



Client Checklist Biocompatibility

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

- [X,p.y] 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 product variants or components 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 Biocompatibility 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 “Biocompatibility”.

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 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. Relevant References

Explanation: The intent of this section is to understand where the primary biological evaluation documentation as well as any other relevant information (e.g. background information on manufacturing) can be found.

Biological Evaluation Documentation
<p>List of documents relevant for BC assessment: [1] XYZ – YYYY-MM-DD</p> <p><i>Guidance:</i> Please list all documents from the official Technical Documentation (TD) that are deemed relevant for the assessment of the BC module and that are containing the information provided within the present Client Checklist Biocompatibility (CCBC). Please ensure to provide the most up-to date information only (e.g., <u>do NOT submit legacy biological test reports in case these were substituted for newer ones</u>).</p>



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2. Production related information

Explanation: The intent of this section is to shortly summarise the product description as far as relevant for a biocompatibility assessment, including variants, if applicable. If an evaluation from a representative medical device is to be used to cover the biological safety of multiple variants, it should be clear how the medical device chosen is considered worst-case considering all impacting factors such as for example materials of construction, manufacturing processes, packaging, sterilisation, shelf-life and intended use. If predicate devices are used to support the biological safety of the current medical device(s) in scope, biological equivalence should be demonstrated to justify leveraging of the appropriate data. The intended use of all medical devices in scope of the review should also be presented in this section.

Product Description

Description of all BC-relevant features of the medical device:

Please compile a brief description of the medical device focusing on BC-related features.

Guidance:

Please provide a high-level description of the medical device. The description should cover high-level information on the device's

- mode of action*
- manufacturing, packaging, sterilisation and life-time*
- dimensions/geometry*
- materials of construction*
- other aspects relevant for BC evaluation.*

Please note that for more detailed information on manufacturing, packaging, sterilisation, device life-time and materials, the subsections in section 4.3, "Biocompatibility relevant background information" should be used.



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Variants under assessment

Description of the variants to be included in the current assessment and identification of worst case variant(s) selected for biological and chemical testing:

Please compile a brief

- *description of the variants to be included in the current assessment focusing on BC-related features AND*
- *information on worst case selection (if applicable).*

Guidance:

Please provide an overview indicating all medical device variants covered by the present biological evaluation including an identification of the worst-case variant(s) selected for the performed testing. The information provided shall support the manufacturer's choice of worst case variant(s) if applicable.



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Predicate devices

☐ Applicable ☐ Not Applicable

Guidance:

If predicate device(s) is/are used to demonstrate biological safety (overall/for individual endpoints) please check the box "applicable" and fill in the part below. If no predicate device(s) is/are used to demonstrate biological safety, please check the box "not applicable" and proceed with "Intended use".

For the objective evidence supporting biological equivalence between the medical device in scope and a predicate device refer to:

[X,p,y]

Guidance:

Please refer to relevant parts of the Technical Documentation showing biological equivalence of the medical device in scope to predicate devices. All relevant aspects such as physical properties, chemical properties and the intended use should be evaluated.

A tabular format for the comparison of the device under assessment and the predicate device is recommended.



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Intended Use
<p>For the information on the intended use, the intended patient population, the devices / accessories intended to be used along with the medical device, the maximum product quantity to be used and contraindications / warning / precautions refer to: [X,p,y]</p> <p><u>Guidance:</u> Please refer to relevant parts of the Technical Documentation describing</p> <ul style="list-style-type: none"> the intended use, the intended patient population, the devices / accessories intended to be used along with the medical device, the maximum product quantity to be used (max. number of devices or max. amount of device to be used simultaneously treatment mode (e.g. use duration, single treatment, repeated treatment with same or new device, intervals between treatments, etc.) and BC-related contraindications, warnings or adverse effects (if applicable).

3. Project Background

Explanation: The intent of this section is to understand relevant background information on the planned change in case the CCBC is submitted within a Change Notification project and on the (predicate) device history.

Changes
<p>For the information on the proposed change(s) refer to: [X,p,y]</p> <p><u>Guidance:</u> Please refer to relevant parts of the Technical Documentation describing the proposed change(s) to e.g., raw materials, altered manufacturing procedures or sterilisation processes. Please also refer to the part of the Technical Documentation identifying change correlated biological hazards which were used as input for biocompatibility re-evaluation. In case this is an initial submission or submission for renewal of an existing certificate, this part would be "N/A".</p>



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History
<p>For the information on the device history refer to: [X,p.y]</p> <p><u>Guidance:</u> Please refer to relevant parts of the Technical Documentation describing the device history. Device history would include the certification history (both under current and former legislation) of the device under assessment and/or of predicate device(s). For submission for renewal of an existing certificate, the device history should additionally include</p> <ul style="list-style-type: none">• the change history of the device under assessment• biocompatibility-related clinical observations (e.g. Field Safety Notice, Field Safety Corrective Action, Events, Complaints). <p>In case of changes, reference to last full biocompatibility assessment performed by TÜV SÜD (project no 07xxxxxxx) might be included.</p>



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4. Documentation of Biological Evaluation

4.1 Categorisation of the medical device

Categorisation	
<input type="checkbox"/> Surface device	<input type="checkbox"/> Skin <input type="checkbox"/> Mucosal membranes <input type="checkbox"/> Breached or compromised surface
<input type="checkbox"/> External communicating device	<input type="checkbox"/> Blood paths, indirect <input type="checkbox"/> Tissue/bone/dentin <input type="checkbox"/> Circulating blood
<input type="checkbox"/> Implant device	<input type="checkbox"/> Tissue/bone <input type="checkbox"/> Blood
Contact duration	<input type="checkbox"/> A - limited (<24h) <input type="checkbox"/> transitory-contacting <input type="checkbox"/> B - prolonged (>24h to 30 days) <input type="checkbox"/> C - long-term (>30 days)
Documented in: [X,p,y] <u>Guidance:</u> Please check the boxes above to indicate the device categorisation as determined in the biological evaluation and provide reference to respective part of the Technical Documentation.	



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4.2 Summary of Biological Evaluation Strategy

Explanation: The intent of this section is to understand the overall biological evaluation strategy employed (part 1) including identification of relevant biological harms/endpoints based on the device categorisation and available chemical information.

Additionally, this section asks for information on the qualification of the evaluator(s) involved in both the biological evaluation as well as in the toxicological risk assessment (part 2).

Part 1 - Biological Evaluation Strategy

Summary of the biological evaluation strategy and endpoint selection based on the device categorisation and chemical information according to the current EN ISO 10993-1 version:
XYZ

Guidance:
Please summarise the biological evaluation strategy that has been applied. The summary should include for example:

- Information on regulatory guidance applied (e.g. EN ISO 10993-1 version).
- Information on identified biological harms/endpoints based on device categorisation and available chemical characterisation.
- Justifications for considering generally applicable harms/endpoints not relevant for the device under evaluation including justification for the omission of testing for certain endpoints.
- Brief information on strategy for hazard/endpoint evaluation (detailed information on evaluation of individual harms/endpoints is collected in section 4.9 of this document).



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Part 2 – Qualification of the evaluator(s)

For the evidence for the qualification of the evaluators involved in the biological evaluation, including toxicological risk assessment, refer to:

[X,p.y]

Guidance:

Please refer to relevant parts of the Technical Documentation providing evidence for a clear subject matter expertise of the author(s) of the biological evaluation and the toxicological risk assessment.

