p><input type="checkbox"/> Yes, documented in</p> <p><input type="checkbox"/> No, please mark N.A. in the table below for section 2.4.</p>
<p>Cleanroom</p>	<p><i>Please identify the cleanroom(s) where the manufacturing takes place</i></p>
<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) Surface microbiological contamination: cfu/m² Product bioburden (action limit): cfu</p> <p><i>The bioburden shall be known to a degree to make decision on resistance</i></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>



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Is all measuring equipment in a calibrated state?	<input type="checkbox"/> Yes, documented in [X,p,y] <input type="checkbox"/> N.A. <input type="checkbox"/> No, please justify:
Are utilities and media under surveillance?	<input type="checkbox"/> Yes, documented in [X,p,y] <input type="checkbox"/> N.A. <input type="checkbox"/> No, please justify: <i>Please specify what media and related acceptance criteria are defined. e.g. for water, compressed air...</i>
Are environmental parameters defined?	<input type="checkbox"/> Yes, documented in <input type="checkbox"/> N.A. <input type="checkbox"/> No, please justify: <i>Please specify where applicable: Temperature: Humidity: Pressure gradient: Air change rates:</i>



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2.5 Process Specification

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

Sterilization process/process category	<i>Please specify the identifier or the applied sterilization process.</i>
Production frequency	<input type="checkbox"/> Single Batch Production/Validation “infrequent” production” <input type="checkbox"/> Multiple Batch Production/Validation “frequent” production”
Product density range covered by the sterilization cycle	<i>Please specify the product densities that are covered by the above- mentioned process.</i>
Is re-sterilization allowed?	<input type="checkbox"/> Yes <i>Please name the amount of resterilizations allowed</i> <input type="checkbox"/> No

2.6 Basic Validation Development Data

Note: Please replace italic text with respective information.

Explanation: The basic validation data include the baseline information related to the validation, including the used validation method, whether a product adoption approach is followed and how the relation to the dose mapping is established.

Validation method	<input type="checkbox"/> VD_{max}^{15} (Overkill for Ø Bioburden < 1.5) <input type="checkbox"/> VD_{max}^{25} (Overkill for Ø Bioburden < 1000) <input type="checkbox"/> Method 1 (Bioburden) <input type="checkbox"/> Method 2 (Fraction Positive) <input type="checkbox"/> Other: <i>Please specify and add rationale for not using a standardized method</i>
Only for product adoption or cycle equivalence: <input type="checkbox"/> N/A	Please provide the approved TÜV SÜD assessed predicate (EN ISO 11137, Annex D. 12.5) project number: _____ Was a product adoption process followed and documented (e.g. based on AAMI TIR 28 or ISO 11137, D:12.5)? <input type="checkbox"/> Yes, documented in [X]



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	<p><input type="checkbox"/> No</p> <p>Have aspects of effects on packaging integrity, product functionality and residuals been assessed?</p> <p><input type="checkbox"/> Yes, documented in [X]</p> <p><input type="checkbox"/> No</p> <p>Was a reduced validation performed based on chamber / process equivalence?</p> <p><input type="checkbox"/> Yes, rationale or data documented in [X]</p> <p><input type="checkbox"/> No</p>
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2.7 PPQ Physical Performance Qualification – Dose Distribution Determination

Explanation: The PPQ or Dose Distribution Study is primarily targeted to demonstrate that your candidate product / device under assessment is being able to be adapted into an existing product category of the contract sterilizer / inhouse sterilization plant. Therefore, some aspects in this section may not be directly correlated to your own medical device. This section investigates how the irradiation source is able to homogeneously irradiate a fully loaded irradiation tote or entire pallet. Therefore, it is important to describe the used product (dummy or real) and in which locations the dosimeters have been placed, including a rationale for the placement scheme. By this, the link is established between the routine sterilization operation and the validation exercise as covered by the two steps PPQ (dose distribution) and MPQ (verification dose experiment).

