|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **ISO 10993-18: Chemical Characterization Sample Submission Form** | | | | |
| **Sponsor Information** | | | | |
| **Quote#:** | **PO#:** | | | |
| **Send Final Report To:** | **Billing Information (if different):** | | | |
| **Company:** | **Company:** | | | |
| **Contact:** | **Contact:** | | | |
| **Address:** | **Address:** | | | |
|  |  | | | |
| **Email:** | **Email:** | | | |
| **Phone:** | **Phone:** | | | |
| **Test Article Information** | | | | |
| **Test Article Name** |  | | | |
| **Test Article Model/Reference ID** |  | | | |
| **Test Article Lot ID** |  | | | |
| **Test Article Expiration Date** |  | | | |
| **Type** | Select | | | |
| **Intended Clinical Use (Please Provide Instructions for Use, If available)** |  | | | |
| **Intended Patient Population** | Adult men (70 kg):  Adult women OR unisex adult (60 kg):  Pregnant women:  Children (60 kg; >1 yr to ≤16 years of age):  Infants (3.5 kg; <1 yr):  Neonate (1.5 kg; very low birthweight infant):  Very low birthweight neonate/preterm neonate (0.5 kg):  Other. If there is a preferred body mass not listed, please write and specify patient population: | | | |
| **Type of Patient Contact** | Direct: | Surface: | Select | |
| External Communicating: | Select | |
| Implant: | Select | |
| Indirect:  (check additional box below if applicable) | | | |
| Breathing gas pathway, Dry: | | | |
| Breathing gas pathway, Contact with condensate: | | | |
| If Other, please describe: | | | |
| **Duration of Patient Contact** | Select | If Permanent, please list the anticipated life span of typical patient: | | |
| Maximum Number of Devices (Patient Exposure) in 1 Day: | | | |
| **Maximum Number of Devices (patient Exposure) in 1 Day (C):** |  |  | | |
| **Can device be cut?** | Select | Note: Cutting will destroy test article | | |
| **Device Physical Description:**  **(Use fields appropriate for device)** | Surface Area (cm2): | | | |
| Patient Contacting Surface Area (cm2):  (If different): | | | |
| Dimensions (Overall LxWxH) (cm): | | | |
| Weight (g): | | | |
| Fill Volume (mL): | | | |
| Is the device of uniform material and processing?: | | | |
| Other: | | | |
| **Type of Product Being Tested** | Select | | | |
| **Is Device Suture?** | Select | If yes, length of one device (cm): | | |
| **Sterilization Technique** | Select | If Other, please describe: | | |
| **Storage Conditions** | Select | Store in Dark: Select | | |
| **Final Report Target Date** | Select | | | |
| If Yes: | Date: | | Priority/Urgent |
| **Please indicate if study is for submission to regulatory agency:** | FDA:  Notified Body:  Internal Documentation:  Other :  Check all that apply | | | |
| **Are there any known incompatible solvents?** | Yes  No : If yes, please indicate: | | | |
| **Should a feasibility study be performed?** | Yes:  No: | | | |
| **Should a solvent compatibility study be performed?** | Yes:  No: | | | |
| **Is there a potential for Cohort of Concern Compounds Being Present?** | Yes:  No:  If Yes, please list: | | | |
| **Packaging Materials (please list):** |  | | | |
| **Processing Aids, Cleaning Agents, Other Materials used in the Manufacturing and Packaging Process (please list):** |  | | | |
| **Are there safety hazards associated with the device (e.g. sharps, drug products?)** | Yes:  No:  If Yes, please list: | | | |
| **Special Instructions (Preparation, handling, parts to be removed, etc. Attach documentation as needed) If parts are to be removed, please describe which parts of the device should be included in the extraction and represent the patient contact surface area reported above** |  | | | |
| **Study Design: Do you have special extraction conditions (e.g. time and temperature, solvents)?** |  | | | |
| **Please provide the following in table/figure below or as separate document(s):**   * **Description of the Materials of Construction (BOM)** * **Photo and/or Detailed Schematic (Please include scale)** * **Engineering Report** * **Instruction For Use** * **FDA Pre-Submission Feedback** | | | | |

**Test Article(s) Materials of Construction: Test Article(s) Photo(s)/Schematic:**

|  |  |  |
| --- | --- | --- |
| Submitter Name |  |  |
| Submitters Signature Date |  |  |

**Revision History**

|  |  |  |  |
| --- | --- | --- | --- |
| **Revision Number** | **Description of Change** | **Date (MM/DD/YY)** | **Approved By** |
| 22-01 | Add revision table to comply with GMP requirements. | 04/29/22 | Michele Donahue |
| 22-02 | Add “Maximum Number of Devices (Patient Exposure) in 1 Day and “Study Design". | 05/20/22 | Courtney Brummett |
| 23-01 | Added additional questions and information requested regarding submitted samples to gain more information to perform most appropriate E&L study. | 5/11/23 | An Nguyen |
| 23-02 | Adding requests for more information, clarify existing request | 07/05/23 | Frona Wilson |
| 23-03 | Correct revision date on first page which was incorrect on last revision | 07/10/23 | Frona Wilson |
| 24-01 | Add section for Intended Patient Population. Add option for Breathing gas pathway, dry and contact with condensate. | 01/25/24 | Courtney Brummett |
| 24-02 | Add Part 18 in the title of the form for clarification. Update form number to 299a. | 03/15/24 | Courtney Brummett |
| 24-03 | Updated title to ISO 10993-18: Chemical Characterization Sample Submission Form. | 03/25/24 | Courtney Brummett |