United Nations Population Fund,
UNFPA Yemen
Haddah St. behind Lazourde Hotel
Sanaa'a.,Yemen
Tel: +967 1 433160
Website: www.unfpa.org
Email:procurement.yemen@unfpa.org

Date: 11/07/2024

Request for Quotation No. YEM/2024/006

Provision of PPE

Dear Sir/Madam,

We hereby solicit your quotation for the supply of Personal Protection Equipment for UNFPA, as per the specifications detailed in **ANNEX I** of this RFQ.

ANNEX II to be filled and submitted along with the quotation.

ANNEX III General specification to be taken under consideration.

The goods are to be delivered maximum in **3 weeks** upon issuing of PO according to the locations mentioned as a delivery point. The quotation shall be valid at least for **3 months** after the closing date.

If you are interested in submitting a quotation for these services, kindly fill in the attached Quotation Form or your company form and send by **E-mail only** to the address indicated **below not later than 21/07/2024, 15:00 (Sana'a time):**

Samples should be submitted to UNFPA premises not later than 21/07/2024, 15:00 (Sana'a time).

Email: procurement.yemen@unfpa.org

Bidders must enter the following text in the email subject line:

RFQ/YEM/2023/006- PPEs for UNFPA

Please submit your quotation in **US Dollars** currency. Conversion of currency into the UNFPA preferred currency, if the offer is quoted differently from what is required, shall be based only on UN Operational Exchange Rate prevailing at the time of competition deadline.

For any technical inquiries please contact al-maqdam@unfpa.org

For any operational inquiries please contact al-busaily@unfpa.org

Bidders should **NOT** submit any Bid to this contact or your Bid will be declared invalid, as UNFPA will not able to guarantee the confidentiality of the Bidding process.

Bidders may request clarifications **not later than 18th July 2024, 13:00 Sana'a time.**

Quotations submitted by email must be free from any form of virus or corrupted contents, or the quotations shall be rejected.

It shall remain your responsibility to ensure that your quotation will reach the address above on **or before the deadline**. Quotations that are received by UNFPA after the deadline indicated above, for whatever reason, shall not be considered for evaluation. Kindly ensure that it is **signed and in the .PDF format**, and free from any virus or corrupted files.

Please take note of the following requirements and conditions pertaining to the supply of the above mentioned goods:

Partial quotes - Not Permitted
Partial delivery – Not Permitted

Alternative Bids are not accepted under this RFQ. In the event of a supplier submitting more than one bid, the following shall apply:

- All bids marked alternative will be rejected and only the base will be evaluated;
- All bids will be rejected if no indication is provided as to which bids are alternative bids.

Bidders may modify their offers in writing prior to the submission deadline. The bidder must submit the proposed modification via email that must be clearly marked as **"MODIFICATION".**

In this case the previous offer will be declined and the modified offer shall be considered for the evaluation process. Also, if the same bidder has submitted several offers before the bid deadline superseding each other only the last received offer will be considered for opening and further evaluation.

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

Best regards,

UNFPA Yemen

Quotation Form

Name of Bidder: _____

Date of Bid: _____

Request for Quotation No: _____

Currency of Bid price: _____

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

Expiration of Validity of Quotation *(The quotation shall be valid for a period of at least 3 months after the Closing date.):*_____

Price Schedule:

Item No.	FOB/FCA price/unit specify port of shipment	Quantity	Transportation cost to port of Destination (specify mode of trp.)	Shipment volume (cmb) and Weight of goods	Total CPT/CFR (Destination port)	Delivery schedule (months)

In your offer, please include:

1. Specific technical specifications of products offered
2. Quality standard of the products

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**

ANNEX II

Questionnaire for Medical Device/Equipment

All documents submitted must be in English or be accompanied with certified translation.

PART I – Submitter and manufacturer information

Submitter:

Name of submitter:	Click here to enter text.
Address:	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.

Status of the submitter:

Legal manufacturer	Yes ☐	No ☐
or		
Distributor – Trader	Yes ☐	No ☐

Legal 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 – Device identification

Device Identification (Trade name, Type, Model, Product Code, Reference(s)):
Click here to enter text.

Intended use / purpose:
Click here to enter text.

Product details (material, dimensions, etc.):
(E.g. If stainless steel product, identify AISI type or composition. If plastic product, identify grade or composition)
Click here to enter text.

Device classification (specify the related regulation, e.g. MDD, FDA, Other)

EU 93/42/EEC directive, Rule# (according to MDD annex IX)

Class: Click here to enter text.

FDA:

Product code: Click here to enter text.
Regulation number: Click here to enter text.
Product class: Click here to enter text.

Other regulation (specify): Click here to enter text.

Nomenclature code (if known – specify GMDN, UMDNS or other): Click here to enter text.

Part III – Quality Management System Certification

Legal Manufacturer:

1. ISO 9001 Yes ☐ No ☐
   a. Certification body: Click here to enter text.
   b. Expiration date: Click here to enter text.

2. ISO 13485 Yes ☐ No ☐
   a. Certification body: Click here to enter text.
   b. Expiration date: Click here to enter text.

3. ISO 14001 or plans for this Yes ☐ No ☐
   a. Certification body: Click here to enter text.
   b. Expiration date: Click here to enter text.

4. ISO 50001 or plans for this Yes ☐ No ☐
   a. Certification body: Click here to enter text.
   b. Expiration date: Click here to enter text.