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

Dose distribution determination (dose mapping)	
Dosimeter type/manufacturer used during dose mapping?	<p><i>Please specify all dosimeter types (e.g. PMMA Dosimeter, Alanine dosimeter etc...) and manufacturer. Traceability to a national standard institute</i></p>



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<p>Are there multiple different pathways the product can take through the sterilizer?</p>	<p><input type="checkbox"/> Yes, documented in [X,p,y] <input type="checkbox"/> No</p> <p>If yes, please describe the different pathways: <i>Please provide a scheme, description or processing map to show the route taken.</i></p>
<p>Is there only one fixed routine load covered by the performed dose mapping?</p>	<p><input type="checkbox"/> Yes, documented in [X,p,y] <input type="checkbox"/> No</p> <p><i>If no, please describe the different loads and how they are covered by a separate dose mapping.</i></p>
<p>How are the products arranged, packed and palletized before routine sterilization?</p>	<p><i>Please describe and add pictures to this submission. The respective data is documented in [X].</i></p>
<p>Was the above-described load used at dose mapping?</p>	<p><input type="checkbox"/> Yes, [X,p,y] <input type="checkbox"/> No. <i>Please provide a description and justification.</i></p>
<p>How many dose mapping runs were performed?</p>	<p><i>Please specify how many singular runs through the sterilizer with dosimeter readings were done. The respective data is documented in [X]</i></p>
<p>Placement scheme and rationale of Dosimeters and amount thereof is provided?</p>	<p><input type="checkbox"/> Yes, documented in [X,p,y] <input type="checkbox"/> No, <i>please justify:</i></p>



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Relation between monitoring (Reference position) and minimum and maximum dose?	<i>Is the dose measured at a reference position or in the minimum and maximum dose positions of the load in routine irradiation?</i>
What is the defined maximum dose which does not damage sterile barrier or product?	<i>Please specify the value that is covered by product development and functional testing for the device in question documented in [X]</i>
Was physical product and sterile barrier testing performed after worst case sterilization?	<input type="checkbox"/> Yes, documented in [X,p,y] <input type="checkbox"/> No, please justify:

2.8 MPQ

Explanation: The MPQ or Verification Dose Experiment is performed to demonstrate which minimum irradiation dose is required to inactivate the individual respective product bioburden on the medical device. It also investigates if the various possible microbiological types have been considered in this investigation. 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

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

Bioburden determination	
Is the product part of a product family?	<input type="checkbox"/> Yes <input type="checkbox"/> No



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<p>If yes, please describe the product family(ies) regarding EN ISO 11137-2 section 4.2 (Defining product family and bioburden)</p>	<p>Please provide a rationale based on the respective product family definitions (examples: bioburden, raw materials, manufacturing place and steps...). Please explain why the respective product(s) are members of the same family. The respective data is documented in [X]</p>
<p>Reference product(s) (master product, simulated product...) chosen to be tested for the microbiological validation (bioburden and sterility testing)</p>	<p>Please specify reference product(s)</p> <p>Rationale for selection of reference product(s):</p> <p>Please add – The respective evidence data is documented in [X]</p>
<p>Which Sample item portion (SIP) is used for Bioburden Testing?</p>	<p>Please add the used SIP; please also add a rationale if a SIP <1 was used.</p>
<p>Was the packaging considered for bioburden?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No, please justify why it was not considered</p> <p>e.g. for double sterile barrier packaging the bioburden of the packaging has to be taken into account.</p>
<p>Tested types of microorganisms:</p>	<p><input type="checkbox"/> Aerobic <input type="checkbox"/> Anaerobic <input type="checkbox"/> Fungi <input type="checkbox"/> Spores</p> <p>This is documented in [X]</p>



