



United Nations Population Fund (UNFPA)


Country Office in Ukraine

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Website: www.unfpa.org

Date: 4/03/2025

DocuSigned by:

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Aos Zeidan, Supply Chain Specialist

Invitation to Bid (ITB) No.UNFPA/UKR/ITB/25/01

Dear Sir/Madam,

We hereby solicit your Bid for the supply of the following items (Medical Equipment) with the following technical specifications per items (goods should be provided on **DAP Kyiv, Ukraine basis, partial bids are allowed under this ITB per items**):

No.	Item	Quantity, pcs	Technical Specifications
1	Infant ventilator with HFOV	1	Please refer to Annex 6 - Technical Specifications
2	Mobile X-ray	2	
3	Neonatal intensive care incubator	2	
4	Birthing bed	2	

If you are interested in submitting a bid for these items/services, kindly fill in the attached submission form and together with other required documents send it to the secure email address indicated below/not later than: **March 14, 2025 at 5:00 PM (Kyiv time)**.

Please ensure to mark your email with the ITB reference number and the words “Sealed bid. Do not open before **March 14, 2025 at 5:00 PM (Kyiv time)**.”.

Secure email address for bid submission ua-procurement@unfpa.org

Note: Do not submit your bid/proposal to the contact person’s email address!

Please submit your quotation in **USD 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.

The UNFPA terms of payment are 100% net payment, 30 days upon complete receipt of goods with shipping documents, invoices and other documentation required by the contract.

Clarifications:

Email address of Contact Person in case of technical questions: seredenko@unfpa.org - Andrii Seredenko, SRH Project Manager, with copying to: grechishnikov@unfpa.org - Maksym Grechishnikov, Procurement and Logistics Associate.

Please send your technical questions no later than **March 10, 2025 at 11:00 AM (Kyiv time)**. UNFPA will provide clarifications by email no later than **March 11, 2025 at 5:00 PM (Kyiv time)**.

Bidding shall be conducted through ONE envelope. The technical bid containing the technical specifications and the financial bid containing the price information shall be submitted together.

Documents to be submitted with the bid:

- a. Completed and signed Bid Submission Form (**Annex - 1**);
- b. Bidders Identification Form (**Annex - 2**);
- c. Product Item Overview Form (**Annex - 3**);
- d. Technical bid, including brochures, photos of medical devices and packaging and product catalogue to demonstrate that specification and quality of the products are in line with the requirements listed in the bidding documents. Please note that brochures of the proposed model shall be provided in both English and Ukrainian language;
- e. Completed and signed Financial bid including the price schedule (**Annex - 4**);
- f. FTP Questionnaire for Medical Devices (**Annex - 5**) (*to be completed for each submitted item*);
- g. Business license: Copy of a current license in the country of legal domicile.
- h. Certificate of conformity and/or Declaration of conformity from Ukrainian regulatory body/Authorized company (which confirms local registration of the product, compliance with the Technical Regulation on medical devices depending on their purpose and permission to use in medical practice) in accordance with requirements of Ukrainian legislation;
- i. Authorization Letter from the Manufacturer to the Bidder which authorizes sales in Ukraine;

j. Authorization Letter from the bidder to a local representative to provide the after sales services, installation, commissioning and training for the staff in Ukraine (if different from the bidder) and a Letter from such a local representative stating that they accept this provision of services;

k. Written Self-Declaration of not being included in the UN Security Council 1267/1989 list, UN Procurement Division List or other UN Ineligibility List.

l. Documents to be submitted for Medical Devices:

- Minimum documentation as per below table corresponding to classification of Medical Devices (ref. European Commission, MEDDEV 93/42/EEC):

Product class (as per EC MEDDEV)	Minimum documentation required for Medical Devices
class I (non-measuring, non-sterile and/or non-reusable surgical instrument, rsi)	<ol style="list-style-type: none"> 1. Copy of ISO 13485 or ISO 9001 QMS certificate. 2. A signed and dated Declaration of Conformity (DoC) according to ISO 17050 stating compliance to the relevant ISO standards and directives (e.g. CE self-declaration 93/42/EEC), and which has a reference to the offered product.
class I measuring class I sterile class I rsi class IIa	<ol style="list-style-type: none"> 1. EC certificate (referencing the name/number of the notifying body), and/or 510k (FDA clearance), and/or approval letter or certificate from national regulatory body. 2. 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 a 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.
class IIb class III	<ol style="list-style-type: none"> 1. EC certificate (referencing the name/number of the notifying body) with an additional copy of EC Design Examination certificate, and/or 510k/PMA FDA clearance, and/or approval letter or certificate from national regulatory body. 2. 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 a reference to the offered product. Proof of compliance to ISO standards in a form of copies of certificates shall be submitted if available.

Delivery and services to be included:

- Bidders are requested to quote based on INCOTERMS 2010, and price of goods should include the delivery on DAP (Kyiv, Ukraine) basis.
- Installation, commissioning and training services are required to be performed by the Bidder, the Bidder shall include the cost of these services in the price of goods. If above mentioned services are requested by the final recipient (maternity unit) later than the UNFPA payment terms – the Bidder will be requested to provide official Guarantee Letter to provide services upon request.

Validity of Bid:

The prices of the bid shall be valid for 90 days after the closing date of bid submission as specified by UNFPA. A bid valid for a shorter period shall be rejected by UNFPA.

Delivery Time:

The maximum allowed delivery time is 60 days upon issuing of purchase order.

All items are subject for pre-shipment inspection while requested by UNFPA CO Ukraine.

Evaluation of Bids:

UNFPA shall compare all substantially responsive bids per Item to determine the lowest priced substantially responsive bid.

A substantially responsive bid is one that conforms to all the terms, conditions, and specifications of the bidding documents without material deviation, reservation, or omission. A material deviation, reservation, or omission is one that:

- a. affects in any substantial way the scope, quality, or performance of the goods and related services specified in the contract; or
- b. limits in any substantial way, inconsistent with the bidding documents, UNFPA's rights or the bidder's obligations under the contract; or
- c. if rectified would unfairly affect the competitive position of other bidders presenting substantially responsive bids.

Contract Award:

UNFPA shall award the contract to the lowest priced bidder(s) per lot whose bid has been determined to be substantially responsive with the bidding documents, including the maximum allowable lead time, and full acceptance of the UNFPA General Terms and Conditions (can be found at: <https://www.unfpa.org/resources/unfpa-general-conditions-goods>).

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

UNFPA reserves the right at the time of award of contract to increase or decrease by up to 20% the quantity of goods specified in this bid without any change in unit price or other terms and conditions.

Attachments:

- Annex 1 - Bid Submission Form
- Annex 2 - Bidders Identification Form
- Annex 3 - Product Item Overview Form
- Annex 4 - Financial bid (Price Schedule Form)
- Annex 5 - FTP Questionnaire for Medical Devices
- Annex 6 - Technical Specifications