|  |
| --- |
| **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://www.tuvsud.com/en/industries/healthcare-and-medical-devices/sterilisation-practices-control-and-validation/biological-safety-checklists).

# Relevant References

|  |
| --- |
| **Biological Evaluation Documentation** |
| List of documents relevant for BC assessment:  *[1] XYZ – YYYY-MM-DD*  *Guidance:*  *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).* |

# Product identification and description

|  |
| --- |
| **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.* |
| **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).* |
| **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]* |
| **Intended Use** |
| 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]* |

# Project background

|  |
| --- |
| **Changes** |
| For the information on the proposed change(s) refer to:  *[X, p.y]*  *Guidance:*  *In case this is an initial submission or submission for renewal of an existing certificate, this part would be “N/A”.* |
| **History** |
| For the information on the device history refer to:  *[X, p.y]* |

# Documentation of Biological Evaluation

## Categorisation of the medical device

|  |  |
| --- | --- |
| **Categorisation** | |
| Surface device | Skin  Mucosal membranes  Breached or compromised surface |
| External communicating device | Blood paths, indirect  Tissue/bone/dentin  Circulating blood |
| Implant device | Tissue/bone  Blood |
| Contact duration | A - limited (< 24 h)  transitory-contacting  B- prolonged (> 24 h to 30 days)  C – long-term (> 30 days) |
| Documented in: *[X, p.y]* | |

## Summary of Biological Evaluation Strategy

|  |
| --- |
| **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* |
| **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]* |

## Biocompatibility relevant background information

### Manufacturing

|  |
| --- |
| **Part 1 - Description of the manufacturing steps and location(s)** |
| For the identification of the manufacturing site(s) refer to:  *[X, p.y]*  For the description of manufacturing steps (for every manufacturing site) refer to:  *[X, p.y]* |
| **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]* |

### Packaging

|  |
| --- |
| **Part 1 - Description of packaging configuration and packaging materials (direct / indirect product contacting materials)** |
| For the description of the packaging configuration and information on packaging materials in direct/indirect device contact refer to:  *[X, p.y]* |
| **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]* |

### Sterilisation

|  |
| --- |
| **Part 1 - Description of sterilisation type and conditions as well as location(s)** |
| For the identification of the sterilisation site(s) and the respective sterilisation conditions refer to:  *[X, p.y]* |
| **Part 2 - Evaluation of the impact of the sterilisation process on the biocompatibility** |
| For the evaluation of potential influences of the sterilisation process on the biocompatibility of the medical device refer to:  *[X, p.y]* |

### Device lifetime

|  |
| --- |
| **Shelf life** |
| **Part 1 - Information on storage conditions and shelf life as described in IFU** |
| For the information on the device´s shelf life refer to:  *[X,p.y]* |
| **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]* |

|  |
| --- |
| **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”.* |
| **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]* |
| **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]* |

|  |
| --- |
| **Duration of use** |
| **Part 1 Description of the duration of use** |
| For the determination of the limit pertaining to maximum use duration refer to:  *[X, p.y]* |
| **Part 2 Evaluation of the impact of the duration of use considering the respective use environment on the biocompatibility** |
| For the evaluation of the impact of the use duration considering the respective use environment on the biocompatibility refer to:  *[X, p.y]* |

|  |
| --- |
| **Reprocessing**  **applicable**  **not applicable**  *Guidance:*  *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.* |
| **Part 1 - Description device reprocessing procedures (if applicable)** |
| For an overview on the reprocessing steps refer to:  *[X, p.y]* |
| **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]* |

### 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]* |

|  |
| --- |
| **Process aids and process residues which have potential to remain in / on the medical device** |
| 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]* |

|  |
| --- |
| **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  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]*  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]* |

