United Nations Population Fund
UNFPA - Yemen
Haddah St. behind Lazourde Hotel
Sana'a., Yemen
Tel: +967 1 433160
Website: www.unfpa.org

Date: 18/09/2024

Invitation to Bid (ITB) No. YEM/2024/004

Dear Sir/Madam,

We hereby solicit your Bid for the supply of the following items with the following technical specifications as stated in **Annex 6:**

Commodity LOT 1: MEDICAL SUPPLIES

Commodity LOT 2: MEDICINES

Bid Submission:

If you are interested in submitting a bid for these items/services, kindly fill in the attached submission forms and send them to the secure email address indicated below/ not later than **09/10/2024, 15:00 (Sana'a time).**

Secure email address for bid submission:

procurement.yemen@unfpa.org

Please ensure to mark your email subject with the ITB reference number:

"ITB/YEM/2024/004 – Required Documentation"

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.

Questions or Clarifications related to the Bid:

Any questions or clarifications relating to the Bid process and/or to the attached documents shall be sent to: for Medicines, Dr. Gamil Zaid at email: zaid@unfpa.org, and for medical supplies Gehad Al-Maqtari at email: al-maqtari@unfpa.org no later than **02/10/2024**.

Note: Do not submit or cc your bid/proposal submission to the contact person's email address mentioned in this section!

Documents to be submitted with the bid:

DOCUMENT CHECKLIST - Please remember to submit the following documents:

No.	DOCUMENT NAME	
1	**Annex 1** - Bid Submission Form - Completed and Signed	●
2	**Annex 2** - Bidders Identification Form - Completed	●
3	**Annex 3** - Product Item Overview Form - Completed	●
4	**Annex 5** - Price Schedule Form - Completed and Signed	●
5	A statement whether any import or export licenses are required in respect of the goods to be purchased including any restrictions on the country of origin, use/dual-use nature of goods or services, including and disposition to end users;	●
6	- Latest Business Registration Certificate; - Latest Internal Revenue Certificate / Tax Clearance; - Manufacturer's Authorization of the Company as a Sales Agent (if Bidder is not the manufacturer);	●
7	Certificate of Exclusive Distributorship in the country (if applicable, and if Bidder is not the manufacturer);	●
8	Complete documentation, information, and declaration of any goods classified or may be classified as "Dangerous Goods"	●
9	Patent Registration Certificates (if any of the technologies submitted in the quotation is patented by the Supplier)	●
10	Written Self-Declaration of not being included in the UN Security Council 1267/1989 list, UN Procurement Division List or other UN Ineligibility List	●
11	Complete Technical bid submission, including detailed Technical specifications, product catalogue, technical data sheets and schematic drawings (when applicable) to demonstrate that specification and quality of the products are in line with the requirements listed in the bidding document.	●
12	**Quality Assurance Documents to be submitted:** Below are Guidelines describing the minimum documentation required to be submitted by the bidders, and can be found in the tables below as per each product group: Pharmaceuticals, medical devices, and IVDs. All certificates and approvals must be valid at the time of bid submission.	

<table>
<tr>
<td>12.1</td>
<td>Documents to be submitted for Pharmaceuticals:
● Annex 4.1 - Fast Track Procurement Questionnaire for Pharmaceuticals - duly completed by bidder and signed for each of the items included in the submission.
● Evidence that the product is registered in the country of intended use
● Evidence that the product is included in the Country's National list of essential medicines.
● GMP certificate for Finished Pharmaceutical Product (FPP) manufacturer
● Certificate of analysis for at least one recently released batch.
● Package insert if applicable and patient information leaflet (PIL).
● Photos of the finished pharmaceutical product and labeling.
● Signed declaration that the product to be supplied meets the locally approved specifications and is manufactured under cGMP</td>
<td>●</td>
</tr>
<tr>
<td>12.2</td>
<td>Documents to be submitted for Medical Devices:
● Annex 4.2 - Fast Track Procurement Questionnaire for Medical Devices - duly completed by the bidder and signed for each item included in the submission.
● Minimum documentation as per the below table corresponding to the classification of Medical Devices (ref. European Commission, MEDDEV 93/42/EEC).
● Photos of the medical device product and packaging (preferably in a format where the dimensions and features can be visible).

<table>
<tr><th>Product class
(as per EC MEDDEV)</th><th>Minimum documentation required for Medical Devices</th></tr>
<tr><td>class I
(non-measuring, non-sterile and/or
non-reusable surgical instrument, rsi)</td><td>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.</td></tr>
<tr><td>class I measuring
class I sterile
class I rsi
class IIa</td><td>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.</td></tr>
<tr><td>class IIb
class III</td><td>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.</td></tr>
</table>

Examples of products in each of the Medical Device EC MEDDEV class:
• Class I (non-measuring, non-sterile, and/or non-reusable surgical instrument) Aprons, bags, baskets, bowls, etc. (largest item class group in UNFPA procurement catalog).
• Class I (measuring, sterile, and/or reusable surgical instruments) Thermometers, scales, catheters, cytobrushes, sterile surgical and gynecological instruments, sterile gloves and supplies, reusable surgical and gynecological instruments, etc.
• Class IIa: Cannulas, needles, blades, pumps (manual, electrical), resuscitators, etc. (Many of the class IIa products are also sterile products.)</td>
<td>●</td>
</tr>
</table>