Evidence can be e.g. a CV detailing the knowledge and experience of the author(s) in the field of biocompatibility/biological evaluation of medical devices and toxicological risk assessment. Especially for toxicological risk assessment, it shall be noted that knowledge in toxicology, medical devices and exposure dose estimation needs to be proven.



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Part 2 - Evaluation of impact of the manufacturing process (and locations if applicable) on biocompatibility

For an evaluation of the influence of the manufacturing process and alternative manufacturing locations on biocompatibility refer to:

[X,p.y]

Guidance:

Please include a reference to the part of the Technical Documentation where influences of the manufacturing process and influences of alternative manufacturing locations (where applicable) on the biocompatibility of the final device are evaluated. The evaluation should include a justification for representativeness of the test item in case alternative manufacturing locations and/or processes exist and not all alternatives were tested.



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4.3.2 Packaging

<p>Part 1 - Description of packaging configuration and packaging materials (direct / indirect product contacting materials)</p> <p>For the description of the packaging configuration and information on packaging materials in direct/indirect device contact refer to: [X,p.y]</p> <p><u>Guidance:</u> Please include a reference to the documentation that identifies the packaging material and the packaging configuration. The references shall include information on all materials that directly and indirectly touch the medical device. This may not only include the sterile barrier components, but any other components used within the sterile barrier like e.g., caps, clips, etc. as well as coatings and printing inks. Note: In case of more complex packaging systems, it is recommended to use a tabular view.</p>



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Part 2 - Evaluation of impact of the packaging material on the biocompatibility

For an evaluation of potential influences of the packaging material on the biocompatibility of the medical device refer to:
[X,p,y]

Guidance:

Please refer to the part of the Technical Documentation evaluating the potential influences of the packaging material on the biocompatibility of the medical device. In case this evaluation is based (partly) on tests performed using the packaging itself, please additionally refer to respective test data.

Note: An evaluation of potential influences of the packaging material on the biocompatibility of the medical device is required in any case and shall consider potential packaging migrants. The evaluation might be based on testing of a device in its final packaging or on testing of the packaging itself. It should be noted that the potential for interaction of the medical device with the packaging materials can be different depending on the device type and packaging used (e.g. solid vs. liquid devices, plastic vs. metal or glass packaging, use of adhesives vs. no adhesives etc.). The individual potential for interaction shall be reflected in the extent of testing as well as in the evaluation effort.

Note: In case biocompatibility test data is leveraged from a predicate device that uses a different packaging system, the evaluation of potential influences of the packaging material on the biocompatibility of the medical device cannot be based on the testing of the predicate device in its final packaging but additional considerations and/or data is required for a comprehensive evaluation.



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4.3.3 Sterilisation

Part 1 - Description of sterilisation type and conditions as well as location(s)
<p>For the identification of the sterilisation site(s) and the respective sterilisation conditions refer to: [X,p,y]</p> <p><u>Guidance:</u> Please refer to the part of the Technical Documentation providing information on</p> <ul style="list-style-type: none">• the sterilisation site(s),• sterilisation type,• sterilisation conditions for every site,• max. no. of sterilisation cycles or max. sterilisation dose allowed.



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Part 2 - Evaluation of the impact of the sterilisation process on the biocompatibility
<p>For the evaluation of potential influences of the sterilisation process on the biocompatibility of the medical device refer to: [X,p,y]</p> <p><i>Guidance:</i> Please refer to the part of the Technical Documentation determining how the applicable sterilisation conditions / procedures may affect biocompatibility. If more than one sterilization site or cycle are used, please explain differences among them and identify the worst-case facility / sterilisation conditions (including re-sterilisation if applicable) to justify e.g. test item selection.</p>

4.3.4 Device life-time

Shelf life
Part 1 - Information on storage conditions and shelf life as described in IFU
<p>For the information on the device´s shelf life refer to: [X,p,y]</p> <p><i>Guidance:</i> Please refer to the part of the Technical Documentation discussing shelf life and storage conditions. Note: In principle, the requested information is expected to be the Instructions for use.</p>



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Part 2 - Evaluation of the impact of the shelf life incl. storage conditions on the biocompatibility

For the evaluation of potential influences of the shelf life under the defined storage conditions on the biocompatibility of the medical device refer to:

[X,p.y]

Guidance:

Please refer to the part of the Technical Documentation evaluating the potential impact of the shelf life under the defined storage conditions on the biocompatibility of the medical device.

Note: Biocompatibility issues may arise inter alia from alteration / degradation of the device materials themselves or from packaging migrants over time.

It should be noted that the potential for changes of the biocompatibility profile of the device can be different depending on the device type and packaging used (e.g. degradable vs. inert devices, solid vs. liquid devices, plastic vs. metal or glass packaging, etc.). The individual potential for changes shall be reflected in the extent of testing as well as in the evaluation effort.



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Handling

☐ Applicable ☐ Not Applicable

Guidance:

If handling steps are defined in the IFU please check the box “applicable” and fill in Parts 1 and 2 below. If no handling steps are defined, please check the box “not applicable” and proceed with “Duration of use”.

Potential handling steps to be performed prior to the use of the device are e.g. soaking before implantation, removal of protective caps, rinsing, connection of individual parts, mixing procedures or other steps.

Part 1 - Description of the device handling

For a summary of required handling steps to be performed before device application refer to:

[X,p,y]

Guidance:

Please refer to the part of the Technical Documentation compiling handling instructions to be performed prior to use.

Note: In principle, the requested information is expected to be the Instructions for use.

Part 2 - Evaluation of the impact of the handling procedures on the biocompatibility

For the assessment of handling procedures impacting the biocompatibility refer to:

[X,p,y]

Guidance:

Please refer to the part of the Technical Documentation evaluating potential influences of the handling procedures on the biocompatibility of the medical device.

It should be noted that the potential for effects of the handling on the device biocompatibility can be different depending on the handling process applied. The individual impact potential shall be reflected in the extent of testing as well as in the evaluation effort.



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Duration of use
Part 1 - Description of the duration of use
<p>For the determination of the limit pertaining to maximum use duration refer to: [X,p,y]</p> <p><u>Guidance:</u> Please refer to the part of the Technical Documentation describing the maximum duration of use as foreseen in the IFU. The maximum duration of use shall consider both the duration of use of the individual device and the cumulative use time in case of repeated use of the same device type is allowed</p>

Part 2 - Evaluation of the impact of the duration of use considering the respective use environment on the biocompatibility
<p>For the evaluation of the impact of the use duration considering the respective use environment on the biocompatibility refer to: [X,p,y]</p> <p><u>Guidance:</u> Please refer to the part of the Technical Documentation evaluating potential influences of the maximum use duration on the biocompatibility of the device is documented. It should be noted that impact potential on the device biocompatibility can be different depending on the duration of use (e.g. short term contact vs. implant to be in place for 10 years or more). Please note that independently from the duration, the use environment can be a significant impact factor for the biocompatibility over the use time. Please also note that use environment might include both the conditions in the body and external conditions (e.g. UV light). The individual impact potential shall be reflected in the extent of testing as well as in the evaluation effort. In case the duration of use is not covered by the performed testing (e.g. implantation tests cover a duration of 1 year but implant can be in the body for 15 years), additional considerations are required to establish biological safety over the complete duration of use.</p>



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<p>Reprocessing</p> <p><input type="checkbox"/> Applicable <input type="checkbox"/> Not Applicable</p> <p><u>Guidance:</u> If the device is re-usable and therefore subjected to a reprocessing procedure, please check the box “applicable” and fill in Parts 1 and 2. If the device is not re-usable, please check the box “not applicable” and proceed with Section 4.3.5 Material Identification.</p>
<p>Part 1 - Description device reprocessing procedures (if applicable)</p> <p>For an overview on the reprocessing steps refer to: [X,p.y]</p> <p><u>Guidance:</u> Please refer to the part of the Technical Documentation describing the reprocessing procedure to be applied in order to allow safe re-use of the device. The referenced document(s) should also include information on the maximally allowed number of reprocessing cycles supported by respective validation data. Note: In principle, the requested information is expected to be the Instructions for use.</p>



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Part 2 - Evaluation of the impact of reprocessing on biocompatibility (if applicable)

For an evaluation of reprocessing effects on the biocompatibility refer to:

[X,p,y]

Guidance:

Please refer to the part of the Technical Documentation evaluating potential influences of reprocessing on the biocompatibility of the device. Please also refer to the part of the Technical Documentation where related test data can be found.

