**Annex- 4 Fast Track Procurement Questionnaire   
for PPE COVID-19**

**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 Surgical Masks:**  a. What is the type according to EN 14683? Click here to enter text.  b. What are tested BFE, Splash (mmHg) and Breathing resistance values?  Click here to enter text. |  |
| **For Surgical Respirators (N95/FFP2 or above):**  a. Write below what is imprinted onto the respirator cup:  Click here to enter text.  b. What are tested BFE, PFE and inward leakage-%?  Click here to enter text.  c. Has the respirator been tested and approved for surgical use? | Yes ☐  No ☐ |
| **For Goggles:**  a. Write below what is imprinted onto the goggle frame according to EN 166:  Click here to enter text.  b. Write below what is imprinted onto the goggle lense according to EN 166:  Click here to enter text. |  |
| **For Coveralls:**  a. What is the type according to EN 13034? Click here to enter text.  b. What is the type fluid resistance value (cmH2O): Click here to enter text. |  |
| Is the language in the packaging and label in ENGLISH? | Yes ☐  No ☐ |
| If no, identify language: Click here to enter text. |  |

**PART IV. Checklist of required documentation**

|  |  |
| --- | --- |
| **Product class  (EC MEDDEV) (EU PPE) - 2016/425**  **Personal protective equipment Category III** | **Minimum documentation required** Documents to be submitted must be true and valid copies. All documents submitted must be in English or be accompanied with certified translation. |
| **class I** (non-measuring, non-sterile and/or non-reusable surgical instrument, rsi)  PPE in this group: a. Examination gloves, non-sterile b. Non-sterile isolation gown c. Non-sterile apron d. Shoe cover e. Head cover f. Face shield | ☐ Copy of ISO 13485\* (or ISO 9001\*) QMS certificate. ☐ A signed and dated Declaration of Conformity (DoC) according to ISO 17050 stating compliance to the relevant ISO standards and directives (submitted by the manufacturer – Note: (**EU PPE**) 2016/425 Personal protective equipment Category III ) and/or (EU MEDDEV 93/42/EEC or MDR 2017/745) and DoC has reference to the offered product.  ☐ Photo of the product and packaging (at various angles if necessary, preferably in a format where the dimensions and features can be visually verified from the photos). |
| **class I measuring class I sterile class I rsi class IIa**  PPE examples: a. Sterile surgical gloves b. Surgical mask Type IIR c. Surgical respirators d. Sterile surgical gown e. Goggles f. Coverall | ☐ Copy of EC certificate (referencing the name/number of the notifying body), and/or 510k FDA clearance, and/or approval letter or certificate from a National Regulatory Body. ☐ A signed and dated DoC according to ISO 17050 stating compliance to critical ISO standards (e.g. for sterilization, ISO 13485 QMS) and directives – Note: (**EU PPE**) 2016/425 Personal protective equipment Category III) and/or (EU MEDDEV 93/42/EEC or MDR 2017/745), and DoC has reference to the offered product. **Note***:* If a sterilization activity is subcontracted to a third party, ISO 13485 QMS compliance is also required from the subcontracting company. Note: NIOSH approved respirator N95 or higher shall be also FDA cleared. ☐ Photo of the product and packaging (at various angles if necessary, preferably in a format where the dimensions and features can be visually verified from the photos). |
| **class IIb  class III** | ☐ Copy of EC certificate (referencing the name/number of the notifying body) with an additional copy EC Design Examination certificate, and/or 510k/PMA FDA clearance, and/or approval letter or certificate from a National Regulatory Body. ☐ A signed and dated DoC according to ISO 17050 stating compliance to critical ISO standards (e.g. ISO 13485 QMS) and directives – Note: (**EU PPE**) 2016/425 Personal protective equipment Category III) and/or (EU MEDDEV 93/42/EEC or MDR 2017/745), and DoC has reference to the offered product. Proof of compliance to ISO standards in a form of copies of certificates shall be submitted if available. ☐ Photo of the product and packaging (at various angles if necessary, preferably in a format where the dimensions and features can be visually verified from the photos). |

\*) UNFPA accepts the versions of currently active standards, which are recognized by the International Organization for Standardization at the time of document submission.