Date: 6September, 2022

**Authorized by:**

**Jaime Nadal**

**UNFPA Representative**

**REQUEST FOR QUOTATION**

**RFQ Nº UNFPA/UKR/RFQ/22/23**

Dear Sir/Madam,

We hereby solicit your quotation for the supply of the **Personal Protective Equipment for health personnel** and delivery to Kyiv, Ukraine (DAP Kyiv) as per specification below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| # | Lots/Item name | Specification | Unit | Q-ty |
| 1 | Gloves | w/o powder, nitrile, size M, disposable | box/100 pcs | 1200 |
| 2 | Gloves | w/o powder, nitrile, size L, disposable | box/100 pcs | 1200 |
| 3 | Coverall | protection, category III, type 6b | pcs | 8400 |
| 4 | Gown | isolation, nonwoven, disposable | pack/10 pcs | 1200 |
| 5 | Disposable masks | disposable, sterile, surgical  | pack/25 pcs | 1440 |
| 6 | Goggle  | medical, safety  | pcs | 6000 |

**The bidder shall not be required to quote for all lots. However, Bidders are encouraged to quote for as many lots as possible. Partial bids are allowed under this tender.**

The goods are to be delivered maximum in 14 days upon issuing of PO (Purchasing Order). The quotation shall be valid at least for 2 months after the closing date.

If you are interested in submitting a quotation for these items, kindly fill in the attached Quotation Form and please send by email to the address indicated below:

|  |  |
| --- | --- |
| Name of contact person at UNFPA: | *Iryna Bohun* |
| Email address of contact person: | **ua-procurement@unfpa.org** |

All prices shall be quoted in Ukrainian Hryvnia (UAH).

**Note: All final prices must be exclusive of VAT tax, since UN and its specialized agencies are exercising zero VAT payer status.**

Your earliest response to this query would be highly appreciated, but not later than **Tuesday,** **13 September, 2022 at 17:00 Kyiv time.**

Note: Current UNFPA supplier policies apply to this solicitation and can be found at: <http://www.unfpa.org/suppliers>.

Kind regards,

Maksym Grechishnikov

Procurement and Logistics Associate

**Quotation Form**

**Name of Bidder:**

**Date of Bid:**

**Request for Quotation No: UNFPA/UKR/RFQ/22/23**

**Currency of Bid price: UAH**

**Delivery time** *(weeks from receipt of order till dispatch):* **2 weeks**

**Expiration of Validity of Quotation** *(The quotation shall
be valid for a period of at least 2 months* *after
the Closing date.):*  **2 months**

**Price Schedule:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| # | Lots | Description of the goods | Unit | Q-ty | DAP Kyiv, unit price, VAT free, UAH | Total |
| 1 | Gloves | w/o powder, nitrile, size M, disposable | box/100 pcs | 1200 |  |  |
| 2 | Gloves | w/o powder, nitrile, size L, disposable | box/100 pcs | 1200 |  |  |
| 3 | Coverall | protection, category III, type 6b | pcs | 8400 |  |  |
| 4 | Gown | isolation, nonwoven, disposable | pack/10 pcs | 1200 |  |  |
| 5 | Disposable masks | disposable, sterile, surgical | pack/25 pcs | 1440 |  |  |
| 6 | Goggle | medical, safety | pcs | 6000 |  |  |
|  | Total amount |  |
|  | Delivery time, days (from date of order) |  |

**In your offer, please include:**

1. Specific technical specifications of products offered
2. Delivery time
3. Quality standards of the products and/or registration certificates
4. Fast Track Procurement Questionnaire for Medical Devices

*Vendor’s Comments:*

**I hereby certify that this company, which I am duly authorized to sign for, accepts the terms and conditions of UNFPA (**<http://www.unfpa.org/resources/unfpa-general-conditions-contract> **) and we will abide by this quotation until it expires.**

**Name and title Date and Place**

**Fast Track Procurement Questionnaire
for Medical Devices**

**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.

**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):** 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**

|  |  |  |
| --- | --- | --- |
| **3.1Is the product CE marked?**Certification body and number: Click here to enter text. | **□** Yes | Start Date: Click here to enter text.Expiry Date: Click here to enter text. |
| **□** 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 |
| **3.3 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 ELECTRICAL or BATTERY-OPERATED PRODUCTS**

|  |  |
| --- | --- |
| If the device contains Lithium metal and Lithium ion batteries, does it comply with clause 38.3 of the recommendations on “Transport Of Dangerous Goods” from the United Nations?  |  Yes ☐ No ☐  |
| Does it comply with the latest IATA Dangerous Goods Regulations (DGR)? |  Yes ☐ No ☐ |
| Testing laboratory, Test Report reference, specify standard  | Click here to enter text. |

**PART IV. Checklist of required documentation**

|  |  |
| --- | --- |
| **Product class (EC MEDDEV)** | **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/ornon-reusable surgical instrument, rsi) | ☐ 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 (for manufacturer), and which 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 measuringclass I sterileclass I rsiclass IIa** | ☐ 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, and which 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.☐ 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, and which 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.