## Chemical characterisation

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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:  *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.* | | | | | |
| **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:  VOC: *XYZ*  SVOC: *XYZ*  NVOC: *XYZ*  Test report:  *LAB-REP-NO-XYZ*  *YYYY-MM-DD*  *[X, p.y] or [X]* | Test item specification: *XYZ*  Documented in:  *[X, p.y]*  Yes, the following routine conditions are covered by the test item:  Materials / processing aids  Manufacturing  Packaging  Sterilisation  Shelf-life  other: *XYZ*  Documented in:  *[X, p.y]*  No, not all of the routine conditions are covered by the test item. Description of differences and justification can be found in: *[X, p.y]*  No, only an individual part was tested, for a description of the part and justification for representativeness refer to: *[X, p.y]* | Type of extraction:  Simulated: *XYZ*  Exaggerated: *XYZ*  Exhaustive: *XYZ*  Other: *XYZ*  Vehicle:  Polar: *XYZ*  Semi-polar: *XYZ*  Non-polar: *XYZ*  other: *XYZ*  Documented in:  *[X, p.y]* | *XYZ*  Documented in:  *[X, p.y]* | Name and address:  *XYZ*  Qualification for the test:  The laboratory was ISO/IEC 17025 accredited / GLP certified for the respective method at the time of testing.  Documented in:  *[X, p.y]*  The laboratory was NOT ISO/IEC 17025 accredited / GLP certified.  For a justification refer to: *[X, p.y]* | Reporting threshold:  *XYZ*  Justification of adequacy of the actual reporting thresholds:  AET was determined.  AET determination included the most vulnerable intended patient population under consideration of worst-case application.  Presence of Cohort of Concern (CoC) Substances in/on the device was determined to be unlikely.  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.  Actual reporting threshold was equal or below AET.  Other justification of the actual reporting threshold.  Documented and - if boxes above not ticked - justified in:  *[X, p.y]*  Organic entities detected above the reporting threshold:  yes; for a list, refer to: *[X, p.y]*  no; for evidence refer to: *[X, p.y]* |
| *Expand as needed*  *Guidance:*  *Please copy the line above if testing for more than one chemical entity was performed (even in case it is reported in the same laboratory report).* |  |  |  |  |  |
| **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** |
| Test methods applied:  Elements: *XYZ*  Anions/Cations: *XYZ*  Test report:  *LAB-REP-NO-XYZ*  *YYYY-MM-DD*  *[X, p.y] or [X]* | Test item specification:  *XYZ*  Documented in:  *[X, p.y]*  Yes, the following routine conditions are covered by the test item:  Materials / processing aids  Manufacturing  Packaging  Sterilisation  Shelf-life  other: *XYZ*  Documented in:  *[X, p.y]*  No, not all of the routine conditions are covered by the test item. Description of differences and justification can be found in: *[X, p.y]*  No, only an individual part was tested, for a description of the part and justification for representativeness refer to: *[X, p.y]* | Type of extraction:  Simulated: *XYZ*  Exaggerated: *XYZ*  Exhaustive: *XYZ*  Other: *XYZ*  Vehicle:  Polar: *XYZ*  Semi-polar: *XYZ*  Non-polar: *XYZ*  other: *XYZ*  Documented in:  *[X, p.y]* | *XYZ*  Documented in:  *[X, p.y]* | Name and address:  *XYZ*  Qualification for the test:  The laboratory was ISO/IEC 17025 accredited / GLP certified for the respective method at the time of testing.  Documented in:  *[X, p.y]*  The laboratory was NOT ISO/IEC 17025 accredited / GLP certified.  For a justification refer to: *[X, p.y]* | Reporting threshold  *XYZ*  Justification of adequacy of the actual reporting thresholds:  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).  Actual reporting threshold was equal or below the toxicologically justified evaluation threshold.  Documented and - if boxes above not ticked - justified in:  *[X, p.y]*  Inorganic entities detected above the reporting threshold:  yes; for a list, refer to: *[X, p.y]*  no; for evidence refer to: *[X, p.y]* |
| *Expand as needed*  *Guidance:*  *Please copy the line above if testing for more than one chemical entity was performed (even in case it is reported in the same laboratory report).* |  |  |  |  |  |
| **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]* | | | | | |
| **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]*  *If chemical analytic testing has been performed, this section would be “N/A”.* | | | | | |

## Degradation

|  |
| --- |
| **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]* |
| **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]* |

## Toxicological risk assessment

|  |
| --- |
| **Toxicological risk assessment** |
| For the toxicological risk assessment refer to:  *[X] or [X, p.y]*  The applied concept for toxicological risk assessment follows  the latest version of EN ISO 10993-17  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]*  The following is covered by the toxicological risk assessment:  Consideration of device worst-case use characteristics (i.a. number, frequency and duration of devices in contact to the body, user population)  Constituent’s and/or extractables/leachables toxicological data (including identification of carcinogens/suspected human carcinogens)  Justifications and methods used to apply TSL  Derivation of TCL/TI  Application of TTC  Estimation of exposure dose and evaluation of the worst case-exposure  Derivation of MOS values  Derivation of combined MOS values was required  Further risk analysis/evaluation/control was required |