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Tested types of microorganisms:	Rationale if not all four categories have been tested:
Is Endotoxin Testing required for the product?	<input type="checkbox"/> Yes <input type="checkbox"/> No. <i>Please specify the method and related results. The data is documented in [X]. (e.g. in case of direct contact to blood, CNS, eye or other systemic exposure)</i> If yes, frequency of testing: <i>Please specify.</i> This is documented in [X]
Recovery Factor (RF)	<i>What is the Bioburden Recovery Factor?</i> This is documented in [X]
How was the RF determined?	<i>Please specify how the RF was determined, e.g. exhaustive extraction or inoculation method</i> This is documented in [X]
Detection limit of the bioburden determination	<i>Please specify the sensitivity of the Bioburden test (e.g. >1 CFU or >3,5 CFU). Please add a justification if the detection limit was used for the average bioburden calculation (e.g. result "<3,5 CFU" was rated as "average = 3,5")</i> This is documented in [X]



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Actual Bioburden Results (incl. RF)		Averages	Number of tested devices
	Lot 1		
	Lot 2		
	Lot 3		
	Overall Average		
Determined verification dose according to EN ISO 11137-2			

MPQ processing – dose verification experiment	
Which SIP is used for sterility testing?	<p>Please specify the used Sample Item Proportion (SIP)</p> <p>This is documented in [X]</p>
Was the packaging considered for the sterility test?	<p><input type="checkbox"/> Yes <input type="checkbox"/> No, please justify why it was not considered</p> <p>e.g. for double sterile barrier packaging the outside of the inner sterile barrier packaging must be sterile..</p>
What was the achieved verification dose?	<p>This is documented in [X]</p>
Result: How many unsterile / sterile samples were found?	<p>e.g. dose determination 1+/100 (last dose audit 0+/10)</p> <p>This is documented in [X]</p>
Test of sterility incubation conditions:	<p>Incubation conditions (time, temperature): Please add</p> <p>This is documented in [X]</p>



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Method validation: Was a bacteriostasis / fungistasis test performed?	<input type="checkbox"/> Yes <input type="checkbox"/> No, <i>please justify</i> If yes, please specify strains used for test: <i>Please name the strains that are documented in [X]</i>
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3. 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 irradiation sterilization to ensure a reproducible SAL $<10^{-6}$.

Note: Please replace italic text with respective information.

Routine Processing	
Sterilization Load density / Range allowed for the sterilization cycle	<i>[e.g. g/cm³]</i> This is documented in [X]
Is the routine load (density and distribution thereof in the load) identical to the load used at dose mapping?	<input type="checkbox"/> Yes <input type="checkbox"/> No, <i>please justify</i>
Allowed Dose Range for the whole load [kGy]	<i>Please specify what dose range is allowed to be achieved in the load based on the routine sterilization cycle description</i> This is documented in [X]
The routine release related dose is measured in the following position	<i>Please specify the positions in the load used for routine release of the load.</i> This is documented in [X]



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Bioburden Limits/levels (Alert, action):	Alert limit/level: <i>10 cfu/device</i> Action limit/level: <i>30 cfu/device</i> This is documented in [X]
On which rationale are the bioburden limits/levels based?	
Please provide bioburden trending data of the last year	<i>Please provide the bioburden trending data as a summary of the last year, if not available at least for the validation LOT.</i>

Explanation: Specific to irradiation sterilization is an effective control strategy to ensure consistent product bioburden over time in order to maintain the established validation approach (e.g. VD_{max}^{25}). Therefore, this section focusses around this topic from different angles and relates this to the continued mandatory dose audits (verification dose confirmations) and also relates this to source replenishment, including repetition of the dose mapping.

Revalidation	
How often are dose audits performed?	<i>Please specify the dose audit frequency</i> This is documented in [X]
How often is bioburden determined?	<i>Please specify the dose audit frequency</i> This is documented in [X]
How often is a dose mapping performed?	<i>Please specify the dose mapping frequency</i> This is documented in [X]



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How often is the validity of product families and processing categories evaluated?	<i>Please specify the frequency of verifying the sterilization</i> This is documented in [X]
Please specify the requalification requirements	<i>What are further criteria that trigger a revalidation study (e.g.product changes...)?</i> This is documented in [X]

Regulatory
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.