The evaluation needs to cover each time point of use, i.e. from

- n=1 - the device processed for the first time to
- n=max -maximum number of reprocessing cycles applied

Both, effects of the influences of reprocessing on the biocompatibility of the materials of construction as well as the potential for accumulation of (superficial) residues from the reprocessing process need to be covered by the evaluation.

4.3.5 Material Identification

Materials of construction with direct and indirect patient contact

For information on device materials of construction including used additives in (in-)direct contact with the human body, their suitability and the type of contact refer to:

[X,p,y]

Guidance:

Please refer to the part of the Technical Documentation detailing information on materials of construction with direct or indirect body contact. Please be aware that e.g., an injection moulded part of a medical device may be composed of different compounds used for injection moulding (e.g., colorant, resin, or other additives). In such cases, information on the individual constituents of the injection moulded part or extruded part is requested (base materials and additives, which remain an integral part of the final material / compound). If a device is composed of several individual components / parts, each composed / manufactured from different individual materials, please provide information on all parts pertaining to biocompatibility – e.g., patient- or user-contacting parts.



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Following information should be easily found with the provided reference(s) for each material used in the device:

- *material type (incl. information on unambiguous technical grade and article number)*
- *material specifications*
- *where applicable: compliance to material standard (e.g. ISO, ASTM) or pharmacopoeias incl. respective evidence such as Certificate of Conformance or Certificate of Analysis*
- *raw material manufacturer (supplier)*
- *body contact (direct or indirect; contact to patient and/or user)*
- *contact duration*
- *part/component made of respective material*
- *part/component manufacturer (inhouse or supplier)*
- *any additives used in part/component manufacturing*
- *additional information where relevant (e.g. amount of material and/or proportion of material)*

Note: The information on materials of construction should be presented in a tabular form to enhance readability.



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Process aids and process residues which have potential to remain in / on the medical device
<p>For the identification on manufacturing aids facilitating the production process and process-derived residues suspected to adhere on the device`s surface/remain in the device with an impact on biocompatibility refer to: [X,p,y]</p> <p><u>Guidance:</u> Please refer to the part of the Technical Documentation detailing information on aids used throughout the entire manufacturing process from raw material to the final finished, packaged, sterilised medical device. Remaining process residues are expected to be identified.</p> <p>Following information should be easily found with the provided reference(s) for each material used in the device:</p> <ul style="list-style-type: none">• Process step where the aid is used• clear identification of aid used (e.g. trade name)• composition and concentration of individual ingredients (as far as known)• material specifications• where applicable: compliance to material standard (e.g. ISO, ASTM) or pharmacopoeias incl. respective evidence such as Certificate of Conformance or Certificate of Analysis• process aid manufacturer (supplier)• objective evidence determining the presence of the process aid on the medical device <p>Note: The information on process aids should be presented in a tabular form to enhance readability.</p>



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CMR 1A/B and/or endocrine-disrupting substances

☐ Applicable ☐ Not Applicable

Guidance:

If the device or a part thereof

- is invasive and comes into direct contact with the human body OR
 - (re)administers medicines, body liquids or other substances, including gases, to/from the body OR
 - transports or stores such medicines, body fluids or substances, including gases, to be (re)administered to the body,
- please check the box "applicable" and fill in the box below. If the device is none of the above, e.g. having contact to intact skin only, please check the box "not applicable" and proceed with Section 4.4 Chemical characterisation.

Identification of CMR 1A/B and/or endocrine-disrupting substances

The medical device contains CMR 1A/B and/or endocrine-disrupting substances from the sources mentioned in GSPR 10.4.1 a) and b) in a concentration >0.1% weight by weight (w/w)

☐ Yes

☐ No

Guidance:

The manufacturer of the medical device needs to determine, whether the device, or those parts thereof or those materials used therein, contain CMR 1A/B and/or endocrine-disrupting substances from the sources mentioned in GSPR 10.4.1 a) and b) in concentrations above 0.1% (w/w).

Please check the box "Yes" only in case one or more CMR 1A/1B or endocrine-disrupting substance is present in a concentration ABOVE 0.1% weight by weight.

For the determination of presence or absence of CMR 1A/B and/or endocrine-disrupting substances contained in the medical device >0.1% (w/w) refer to:

[X,p,y]

Guidance:

Please refer to the part of the Technical Documentation detailing information on how the presence or absence of CMR 1A/B and/or endocrine-disrupting substances >0.1% (w/w) has been determined.



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For the justification required according GSPR 10.4.2 in case the medical device contains CMR 1A/B and/or endocrine-disrupting substances in a concentration >0.1% weight by weight (w/w) refer to:

[X,p,y]

Guidance:

Please refer to the part of the Technical Documentation detailing the justification for the presence of CMR 1A/B and/or endocrine-disrupting substances in a concentration >0.1% weight by weight (w/w).

The justification shall be in line with all subpoints of MDR GSPR 10.4.2 and where applicable/available with scientific committee guidelines as stated in MDR GSPRs 10.4.3 and 10.4.4.

It should be noted that the justification and benefit-risk assessment generally need to consider performance related, mechanical, toxicological and clinical aspects. However, only toxicological aspects are relevant for the biocompatibility review. The overall justification and benefit-risk assessment will be covered within different modules.



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4.4 Chemical characterisation

Explanation: The intent of this section is to provide further, in-depth detail on the performed chemical characterisation for review. In case chemical analytic testing has been performed, details of the testing are requested in tabular form to get a high-level understanding of important aspects. If chemical characterisation is done by other means (e.g. paper based), details on this are requested below that table.

Chemical analytic testing

For a high-level overview, the table below summarises key features / findings of the chemical analytical characterisation and references to the part of the Technical Documentation where detailed information can be found:

Guidance:

Please fill in the table with information providing an overview of the chemical characterisation procedure. More precisely, it is required to tick applicable boxes, provide short high-level excerpts (e.g., for the extraction conditions, methods and applied standards) and to supplement all inserted information with references to parts of the Technical Documentation that provide a comprehensive overview of the experimental details and results as well as laboratory test reports.

Please note that there are separate queries for testing for organic substances (Part 1) and inorganic substances (Part 2). In case chemical analytic testing is performed but the testing does not cover all types of chemical entities (i.e. VOC, SVOC, NVOC, elements, anions and cations), justification for the omission of testing for specific chemical entities shall be provided (Part 3).

For the sake of clarity, for each method applied (e.g. GC-MS) one line shall be filled in even if several methods are reported in one laboratory test report. Information that is applicable for all/several methods does not need to be provided in every line repeatedly. For example, if the same test item was used for all methods, the information on the test item can be filled in for the first method only and for all other methods it is referenced to the information provided for the first method.