## Physical characterisation

|  |
| --- |
| **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”.* |
| **Part 1 - Description of physical characteristics** |
| For a summary of the physical characteristics relevant in the context of biocompatibility refer to:  *[X, p.y]* |
| **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]* |

|  |
| --- |
| **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]*  For information on how particle amount, size and properties was determined refer to:  *[X, p.y]* |
| **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]* |

## Biological testing

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:

| **Type of test**  **(Report No. and report date)** | **Final product tested?**  **(Yes/No)** | **Extraction conditions** | **Applied standard for testing and sample preparation** | **Result** | **Test Facility** | **Comments** |
| --- | --- | --- | --- | --- | --- | --- |
| *XYZ*  *LAB-REP-NO-XYZ*  *YYYY-MM-DD*  *[X, p.y] or [X]* | Test item specification:  *XYZ*  Documented in:  *[X, p.y]*  Yes, the following routine conditions are covered by the test item:  Materials / processing aids  Manufacturing  Packaging  Sterilization  Shelf-life  other: *XYZ*  Documented in:  *[X, p.y]*  No, not all of the routine conditions are covered by the test item. Description of differences and justification can be found in: *[X, p.y]*  ☐ No, only an individual part was tested, for a description of the part and justification for representativeness refer to: *[X, p.y]* | Type of extraction:  6 cm2/ml ± 10%  3 cm2/ml ± 10%  0.2g /ml ± 10%  0.1g /ml ± 10%  other: *XYZ*  Time / Temperature:  37±1°C for 24±2 h  37±1°C for 72±2 h  50±2°C for 72±2 h  70±2°C for 24±2 h  121±2°C for 1±0.1 h  other: *XYZ*  Vehicle:  Polar: *XYZ*  Non-polar: *XYZ*  other: *XYZ*  Documented in:  *[X, p.y]* | Testing:  *XYZ*  Sample preparation:  *XYZ*  Documented in:  *[X, p.y]* | passed / met pre-defined acceptance criteria: *XYZ.*  failed: *XYZ.*  Documented in:  *[X, p.y]*  the result needs further interpretation. For interpretation refer to: *[X, p.y]* | Qualification for the test:  The laboratory was ISO/IEC 17025 accredited / GLP certified for the respective method at the time of testing.  Documented in: *[X, p.y]*  The laboratory was NOT ISO/IEC 17025 accredited / GLP certified.  For a justification refer to: *[X, p.y]* | *XYZ*  *Guidance:*  *Please report any unexpected observations or deviations from test protocol encountered during endpoint testing.* |
| *Expand as needed*  *Guidance:*  *Please copy the line above if testing for more than one endpoint was performed.* |  |  |  |  |  |  |

