**Annex II**

**SUPPLIER MUST COMPLETE THIS QUESTIONNAIRE**

**PART I. Manufacturer information**

**Bidder (if not manufacturer):** Click here to enter text.

**Manufacturer:** Name of manufacturer: Click here to enter text.  
 Country: Click here to enter text.  
 Address (office): Click here to enter text.  
 Address (manufacturing site(s)): Click here to enter text.  
 Contact person’s name: Click here to enter text.  
 Email: Click here to enter text.  
 Phone: Click here to enter text.

Link to online catalog: Click here to enter text.

**PART II. Product information**

**Product Identification** (Trade name, Type, Model, Package size, Intended use, etc.)**:** Click here to enter text.

**Product Code, Reference number(s) per each size:** Click here to enter text.

**Product details** (materials, dimensions, size, volume, features, etc. For electrical devices specify voltage, frequency and plug supplied.)**:** *(E.g. If a stainless steel product, identify AISI type or composition. If a plastic product, identify type or composition.)* Click here to enter text.

## PART III. Regulatory Status

|  |  |  |
| --- | --- | --- |
| **3.1.aIs the product CE certified?**  Notified Body name and NB number:  Click here to enter text. | **□** Yes | Start Date: Click here to enter text. Expiry Date: Click here to enter text. |
| **□** No | |
| **3.1.bHas the product EC Design Examination certificate?**  Notified Body name and number:  Click here to enter text. | **□** Yes, EN ISO no.: Click here to enter text.  Product code in certificate:  Click here to enter text. | |
| **□** No | |
| **3.1.cHas the product a CE mark on the product or package label?** | **□** Yes | |
| **□** No | |
| **3.2Is the product FDA approved?**  510k clearance #: Click here to enter text.  PMA clearance #: Click here to enter text. | **□** Yes | Start Date: Click here to enter text. Expiry Date: Click here to enter text. |
| **□** No | |
| **3.2.b Is the product CDC or NIOSH approved?** | **□** Yes | NIOSH TC no.: Click here to enter text. |
| **□** No | |
| **3.3 Is the product approved by National Regulatory Agency or Department?**  Name of agency and type of approval: Click here to enter text. | **□** Yes | Start Date: Click here to enter text. Expiry Date: Click here to enter text. |
| **□** No | |
| **3.4 Provide details of any other current regulatory approvals for this product.**  Name of jurisdiction and type of approval: Click here to enter text. | **□** Yes | Start Date: Click here to enter text. Expiry Date: Click here to enter text. |
| **□** No | |

**3.5 Manufacturer** QMS ISO 13485 Yes ☐ No ☐  
 QMS ISO 9001 Yes ☐ No ☐

* 1. Certification body and number: Click here to enter text.
  2. Expiration date: Click here to enter text.

**3.6 FOR STERILE PRODUCTS** - If the manufacturing process is subcontracted:

|  |  |
| --- | --- |
| **Name and address of the subcontractor** | **QMS certification of the subcontractor - Identify Regulatory body and/or number and expiry date** |
| Click here to enter text. | Click here to enter text. |

**3.7 FOR PERSONAL PROTECTIVE EQUIPMENT**

|  |  |
| --- | --- |
| **For Gown:**  a. Is the type compliant with the EN 13795 high performance level, or AAMI  level 3 performance or equivalent? Click here to enter text.    b. Is the gown water and liquids proof? Click here to enter text. | Yes ☐  No ☐  Yes ☐  No ☐ |
| Is the language in the packaging and label in ENGLISH? | Yes ☐  No ☐ |
| If no, identify language: Click here to enter text. |  |