Further guidance is provided in the table below.

In case chemical characterisation was done by other means, please state here "N/A" and fill in the line "Alternative chemical characterisation" below the lines related to testing.



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Part 1 - Testing for organic entities					
Type of test (Report No. and report date)	Final product tested? (Yes/No)	Extraction conditions	Applied standard version for testing and sample preparation	Test Facility	Results
Test method applied: <input type="checkbox"/> VOC: XYZ <input type="checkbox"/> SVOC: XYZ <input type="checkbox"/> NVOC: XYZ <i>Guidance:</i> For the selected type of chemical entities, please further specify the applied method after the respective colon (e.g. HS-GC/MS). Test report: LAB-REP-NO-XYZ YYYY-MM-DD [X,p,y] or [X]	Test item specification: XYZ <i>Guidance:</i> Please add here the name, article no. and lot no. of the test item. Documented in: [X,p,y] <input type="checkbox"/> Yes, the following routine conditions are covered by the test item: <input type="checkbox"/> Materials/processing aids <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging	Type of extraction: <input type="checkbox"/> Simulated: XYZ <input type="checkbox"/> Exaggerated: XYZ <input type="checkbox"/> Exhaustive: XYZ <input type="checkbox"/> Other: XYZ <i>Guidance:</i> For the selected type(s) of extraction, please add relevant details such as duration, temperature, surface/volume ratio, number of cycles or confirmation of exhaustiveness, etc. after the respective colon. Please additionally add an explanation why the conditions are considered simulating/exaggerating/exhaustive.	XYZ <i>Guidance:</i> Please indicate the version of the standard. In case a legacy version of the EN ISO 10993-18 was applied, please provide additionally reference to a gap analysis to verify the validity. In case product-specific standards with chemical analytical testing requirements	Name and address: XYZ <i>Guidance:</i> Please identify the test facility unequivocally. Qualification for the test: <input type="checkbox"/> The laboratory was ISO/IEC 17025 accredited / GLP certified for the respective method at the time of testing. Documented in: [X,p,y]	Reporting threshold: XYZ <i>Guidance:</i> Please identify the actual reporting thresholds for the individual analytical method, as specified in the test report. Justification of adequacy of the actual reporting thresholds: <i>Guidance:</i> Please explain why the actual reporting threshold is relevant to toxicological risk assessment, i.e. why anything below that threshold can be regarded as toxicologically safe.



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<p><u>Guidance:</u> Identify the test report number assigned by the test laboratory, include the test report date and refer to the part of the document where the test report can be found.</p>	<p> <input type="checkbox"/> Sterilisation <input type="checkbox"/> Shelf-life <input type="checkbox"/> Other: XYZ </p> <p><u>Guidance:</u> Please specify here any procedures like e.g. handling, reprocessing, etc. that were carried out for test item preparation to represent the final clinical conditions</p> <p>Documented in: [X,p,y]</p> <p> <input type="checkbox"/> No, <u>not all</u> of the routine conditions are covered by the test item. Description of differences and justification can be found in: [X,p,y] </p> <p> <input type="checkbox"/> No, <u>only an individual</u> part was tested, for a description of the part and justification for representativeness refer to: [X,p,y] </p>	<p>In case "Other" is selected, please additionally include a reference to the part of the Technical Documentation where it is justified why non-normative extraction conditions were used.</p> <p><input type="checkbox"/></p> <p>Vehicle:</p> <p> <input type="checkbox"/> Polar: XYZ <input type="checkbox"/> Semi-polar: XYZ <input type="checkbox"/> Non-polar: XYZ <input type="checkbox"/> Other: XYZ </p> <p><u>Guidance:</u> For the selected extraction vehicle(s), please add relevant details such as duration, temperature, surface/volume ratio, etc. after the respective colon.</p> <p>Documented in: [X,p,y]</p>	<p>are available (e.g. ISO 11979-5), the manufacturer shall provide a rationale why the standard used for testing can be considered as state of the art to fulfil the GSPRs. .</p> <p>Documented in: [X,p,y]</p>	<p> <input type="checkbox"/> The laboratory was <u>NOT</u> ISO/IEC 17025 accredited / GLP certified. </p> <p><u>For a justification refer to:</u> [X,p,y]</p> <p><u>Guidance:</u> In case testing was performed in a non-ISO 17025-accredited or non-GLP environment, it is required to clearly demonstrate that both the laboratory and methods are suitably qualified for the analytical tasks conducted. This shall be demonstrated as part of the justification.</p>	<p> <input type="checkbox"/> AET was determined. <input type="checkbox"/> AET determination included the most vulnerable intended patient population under consideration of worst-case application </p> <p> <input type="checkbox"/> Presence of Cohort of Concern (CoC) Substances in/on the device was determined to be unlikely. <u>Guidance:</u> This can be determined based on information gathering on materials and processing, compositional analyses, </p> <p> <input type="checkbox"/> Presence of Cohort of Concern (CoC) Substances in/on the device is known or likely, therefore these substances were toxicologically risk assessed on their own. </p> <p> <input type="checkbox"/> Actual reporting threshold was equal or below AET <input type="checkbox"/> Other justification of the actual reporting threshold. </p> <p>Documented and - if boxes above not ticked - justified in: [X,p,y]</p>
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					<p>Organic entities detected above the reporting threshold:</p> <p><input type="checkbox"/> Yes; for a list, refer to: [X,p,y]</p> <p><input type="checkbox"/> No; for evidence refer to: [X,p,y]</p> <p><u>Guidance:</u> The list of detected substances should be in tabulated format and fulfilling appropriate identification requirements (e.g., Chemical IUPAC name, CAS number, level of identification) and quantification information.</p>
<p><i>Expand as needed</i></p> <p><u>Guidance::</u> Please copy the line above if testing for more than one type of chemical entities was performed (even in case it is reported in the same laboratory report). Please do not add outdated test data if newer tests are available.</p>					



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Part 2 - Testing for inorganic entities					
Type of test (Report No. and report date)	Final product tested? (Yes/No)	Extraction conditions	Applied standard version for testing and sample preparation	Test Facility	Results
<p>Test method applied:</p> <p><input type="checkbox"/> Elements: XYZ</p> <p><input type="checkbox"/> Anions/Cations: XYZ</p> <p><u>Guidance:</u> For the selected type of chemical entities, please further specify the applied method after the respective colon (e.g. ICP-MS).</p> <p>Test report: LAB-REP-NO-XYZ YYYY-MM-DD [X,p,y] or [X]</p>	<p>Test item specification: XYZ</p> <p><u>Guidance:</u> Please add here the name, article no. and lot no. of the test item.</p> <p>Documented in: [X,p,y]</p> <p><input type="checkbox"/> Yes, the following routine conditions are covered by the test item:</p> <p><input type="checkbox"/> Materials/processing aids</p> <p><input type="checkbox"/> Manufacturing</p> <p><input type="checkbox"/> Packaging</p>	<p>Type of extraction:</p> <p><input type="checkbox"/> Simulated: XYZ</p> <p><input type="checkbox"/> Exaggerated: XYZ</p> <p><input type="checkbox"/> Exhaustive: XYZ</p> <p><input type="checkbox"/> Other: XYZ</p> <p><u>Guidance:</u> For the selected type(s) of extraction, please add relevant details such as duration, temperature, surface/volume ratio, number of cycles or confirmation of exhaustiveness, etc. after the respective colon. Please additionally add an explanation why the conditions are considered simulating/exaggerating/exhaustive.</p>	<p>XYZ</p> <p><u>Guidance:</u> Please indicate the version of the standard. In case a legacy version of the EN ISO 10993-18 was applied, please provide additionally reference to a gap analysis to verify the validity. In case product-specific standards with chemical analytical testing requirements</p>	<p>Name and address: XYZ</p> <p><u>Guidance:</u> Please identify the test facility unequivocally.</p> <p>Qualification for the test:</p> <p><input type="checkbox"/> The laboratory was ISO/IEC 17025 accredited / GLP certified for the respective method at the time of testing.</p> <p>Documented in: [X,p,y]</p>	<p>Reporting threshold: XYZ</p> <p><u>Guidance:</u> Please identify the actual reporting thresholds for the individual analytical method, as specified in the test report.</p> <p>Justification of adequacy of the actual reporting thresholds:</p> <p><u>Guidance:</u> Please explain why the actual reporting threshold is relevant to toxicological risk assessment, i.e. why anything below that threshold can be regarded as toxicologically safe.</p>