## Endpoint evaluation

|  |  |  |
| --- | --- | --- |
| **Evaluation of applicable biological and/or toxicological endpoints** | | |
| 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: | | |
| **Biological effect/endpoint**  *Guidance:*  *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.* | **Addressed by**  T10993 = Biological tests from ISO 10993-Series  T = other (biological) Tests  *Guidance:*  *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.* | **Reference to endpoint evaluation in Technical Documentation**  *Guidance:*  *Please refer to the part of the Technical Documentation evaluating the respective endpoint (generally, this is a section of the Biological Evaluation Report).* |
| Cytotoxicity | Biological testing  T10993  T  Other data  Chemical Characterisation and tox. risk assessment  Clinical Data/PMS data  Literature | For an evaluation of cytotoxicity refer to: *XYZ* |
| Sensitisation | Biological testing  T10993  T  Other data  Chemical Characterisation and tox. risk assessment  Clinical Data/PMS data  Literature | For an evaluation of Sensitisation refer to: *XYZ* |
| Irritation / Intracutaneous reactivity | Biological testing  T10993  T  Other data  Chemical Characterisation and tox. risk assessment  Clinical Data/PMS data  Literature | For an evaluation of Irritation / Intracutaneous reactivity refer to: *XYZ* |
| Acute Systemic Toxicity | Biological testing  T10993  T  Other data  Chemical Characterisation and tox. risk assessment  Clinical Data/PMS data  Literature | For an evaluation of Acute Systemic Toxicity refer to: *XYZ* |
| Material-mediated Pyrogenicity | Biological testing  T10993  T  Other data  Chemical Characterisation and tox. risk assessment  Clinical Data/PMS data  Literature | For an evaluation of Material-mediated Pyrogenicity refer to: *XYZ* |
| Subacute Toxicity | Biological testing  T10993  T  Other data  Chemical Characterisation and tox. risk assessment  Clinical Data/PMS data  Literature | For an evaluation of Subacute Toxicity refer to: *XYZ* |
| Subchronic Toxicity | Biological testing  T10993  T  Other data  Chemical Characterisation and tox. risk assessment  Clinical Data/PMS data  Literature | For an evaluation of Subchronic Toxicity refer to: *XYZ* |
| Chronic Toxicity | Biological testing  T10993  T  Other data  Chemical Characterisation and tox. risk assessment  Clinical Data/PMS data  Literature | For an evaluation of Chronic Toxicity refer to: *XYZ* |
| Genotoxicity | Biological testing  T10993  T  Other data  Chemical Characterisation and tox. risk assessment  Clinical Data/PMS data  Literature | For an evaluation of Genotoxicity refer to: *XYZ* |
| Implantation | Biological testing  T10993  T  Other data  Chemical Characterisation and tox. risk assessment  Clinical Data/PMS data  Literature | For an evaluation of Implantation refer to: *XYZ* |
| Hemocompatibility (material-induced haemolysis) | Biological testing  T10993  T  Other data  Chemical Characterisation and tox. risk assessment  Clinical Data/PMS data  Literature | For an evaluation of Hemocompatibility (material-induced haemolysis) refer to: *XYZ* |
| Hemocompatibility (mechanically induced haemolysis) | Biological testing  T10993  T  Other data  Chemical Characterisation and tox. risk assessment  Clinical Data/PMS data  Literature | For an evaluation of Hemocompatibility (mechanically induced haemolysis) refer to: *XYZ* |
| Hemocompatibility (Coagulation, in vitro) | Biological testing  T10993  T  Other data  Chemical Characterisation and tox. risk assessment  Clinical Data/PMS data  Literature | For an evaluation of Hemocompatibility (Coagulation, in vitro) refer to: *XYZ* |
| Hemocompatibility (Platelet activation, in vitro) | Biological testing  T10993  T  Other data  Chemical Characterisation and tox. risk assessment  Clinical Data/PMS data  Literature | For an evaluation of Hemocompatibility (Platelet activation, in vitro) refer to: *XYZ* |
| Hemocompatibility (Complement, in vitro) | Biological testing  T10993  T  Other data  Chemical Characterisation and tox. risk assessment  Clinical Data/PMS data  Literature | For an evaluation Hemocompatibility (Complement, in vitro) refer to: *XYZ* |
| Hemocompatibility (Haematology, in vitro) | Biological testing  T10993  T  Other data  Chemical Characterisation and tox. risk assessment  Clinical Data/PMS data  Literature | For an evaluation of Hemocompatibility (Haematology, in vitro) refer to: *XYZ* |
| Hemocompatibility (Thrombosis, in vivo/ex vivo) | Biological testing  T10993  T  Other data  Chemical Characterisation and tox. risk assessment  Clinical Data/PMS data  Literature | For an evaluation of Hemocompatibility (Thrombosis, in vivo/ex vivo) refer to: *XYZ* |
| Carcinogenicity | Biological testing  T10993  T  Other data  Chemical Characterisation and tox. risk assessment  Clinical Data/PMS data  Literature | For an evaluation of Carcinogenicity refer to: *XYZ* |
| Reproductive-/Developmental Toxicity | Biological testing  T10993  T  Other data  Chemical Characterisation and tox. risk assessment  Clinical Data/PMS data  Literature | For an evaluation of Reproductive-/Developmental Toxicity refer to: *XYZ* |
| Toxicokinetics | Biological testing  T10993  T  Other data  Chemical Characterisation and tox. risk assessment  Clinical Data/PMS data  Literature | For an evaluation of Toxicokinetics refer to: *XYZ* |
| Immuno-toxicology | Biological testing  T10993  T  Other data  Chemical Characterisation and tox. risk assessment  Clinical Data/PMS data  Literature | For an evaluation of Immuno-toxicology refer to: *XYZ* |
| Other: | Biological testing  T10993  T  Other data  Chemical Characterisation and tox. risk assessment  Clinical Data/PMS data  Literature | For an evaluation of XXX refer to: *XYZ* |
| *Expand as needed* |  |  |

# Release by client

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| YYYY-MM-DD | |  | *Please sign the document so the provided rationales and data herein can be officially used by the reviewer* |  |  |
| Date | |  | Signature |  | Name / Title. Position |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  | Name of Legal Manufacturer |