If the manufacturing processes are subcontracted:

Subcontracted activity / process	Name / address of the subcontractor	QMS certification of the subcontractor
Click here to enter	Click here to enter text.	Click here to enter text.

text.		
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.

Submitter (if the submitter is not the legal manufacturer):

1. ISO 9001 Yes ☐ No ☐
   a. Certification body: Click here to enter text.
   b. Expiration date: Click here to enter text.

2. ISO 13485 Yes ☐ No ☐
   a. Certification body: Click here to enter text.
   b. Expiration date: Click here to enter text.

Part IV – Regulatory certification

Is the **device CE marked?** Yes ☐ No ☐

For devices other than Class I excluding Class I sterile devices / Class I with measuring function / Class I reusable surgical instruments

Nature of the EC certification (MDD 93/42/EEC): Annex II.3 ☐ Annex V ☐

Identification of the Notified Body (+ identification number): Click here to enter text.

Is the device **FDA** approved? Yes ☐ No ☐

For FDA approved device: Manufacturer name: Click here to enter text.

Manufacturer listing #: Click here to enter text.

If the device is "510k cleared", indicate the 510k clearance #: Click here to enter text.
If the device is "PMA cleared", indicate the PMA clearance #: Click here to enter text.

Other regulatory clearance / registration (specify Canada, Japan, Australia): Click here to enter text.

Applicable regulation: Click here to enter text.

Certification / license number: Click here to enter text.

Part V – Compliance to technical standards

If the declaration of compliance is based on report(s) issued by an independent testing laboratory, the reference of the test report must be indicated (mandatory for safety compliance of electro-medical devices)

Standard # and date	Fully or partially applied	Identification of the Testing laboratories, where used	Test report reference
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.

Part VI – Other information

VI-1 INSTALLATION / SPARES / SERVICE

1. Is installation necessary? Yes ☐ No ☐

   Specify tools required (if Yes): Click here to enter text.

2. Is training required? Yes ☐ No ☐

   Specify who will provide training and specify costs if applicable: Click here to enter text.

3. Are spare parts available? Yes ☐ No ☐

   Specify source and if additional costs required: Click here to enter text.

   Specify period supply of spare parts is guaranteed: Click here to enter text.

4. Information available on service/maintenance? Yes ☐ No ☐

   Attached information: Click here to enter text.

5. Electrical Medical Device/Equipment Yes ☐ No ☐

   Specify voltage and frequency available: Click here to enter text.
   Specify all plug types available: Click here to enter text.

VI-2 DECONTAMINATION

Only for re-usable devices.

1. Specify method for cleaning: Click here to enter text.
2. Specify instructions for disinfection: Click here to enter text.
3. Specify any restrictions on detergent/disinfectant types: Click here to enter text.
4. Specify sterilization method required before re-use: Click here to enter text.

VI-3 WARRANTY

Specify recommended maximum number of uses or years of use or period of use:
Click here to enter text.

VI-4 SAFE DISPOSAL

Specify instructions for safe disposal: Click here to enter text.

Checklist of Required documentation:

Documents to be submitted must be true and valid copies.

☐ Copy of manufacturing licence

☐ Letter of authorization to act on behalf of manufacturer if submission is not from the manufacturer

☐ Copy of ISO 9001 certificate (for manufacturer and for trader)

☐ Copy of ISO 13485 certificate (for manufacturer and for trader)

☐ Complete and detailed technical specifications of the product (incl. **manufacturer's product code**)

☐ **CE certificate** (additionally for EC class III items EC Design Dossier)

☐ Declaration of conformity (signed and dated, according to ISO 17050, specifying the relevant directives, regulations and standards, and attaching copy of certificates)

☐ Manufacturer's EC Representative (EC Rep) contact details and country information

☐ **FDA 510k Premarket approval device letter/ Device licence (Australia, Japan, Canada)**

☐ Evidence that product has been sold to Europe or U.S. or other large market areas with strong regulatory systems.

☐ Evidence of clinical studies to all but class I non-sterile, non-measuring medical devices: e.g. a copy of study results

☐ Product technical data sheet

☐ **Photos of the product, packaging and labelling** at various angles if necessary

☐ Instruction for use in English, Spanish and French

☐ User, installation and/or assembly manual, if applicable

☐ Service/repair (after sale) services with contact details, if applicable

☐ Information on cleaning, disinfecting and sterilization methods (for reusable devices only)

☐ Certificates for product-specific safety standards, such as ISO 10993-1.

☐ Certificate for sterilization process, such as ISO 17665 (Steam sterilization), ISO 11135 (ETO sterilization), ISO 11137 (Gamma Irradiation), or other equivalent.

☐ Manufacturer's Post-market study report from 3 last years

☐ Quality Assurance process (for the manufacturer and/or for the trader)

S. Specify any other documentation provided (e.g. any test results or relevant standards):

☐ ISO 14001. If not available, a signed commitment letter from a manufacturer

☐ Other relevant certificates related to Environmental and/or Energy management, such as ISO 50001, or FSC certificates for the carton and paper used in packaging (for manufacturer and for trader).

☐ Manufacturer's copy of the latest audit report (audited by an European health product distributor)

☐ Copy of third party laboratory test reports, if available (Laboratory name and ISO 17025 accreditation status), if applicable.