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<p><u>Guidance:</u> Identify the test report number assigned by the test laboratory, include the test report date and refer to the part of the document where the test report can be found.</p>	<p> <input type="checkbox"/> Sterilisation <input type="checkbox"/> Shelf-life <input type="checkbox"/> Other: XYZ </p> <p><u>Guidance:</u> Please specify here any procedures like e.g. handling, reprocessing, etc. that were carried out for test item preparation to represent the final clinical conditions</p> <p>Documented in: [X,p,y]</p> <p> <input type="checkbox"/> No, <u>not all</u> of the routine conditions are covered by the test item. Description of differences and justification can be found in: [X,p,y] </p> <p> <input type="checkbox"/> No, <u>only an individual part</u> was tested, for a description of the part and justification for representativeness refer to: [X,p,y] </p>	<p>In case "Other" is selected, please additionally include a reference to the part of the Technical Documentation where it is justified why non-normative extraction conditions were used.</p> <p>Vehicle:</p> <p> <input type="checkbox"/> Polar: XYZ <input type="checkbox"/> Semi-polar: XYZ <input type="checkbox"/> Non-polar: XYZ <input type="checkbox"/> Other: XYZ </p> <p><u>Guidance:</u> For the selected extraction vehicle(s), please add relevant details such as duration, temperature, surface/volume ratio, etc. after the respective colon.</p> <p>Documented in: [X,p,y]</p>	<p>are available (e.g. ISO 11979-5), the manufacturer shall provide a rationale why the standard used for testing can be considered as state of the art to fulfil the GSPRs. .</p> <p>Documented in: [X,p,y]</p>	<p> <input type="checkbox"/> The laboratory was <u>NOT</u> ISO/IEC 17025 accredited / GLP certified. </p> <p><u>For a justification refer to:</u> [X,p,y]</p> <p><u>Guidance:</u> In case testing was performed in a non-ISO 17025-accredited or non-GLP environment, it is required to clearly demonstrate that both the laboratory and methods are suitably qualified for the analytical tasks conducted. This shall be demonstrated as part of the justification.</p>	<p> <input type="checkbox"/> A toxicologically justified evaluation threshold was determined for the most vulnerable intended patient population under consideration of worst-case application (e.g., PDEs from elements from ICH Q3D where applicable). </p> <p> <input type="checkbox"/> Actual reporting threshold was equal or below the toxicologically justified evaluation threshold </p> <p>Documented and - if boxes above not ticked - justified in: [X,p,y]</p> <p>Inorganic entities detected above the reporting threshold:</p> <p> <input type="checkbox"/> yes; for a list, refer to: [X,p,y] <input type="checkbox"/> no; for evidence refer to: [X,p,y] </p> <p><u>Guidance:</u> The list of detected substances should be in tabulated format and fulfilling appropriate identification requirements and quantification information.</p>
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Expand as needed

Guidance:

Please copy the line above if testing for more than one type of chemical entities was performed (even in case it is reported in the same laboratory report).

Please do not add outdated test data if newer tests are available.



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Part 3 - Justification for the omission of testing for specific chemical entities

For the justification for the omission of testing for specific chemical entities please refer to:

[X,p,y]

Guidance:

If not all types of chemical entities are covered by the performed testing (i.e. VOC, SVOC, NVOC, elements, anions and cations), please refer to the part of the Technical Documentation justifying the omission of testing for the specific chemical entity/entities.



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Alternative chemical characterisation

For a justification for omission of chemical analytic testing as well as documentation of alternative chemical characterisation please refer to:
[X,p,y]

Guidance:

A chemical characterisation in line with the standards requirements does not necessarily require chemical analytic testing. Depending on the device type a comprehensive chemical characterisation can also be performed by other means, e.g. on the basis of available compositional data.

In case no chemical analytic testing has been performed, please refer to the part of the Technical Documentation

- justifying the omission of chemical analytic testing*
- documenting the performed chemical characterisation.*

If chemical analytic testing has been performed, this section would be "N/A".



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4.5 Degradation

Explanation: The intent of this section is to understand the degradation potential of the device under assessment and to locate relevant information on degradation (such as determination of degradation potential as well as evaluation of the impact of any degradation on the biocompatibility) in the manufacturer's Technical Documentation.

Part 1 - Degradation potential

- ☐ The medical device or parts thereof have no potential to be degraded under the conditions of manufacture, sterilisation, transport, storage, and use. Documented in: [x,p,y]
- ☐ The medical device or parts thereof have the potential to be degraded under the conditions of manufacture, sterilisation, transport, storage, and use. Documented in: [x,p,y]
- ☐ The medical device or parts thereof are intended to be degraded under clinical use conditions. Documented in: [x,p,y]

Guidance:

Please select the applicable degradation potential for the device under assessment

Part 2 - Evaluation of the impact of degradation on biocompatibility in case of intended or unintended degradation (if applicable)

Guidance:

If the device under assessment is intended to be degraded or has the potential to be degraded, please fill in Part 2 below. If the device under assessment has no potential to degrade, please proceed with section 4.6 "Toxicological risk assessment".

For an evaluation of potential biocompatibility issues arising from intended or unintended degradation refer to:
[X,p,y]

Guidance:

Please refer to the part of the Technical Documentation detailing

- the approach to determine the degradation potential and
- the evaluation of the impact of degradation on biocompatibility
- for medical devices intended to degrade: proposed mechanism of degradation.

If degradation testing was performed, respective test data shall be referenced here as well.



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4.6 Toxicological risk assessment

Explanation: The intent of this section is to get a high-level understanding of important aspects of the performed toxicological risk assessment and help to locate these aspects in the manufacturer's Technical Documentation.

