All testing requires completion of Sections 1 and 2.

For Chemical Characterization under ISO 10993-18, please complete Section 3.

For Toxicology Endpoints such as cytotoxicity, sensitization, irritation, etc. please complete Section 4.

See the associated Biocompatibility Questionnaire Guidance Document for instructions on completing this form.

Additional guidance for each field can be displayed by hovering over the **ⓘ** icon.

|  |  |  |  |
| --- | --- | --- | --- |
| **Section 1: General Information** | | | |
| **Company Name** | Click or tap here to enter text. | | |
| **Contact Name** | Click or tap here to enter text. | | |
| **Marketed Device Name** | Click or tap here to enter text. | | |
| **Intended Use ⓘ** | Click or tap here to enter text. | | |
| **Scope ⓘ** | Click or tap here to enter text. | | |
| **Submissions ⓘ** | Click or tap here to enter text. | | |
| **Sample Date ⓘ** | Click or tap here to enter text. | | |
| **Section 2: Device Information** | | | |
| 1. Contact Categorization per Choose an item. including: **ⓘ**  * Nature of Contact * Duration of patient contact | | Choose an item.  Choose an item.  Click or tap here to enter text. |
| 1. Patient contacting and non-patient contacting portions of the device? **ⓘ** | | Click or tap here to enter text. |
| 1. Cumulative Clinical Exposure **ⓘ** | | Click or tap here to enter text. |
| 1. Fluid conduit or pathway to the body? Please Describe. **ⓘ** | | Click or tap here to enter text. |
| 1. Any device specific standard or guidance? **ⓘ** | | Choose an item.  Click or tap here to enter text. |
| 1. Nature of test article submitted. **ⓘ** | | Choose an item.  Click or tap here to enter text. |
| 1. Does device require disassembly for testing? **ⓘ** | | Choose an item.  Click or tap here to enter text. |
| 1. Pictures (preferred) or CAD drawings of overall device? **ⓘ**   Attached, or explain in space provided | | Click or tap here to enter text. |
| 1. Device surface area **ⓘ** | | Click or tap here to enter text. |
| 1. Device thickness **ⓘ** | | Choose an item. |
| 1. Instructions for use Attached or explain in space provided **ⓘ** | | Click or tap here to enter text. |
| 1. Stability testing of the test article (if your answer is n/a or in progress you will be required to sign a memo attesting that your samples will be stable for the duration of testing). **ⓘ** | | Choose an item.  Click or tap here to enter text. |
| 1. Expiration date associated with the test article. **ⓘ** | | Click or tap here to enter text. |
| 1. Characterization of test article. Please provide a Certificate of Analysis, a Certificate of Testing, a marketed label, or provide information for the following (when applicable):   Physical Description (including but not limited to): Color, State of Matter (solid, liquid, etc.), Viscosity, pH  Composition: Please list component materials and their proportions  Special Handling and/or Precautions | | Click or tap here to enter text. |

The Sponsor is responsible for all test article characterization specified in the Good Laboratory Practices (GLP) regulations (21 CFR 58.105). The Sponsor is responsible for maintaining records of manufacture that would provide information on the composition of the test article and would be able to supply those records if requested by regulatory authorities.

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| **Section 3: For Chemical Characterization under ISO 10993-18**  N/A |

|  |  |
| --- | --- |
| **Manufacturing Information ⓘ** | |
| Manufacturing site | Click or tap here to enter text. |
| Special treatments, if applicable  e.g., mold releases, slip agents, machining oils, cleaning process, etc. | Click or tap here to enter text. |
| Sterilization processes | Click or tap here to enter text. |
| Final product specifications | Click or tap here to enter text. |
| **Packaging Information** | |
| Part name | Click or tap here to enter text. |
| Part number | Click or tap here to enter text. |
| Material composition | Click or tap here to enter text. |
| Manufacturer (including location) | Click or tap here to enter text. |

| **Option 1: For Liquid / Powder Medical Devices ⓘ** | | | | |
| --- | --- | --- | --- | --- |
| Raw Material Component (CAS #) | Part Number OR  Raw Material Number | Content  (wt/wt%) | Supplier | Function |
| Click or tap here to enter text. | Enter text. | ## | Enter text. | Enter text. |
| Click or tap here to enter text. | Enter text. | ## | Enter text. | Enter text. |
| Click or tap here to enter text. | Enter text. | ## | Enter text. | Enter text. |
| Click or tap here to enter text. | Enter text. | ## | Enter text. | Enter text. |
| Click or tap here to enter text. | Enter text. | ## | Enter text. | Enter text. |

| **Option 2: For Solid Medical Devices** | | | | | |
| --- | --- | --- | --- | --- | --- |
| Component | Part Number | Material **ⓘ** | Material Supplier | Part Manufacturer | Material Rationale **ⓘ** |
| Enter text. | ### | Enter text. | Enter text. | Enter text. | Enter text. |
| Enter text. | ### | Enter text. | Enter text. | Enter text. | Enter text. |
| Enter text. | ### | Enter text. | Enter text. | Enter text. | Enter text. |
| Enter text. | ### | Enter text. | Enter text. | Enter text. | Enter text. |
| Enter text. | ### | Enter text. | Enter text. | Enter text. | Enter text. |

|  |
| --- |
| **Section 4: For Toxicology Endpoints ⓘ**  N/A |

|  |  |
| --- | --- |
| 1. Submitted Material Type **ⓘ** | Plastic / Polymer  Metal  Elastomer  Combination device  Coated material / Composite / Laminate  Other: Click or tap here to enter text. |
| 1. Test Article Treatment **ⓘ** | Test entire test article  Do NOT sub-divide (cut) test article for extraction.  Test a portion of the test article, described in detail below  Click or tap here to enter text. |
| **For Extraction Tests ONLY ⓘ** | |
| 1. Cytotoxicity **ⓘ**   MEM Elution Test | Extract for: Choose an item.  Click or tap here to enter text. |
| 1. Other Tests **ⓘ** | Extract for: **ⓘ** Choose an item.  Click or tap here to enter text. |
| Extract with: Choose an item.  Click or tap here to enter text. |

Received by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_