Toxicological risk assessment
<p>For the technological risk assessment refer to: [X] or [X,p,y]</p> <p><u>Guidance:</u> Please provide reference to the part of the Technical Documentation including the toxicological risk assessment. Additionally, please check the boxes below that are applicable to the submitted toxicological risk assessment.</p> <p>The applied concept for toxicological risk assessment follows</p> <p><input type="checkbox"/> the latest version of EN ISO 10993-17</p> <p><input type="checkbox"/> a superseded version of EN ISO 10993-17 or other concept for toxicological risk assessment; for a justification for the adequacy of the existing toxicological risk assessment (e.g., gap and impact assessment towards the latest version of EN ISO 10993-17, information on changes), and additional measures where needed refer to: [X,p,y]</p> <p>The following is covered by the toxicological risk assessment:</p> <p><input type="checkbox"/> consideration of device worst-case use characteristics (i.a. number, frequency and duration of devices in contact to the body, user population)</p> <p><input type="checkbox"/> Constituent's and/or extractables/leachables toxicological data (including identification of carcinogens/suspected human carcinogens)</p> <p><input type="checkbox"/> Justifications and methods used to apply TSL <u>Guidance:</u> Please note that justification shall consider the presence of Cohort of Concern substances as TSL is not applicable to CoCs.</p> <p><input type="checkbox"/> Derivation of TCL/TI</p> <p><input type="checkbox"/> Application of TTC <u>Guidance:</u> Please note that justification shall consider the presence of Cohort of Concern substances as TTC is not applicable to CoCs.</p> <p><input type="checkbox"/> Estimation of exposure dose and evaluation of the worst case-exposure</p> <p><input type="checkbox"/> Derivation of MOS values</p> <p><input type="checkbox"/> Derivation of combined MOS values was required</p> <p><input type="checkbox"/> Further risk analysis/evaluation/control was required</p>



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4.7 Physical characterisation

Explanation: The intent of this section is to provide further, in-depth detail for review, with a particular emphasis on physical characteristics including particles where applicable.

Relevance of physical characteristics for biocompatibility evaluation

☐ Relevant ☐ Not Relevant

Guidance:

If physical characteristics are considered relevant for the biocompatibility evaluation, please check the box “applicable” and fill in Parts 1 and 2 below. If not, please check the box “not applicable” and proceed with “MDR only - Particles”.

Physical characteristics are considered relevant for biocompatibility evaluation e.g. for implants, devices with blood contact or devices containing nanomaterials.

Part 1 - Description of physical characteristics

For a summary of the physical characteristics relevant in the context of biocompatibility refer to:

[X,p,y]

Guidance:

Please refer to the part of the Technical Documentation determining the physical characteristics of the medical device.

Relevant physical characteristics are for example surface properties like roughness, porosity or for nanomaterials the particle size.



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Part 2 - Evaluation of the impact of physical properties on biocompatibility

For an evaluation of the effect of physical properties on the biocompatibility refer to:
[X,p,y]

Guidance:

Please refer to the part of the Technical Documentation evaluating how physical device characteristics impact on the biocompatibility of the device.

Particles

☐ Applicable ☐ Not Applicable

Guidance:

Under MDR, requirements related to particles apply unless the device has contact with intact skin only.

If this is a MDR submission and particles are relevant for the device under assessment, please check the box “applicable” and fill in Parts 1 and 2 below. If not, please check the box “not applicable” and proceed with section 4.8 “Biological Testing”.

Part 1 - Description of the state (number, size, and properties) of particles in/on the product

For a description of particles on / in the device and their characterisation refer to:
[X,p,y]

Guidance:

Please refer to the part of the Technical Documentation providing information on particles that are either intentionally or unintentionally on / in the medical device.

Please note that information is required for particles that are present in/on the final product and those that may be generated during transport/storage and/or by degradation/corrosion during use.



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Relevant information on particles is the size and number of particles, their chemical identity or their most likely origin (e.g. from environment such as dust, from processing aids or the material itself).

Note: Information on intentional nanoparticles is to be provided in the section above (Part 1 – Description of physical characteristics and Part 2 – Evaluation of the impact of physical properties on biocompatibility).

For information on how particle amount, size and properties was determined refer to:

[X,p.y]

Guidance:

Please refer to the part of the Technical Documentation providing information on how the particle amount, size and properties were determined.

Particle amount, size and properties can be determined by different approaches, testing might not be required for all medical device types. However, if specific testing requirements for the different device types apply (e.g. for cardiovascular products, breathing pathway devices, active implantable medical devices, etc.) it needs to be shown that these requirements were met.



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Part 2 - Evaluation of the impact of the presence of particles on biocompatibility (if applicable)

For the evaluation of potential biocompatibility issues arising from the presence of particles refer to:
[X,p.y]

Guidance:

Please refer to the part of the Technical Documentation evaluating the effect of particles on the biocompatibility of the medical device.



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4.8 Biological testing

Explanation: The intent of this section is to provide detailed information on how biological testing was performed in a condensed form.

Adequacy of the selected test conditions should be demonstrated in this section.

Please only reference performed biological tests, as the reference to rationales for omitted testing should be presented in section 4.9 “Endpoint evaluation” of this document.

For a high-level overview, the table below summarises key features / findings of the biological testing and references to the part of the Technical Documentation where detailed information can be found:

Guidance:

*Please fill in the table with information providing an overview of the biological testing efforts. More precisely, it is required to tick applicable boxes, provide short high-level excerpts (e.g., for the extraction conditions, results and applied standards) and to supplement all inserted information with references to parts of the Technical Documentation that provide a comprehensive overview of the experimental details and results as well as laboratory test reports. Further guidance is provided in the table below.
Please expand the table for all performed biological tests.*



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Type of test (Report No. and report date)	Final product tested? (Yes/No)	Extraction conditions	Applied standard version for testing and sample preparation	Results	Test Facility	Comments
Test report: LAB-REP-NO-XYZ YYYY-MM-DD [X,p,y] or [X] <u>Guidance:</u> Identify the type of test, the test report number assigned by the test laboratory, include the test report date and refer to the part of the document where the test report can be found.	Test item specification: XYZ <u>Guidance:</u> Please add here the name, article no. and lot no. of the test item. Documented in: [X,p,y] <input type="checkbox"/> Yes, the following routine conditions are covered by the test item: <input type="checkbox"/> Materials/ processing aids <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization	Type of extraction: <input type="checkbox"/> 6 cm ² /ml ± 10% <input type="checkbox"/> 3 cm ² /ml ± 10% <input type="checkbox"/> 0.2g /ml ± 10% <input type="checkbox"/> 0.1g /ml ± 10% <input type="checkbox"/> other: XYZ <u>Guidance:</u> In case "Other" is selected, please include a reference to the part of the Technical Documentation where it is justified why non-normative extraction ratio was used. Time/Temperature: <input type="checkbox"/> 37±1°C for 24±2 h <input type="checkbox"/> 37±1°C for 72±2 h <input type="checkbox"/> 50±2°C for 72±2 h	Testing: XYZ Sample Preparation: XYZ <u>Guidance:</u> Please indicate the version of the standards applied for BOTH testing and sample preparation. In case a legacy version of the EN ISO 10993-X was applied, please provide	<input type="checkbox"/> Passed/met pre-defined acceptance criteria: XYZ <input type="checkbox"/> Failed: XYZ <u>Guidance:</u> Please provide the results of the testing in a very condensed format. E.g., for cytotoxicity, add the grade / % of growth inhibition, grade of test group vs. control group, etc. Documented in: [X,p,y] <input type="checkbox"/> The results need further interpretation. For interpretation refer to: [X,p,y]	Qualification for the test: <input type="checkbox"/> The laboratory was ISO/IEC 17025 accredited / GLP certified for the respective method <u>at</u> <u>the time of testing.</u> Documented in: [X,p,y] <input type="checkbox"/> The laboratory was <u>NOT</u> ISO/IEC 17025 accredited / GLP certified. <u>For a justification refer to:</u> [X,p,y] <u>Guidance:</u> In case testing was performed in a non-ISO	XYZ <u>Guidance:</u> Please report any unexpected observations or deviations from test protocol encountered during endpoint testing.



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<p><u>Guidance:</u> Identify the test report number assigned by the test laboratory, include the test report date and refer to the part of the document where the test report can be found.</p>	<p><input type="checkbox"/> Shelf-life <input type="checkbox"/> Other: XYZ</p> <p><u>Guidance:</u> handling, reprocessing, etc. please specify</p> <p>Documented in: [X,p,y]</p> <p><input type="checkbox"/> No, <u>not all</u> of the <u>routine conditions are covered</u> by the test item. Description of differences and justification can be found in: [X,p,y]</p> <p><input type="checkbox"/> No, <u>only an individual part was tested</u>, for a description of the part and justification representativeness refer to: [X,p,y]</p>	<p><input type="checkbox"/> 70±2°C for 24±2 h <input type="checkbox"/> 121±2°C for 1±0.1 h <input type="checkbox"/> other: XYZ</p> <p><u>Guidance:</u> In case "Other" is selected, please include a reference to the part of the Technical Documentation where it is justified why non-normative extraction conditions were used.</p> <p>Vehicle:</p> <p><input type="checkbox"/> Polar: XYZ <input type="checkbox"/> Non-polar: XYZ <input type="checkbox"/> Other: XYZ</p> <p>Documented in: [X,p,y]</p>	<p>additionally reference to a gap analysis to verify the validity. In case product-specific standards with biological testing testing requirements are available (e.g. ISO 11979-5), the manufacturer shall provide a rationale why the standard used for testing can be considered as state of the art to fulfil the GSPRs.</p> <p>Documented in: [X,p,y]</p>	<p><u>Guidance:</u> Interpretation is needed e.g. in case the result is ambiguous (e.g. acceptance criteria met, but with very low safety margin), when the acceptance criteria were not met or when controls were outside the historical values.</p>	<p>17025-accredited or non-GLP environment, it is required to clearly demonstrate that both the laboratory and methods are suitably qualified for the tasks conducted. This shall be demonstrated as part of the justification</p>	
Expand as needed	<p><u>Guidance:</u> Please copy the line above if testing for more than one endpoint was performed.</p>					



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4.9 Endpoint Evaluation

Explanation: The intent of this section is to understand based on which data the applicable biological and/or toxicological endpoints are assessed by the manufacturer (including justification for omission of biological testing). This section shall also help to locate the endpoint evaluation in the manufacturer's Technical Documentation.

Evaluation of applicable biological and/or toxicological endpoints		
<p>For a high-level overview, the table below summarises data input used for evaluation of the biological and/or toxicological endpoints identified to be applicable in section 4.2 of this document and references to the part of the Technical Documentation where a detailed evaluation can be found:</p>		
Biological effect/endpoint	Addressed by	Reference to endpoint evaluation in Technical Documentation
<p><u>Guidance:</u> Please delete the lines for any biological effect/endpoint that is not applicable for the device under assessment. This should be in line with the information provided in section 4.2 of this document.</p>	<p>Addressed by T_{10993} = Biological tests from ISO 10993-Series T = other (biological) Tests</p> <p><u>Guidance:</u> Please select any data set that is used within the endpoint evaluation to support safety in relation to the respective biological and/or toxicological endpoint.</p>	<p><u>Guidance:</u> Please refer to the part of the Technical Documentation evaluating the respective endpoint (generally this is a section of the Biological Evaluation Report). Please ensure that the evaluation covers all data sets selected in the middle column to be supporting safety. In case clinical/PMS and/or literature data is used, the evaluation needs to demonstrate that the data is relevant for the specific endpoint. In case a performed biological test was failed, the endpoint evaluation shall establish why the risk related to the endpoint is anyhow acceptable.</p>
Cytotoxicity	<p>Biological testing <input type="checkbox"/> T_{10993} <input type="checkbox"/> T</p> <p>Biological testing from predicate device <input type="checkbox"/> T_{10993} <input type="checkbox"/> T</p> <p>Other data <input type="checkbox"/> Chemical Characterisation and toxic risk assessment <input type="checkbox"/> Clinical Data/PMS data <input type="checkbox"/> Literature</p>	<p>For an evaluation of cytotoxicity refer to: XYZ</p>



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Sensitisation	<p>Biological testing <input type="checkbox"/> T₁₀₉₉₃ <input type="checkbox"/> T</p> <p>Biological testing from predicate device <input type="checkbox"/> T₁₀₉₉₃ <input type="checkbox"/> T</p> <p>Other data <input type="checkbox"/> Chemical Characterisation and toxic risk assessment <input type="checkbox"/> Clinical Data/PMS data <input type="checkbox"/> Literature</p>	For an evaluation of Sensitisation refer to: XYZ
Irritation / Intracutaneous reactivity	<p>Biological testing <input type="checkbox"/> T₁₀₉₉₃ <input type="checkbox"/> T</p> <p>Biological testing from predicate device <input type="checkbox"/> T₁₀₉₉₃ <input type="checkbox"/> T</p> <p>Other data <input type="checkbox"/> Chemical Characterisation and toxic risk assessment <input type="checkbox"/> Clinical Data/PMS data <input type="checkbox"/> Literature</p>	For an evaluation of Irritation / Intracutaneous reactivity refer to: XYZ
Acute Systemic Toxicity	<p>Biological testing <input type="checkbox"/> T₁₀₉₉₃ <input type="checkbox"/> T</p> <p>Biological testing from predicate device <input type="checkbox"/> T₁₀₉₉₃ <input type="checkbox"/> T</p> <p>Other data <input type="checkbox"/> Chemical Characterisation and toxic risk assessment <input type="checkbox"/> Clinical Data/PMS data <input type="checkbox"/> Literature</p>	For an evaluation of Acute Systemic Toxicity refer to: XYZ
Material-mediated Pyrogenicity	<p>Biological testing <input type="checkbox"/> T₁₀₉₉₃ <input type="checkbox"/> T</p> <p>Biological testing from predicate device <input type="checkbox"/> T₁₀₉₉₃ <input type="checkbox"/> T</p> <p>Other data <input type="checkbox"/> Chemical Characterisation and toxic risk assessment <input type="checkbox"/> Clinical Data/PMS data <input type="checkbox"/> Literature</p>	For an evaluation of Material-mediated Pyrogenicity refer to: XYZ



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Subacute Toxicity	<p>Biological testing <input type="checkbox"/> T₁₀₉₉₃ <input type="checkbox"/> T</p> <p>Biological testing from predicate device <input type="checkbox"/> T₁₀₉₉₃ <input type="checkbox"/> T</p> <p>Other data <input type="checkbox"/> Chemical Characterisation and toxic risk assessment <input type="checkbox"/> Clinical Data/PMS data <input type="checkbox"/> Literature</p>	For an evaluation of Subacute Toxicity refer to: XYZ
Subchronic Toxicity	<p>Biological testing <input type="checkbox"/> T₁₀₉₉₃ <input type="checkbox"/> T</p> <p>Biological testing from predicate device <input type="checkbox"/> T₁₀₉₉₃ <input type="checkbox"/> T</p> <p>Other data <input type="checkbox"/> Chemical Characterisation and toxic risk assessment <input type="checkbox"/> Clinical Data/PMS data <input type="checkbox"/> Literature</p>	For an evaluation of Subchronic Toxicity reactivity refer to: XYZ
Chronic Toxicity	<p>Biological testing <input type="checkbox"/> T₁₀₉₉₃ <input type="checkbox"/> T</p> <p>Biological testing from predicate device <input type="checkbox"/> T₁₀₉₉₃ <input type="checkbox"/> T</p> <p>Other data <input type="checkbox"/> Chemical Characterisation and toxic risk assessment <input type="checkbox"/> Clinical Data/PMS data <input type="checkbox"/> Literature</p>	For an evaluation of Chronic Toxicity refer to: XYZ
Genotoxicity	<p>Biological testing <input type="checkbox"/> T₁₀₉₉₃ <input type="checkbox"/> T</p> <p>Biological testing from predicate device <input type="checkbox"/> T₁₀₉₉₃ <input type="checkbox"/> T</p> <p>Other data <input type="checkbox"/> Chemical Characterisation and toxic risk assessment <input type="checkbox"/> Clinical Data/PMS data <input type="checkbox"/> Literature</p>	For an evaluation of Genotoxicity refer to: XYZ



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Implantation	<p>Biological testing <input type="checkbox"/> T₁₀₉₉₃ <input type="checkbox"/> T</p> <p>Biological testing from predicate device <input type="checkbox"/> T₁₀₉₉₃ <input type="checkbox"/> T</p> <p>Other data <input type="checkbox"/> Chemical Characterisation and toxic risk assessment <input type="checkbox"/> Clinical Data/PMS data <input type="checkbox"/> Literature</p>	For an evaluation of Implantation refer to: XYZ
Hemocompatibility (material-induced haemolysis)	<p>Biological testing <input type="checkbox"/> T₁₀₉₉₃ <input type="checkbox"/> T</p> <p>Biological testing from predicate device <input type="checkbox"/> T₁₀₉₉₃ <input type="checkbox"/> T</p> <p>Other data <input type="checkbox"/> Chemical Characterisation and toxic risk assessment <input type="checkbox"/> Clinical Data/PMS data <input type="checkbox"/> Literature</p>	For an evaluation of Hemocompatibility (material-induced haemolysis) reactivity refer to: XYZ
Hemocompatibility (mechanically-induced haemolysis)	<p>Biological testing <input type="checkbox"/> T₁₀₉₉₃ <input type="checkbox"/> T</p> <p>Biological testing from predicate device <input type="checkbox"/> T₁₀₉₉₃ <input type="checkbox"/> T</p> <p>Other data <input type="checkbox"/> Chemical Characterisation and toxic risk assessment <input type="checkbox"/> Clinical Data/PMS data <input type="checkbox"/> Literature</p>	For an evaluation of Hemocompatibility (mechanically-induced haemolysis) refer to: XYZ
Hemocompatibility (Coagulation, in vitro)	<p>Biological testing <input type="checkbox"/> T₁₀₉₉₃ <input type="checkbox"/> T</p> <p>Biological testing from predicate device <input type="checkbox"/> T₁₀₉₉₃ <input type="checkbox"/> T</p> <p>Other data <input type="checkbox"/> Chemical Characterisation and toxic risk assessment <input type="checkbox"/> Clinical Data/PMS data <input type="checkbox"/> Literature</p>	For an evaluation of Hemocompatibility (Coagulation, in vitro) refer to: XYZ



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Hemocompatibility (Platelet activation, in vitro)	Biological testing <input type="checkbox"/> T ₁₀₉₉₃ <input type="checkbox"/> T Biological testing from predicate device <input type="checkbox"/> T ₁₀₉₉₃ <input type="checkbox"/> T Other data <input type="checkbox"/> Chemical Characterisation and toxic risk assessment <input type="checkbox"/> Clinical Data/PMS data <input type="checkbox"/> Literature	For an evaluation of Hemocompatibility (Platelet activation, in vitro) refer to: XYZ
Hemocompatibility (Complement, in vitro)	Biological testing <input type="checkbox"/> T ₁₀₉₉₃ <input type="checkbox"/> T Biological testing from predicate device <input type="checkbox"/> T ₁₀₉₉₃ <input type="checkbox"/> T Other data <input type="checkbox"/> Chemical Characterisation and toxic risk assessment <input type="checkbox"/> Clinical Data/PMS data <input type="checkbox"/> Literature	For an evaluation of Hemocompatibility (Complement, in vitro) refer to: XYZ
Hemocompatibility (Haematology, in vitro)	Biological testing <input type="checkbox"/> T ₁₀₉₉₃ <input type="checkbox"/> T Biological testing from predicate device <input type="checkbox"/> T ₁₀₉₉₃ <input type="checkbox"/> T Other data <input type="checkbox"/> Chemical Characterisation and toxic risk assessment <input type="checkbox"/> Clinical Data/PMS data <input type="checkbox"/> Literature	For an evaluation of Hemocompatibility (Haematology, in vitro) refer to: XYZ
Hemocompatibility (Thrombosis, in vivo/ex vivo)	Biological testing <input type="checkbox"/> T ₁₀₉₉₃ <input type="checkbox"/> T Biological testing from predicate device <input type="checkbox"/> T ₁₀₉₉₃ <input type="checkbox"/> T Other data <input type="checkbox"/> Chemical Characterisation and toxic risk assessment <input type="checkbox"/> Clinical Data/PMS data <input type="checkbox"/> Literature	For an evaluation of Hemocompatibility (Thrombosis, in vivo/ex vivo) refer to: XYZ



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Carcinogenicity	<p>Biological testing <input type="checkbox"/> T₁₀₉₉₃ <input type="checkbox"/> T</p> <p>Biological testing from predicate device <input type="checkbox"/> T₁₀₉₉₃ <input type="checkbox"/> T</p> <p>Other data <input type="checkbox"/> Chemical Characterisation and toxic risk assessment <input type="checkbox"/> Clinical Data/PMS data <input type="checkbox"/> Literature</p>	For an evaluation of Carcinogenicity refer to: XYZ
Reproductive-/Developmental Toxicity	<p>Biological testing <input type="checkbox"/> T₁₀₉₉₃ <input type="checkbox"/> T</p> <p>Biological testing from predicate device <input type="checkbox"/> T₁₀₉₉₃ <input type="checkbox"/> T</p> <p>Other data <input type="checkbox"/> Chemical Characterisation and toxic risk assessment <input type="checkbox"/> Clinical Data/PMS data <input type="checkbox"/> Literature</p>	For an evaluation of Reproductive-/Developmental Toxicity refer to: XYZ
Toxicokinetics	<p>Biological testing <input type="checkbox"/> T₁₀₉₉₃ <input type="checkbox"/> T</p> <p>Biological testing from predicate device <input type="checkbox"/> T₁₀₉₉₃ <input type="checkbox"/> T</p> <p>Other data <input type="checkbox"/> Chemical Characterisation and toxic risk assessment <input type="checkbox"/> Clinical Data/PMS data <input type="checkbox"/> Literature</p>	For an evaluation of Toxicokinetics refer to: XYZ
Immuno-toxicology	<p>Biological testing <input type="checkbox"/> T₁₀₉₉₃ <input type="checkbox"/> T</p> <p>Biological testing from predicate device <input type="checkbox"/> T₁₀₉₉₃ <input type="checkbox"/> T</p> <p>Other data <input type="checkbox"/> Chemical Characterisation and toxic risk assessment <input type="checkbox"/> Clinical Data/PMS data <input type="checkbox"/> Literature</p>	For an evaluation of Immuno-toxicology refer to: XYZ



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Other	Biological testing <input type="checkbox"/> T ₁₀₉₉₃ <input type="checkbox"/> T Biological testing from predicate device <input type="checkbox"/> T ₁₀₉₉₃ <input type="checkbox"/> T Other data <input type="checkbox"/> Chemical Characterisation and toxic risk assessment <input type="checkbox"/> Clinical Data/PMS data <input type="checkbox"/> Literature	For an evaluation of XXX refer to: XYZ
Expand as needed		

Release by client:

Please sign the document so the provided rationales and data herein can be officially used by the reviewer

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