12.3	**Documents to be submitted for In Vitro Diagnostics (IVD):** ● **Annex 4.2** - Fast Track Procurement Questionnaire for IVD products - duly completed by bidder and signed for each of the items included in the submission. ● Evidence that the product is registered in the country of intended use. ● Evidence that the product is included in the Country National list of essential medicines. Minimum documentation: ● ISO 13485 QMS certificates, and GMP certificate if available. ● A signed and dated DoC according to ISO 17050 stating compliance to critical ISO standards and directives, and which has reference to the offered product. ● Copy of EC certificate 98/79/EC, and/or 510k/PMA clearance (FDA), and/or other Stringent Regulatory Agency certificates or approval letters. ● Certificate of analysis for at least recently released batch. ● Proof of WHO prequalification (if not prequalified, see list of other options below). ● Photos of the finished IVD product and labelling. If the IVD product is not WHO prequalified or mentioned on WHO webpage as such, the product* must have undergone: 1) a WHO Emergency Use Evaluation and Listing of IVDs (EUAL), or 2) an US FDA Emergency Use of Medical Products and Related Authorities (EUA), or 3) an approval process from Stringent Regulatory Authority (SRA) designated by Global Harmonization Task Force (GHFT) Competent Authority. * Any product registered for "Research Use Only" or "For Export Only" is not acceptable, unless specifically authorized in writing by UNFPA.	●

Partial Bids:

Partial Lots are **allowed** under this ITB. Bidders can submit their offers for Lot 1 or Lot 2 or both. Note: Partial bids mean that the bidder does not have to offer all requested Lots in order to submit a complete bid. However, within each Lot, full quantities/items must be offered.

UNFPA reserves the right to make multiple arrangements for any item(s) where, in the opinion of UNFPA, the lowest Bidder cannot fully meet the delivery or quality requirements or if it is deemed to be in UNFPA's best interest to do so.

INCOTERMS 2020:

- Freight cost **DAP** (UNFPA Sana'a warehouse and Aden Warehouse)

Validity of Bid:

The prices of the bid shall be valid for *90 days depending* 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 **3 weeks** upon issuing of purchase order.

Evaluation of Bids:

UNFPA shall compare all substantially responsive bids 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.

d. Bidder's full acceptance of the UNFPA General Terms and Conditions.

e. Adherence to the requested Delivery Time in this Bid document.

f. Physical inspection of registered office, facilities/warehouses will be conducted for the potential suppliers under consideration

Contract Award:

UNFPA shall award the contract to the lowest priced bidder(s) whose bid has been determined to be substantially responsive with the bidding documents, including the maximum allowable lead time. Note: if partial bids are allowed, the lowest evaluated bidder will be evaluated by **commodity** type.

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

Attachments:

- **Annex 1 - Bid Submission Form**
- **Annex 2 - Bidders Identification Form**
- **Annex 3 - Product Item Overview Form**
- **Annex 4 - Fast Track Procurement Questionnaire**
- **Annex 5 - Price Schedule Form**
- **Annex 6 – Technical Specifications**
- **Annex 7 – Distribution List**

Annex 1 - Bid Submission Form

Invitation to Bid (ITB) No. UNFPA/ YEM/2024/004

Name of Bidder: _____

Contact Person: _____

Title: _____

Email Address: _____

Telephone Number: _____

Date of Bid: _____

Bid No: _____

Currency of Bid price: _____

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

(Note: maximum number of days is: 3 weeks)

Expiration of Validity of Bid/Proposal *(The bid shall be valid for a period of at least 90 days after the Closing date.):* _____

Vendor's Comments:

I hereby certify that this company, which I am duly authorized to sign for, accepts the General Terms and Conditions of UNFPA http://www.unfpa.org/resources/unfpa-general-conditions-contract **and we will abide by this bid/proposal until it expires.**

We undertake, if our bid/proposal is accepted, to commence and complete delivery of all items in the contract within the time frame stipulated.

We understand that you are not bound to accept any bid you may receive and that a bidding contract would result only after final negotiations are concluded on the basis of the technical and price bids proposed.

_____ _____

Name and title **Date and Place**

Annex 2 - Bidders Identification Form

Invitation to Bid (ITB) No. UNFPA/ YEM/2024/004

1. **Organization**

Company/Institution Name	
Address, City, Country	
Telephone/FAX	
Website	
Date of establishment	
Legal Representative: Name/Surname/Position	
Legal structure: natural person/Co.Ltd, NGO/institution/other (please specify)	
Organizational Type: Manufacturer, Wholesaler, Trader, Service provider, etc.	
Areas of expertise of the organization	
Current Licenses, if any, and permits (with dates, numbers and expiration dates)	
Years supplying to UN organizations	
Years supplying to UNFPA	
Production Capacity	
Subsidiaries in the region (please indicate names of subsidiaries and addresses, if relevant to the bid)	
Commercial Representatives in the country: Name/Address/Phone (for international companies only)	

2. **Quality Assurance Certification**

International Quality Management System (QMS)	
List of other ISO certificates or equivalent certificates	
Presence and characteristics of in-house quality control laboratory (if relevant to bid)	

3. **Expertise of Staff**

Total number of staff	
Number of staff involved in similar supply contracts	

4. **Client Reference List**

Please provide references of main client details.

Name of company	Contact person	Telephone	E-mail
1.			
2.			
3.			

5. **Previous Experience and Similar main projects**

Project	Country/Region	Type of Commodity	Project value in USD
1.			
2.			
3.			

6. **Contact details of persons that UNFPA may contact for requests for clarification during bid evaluation**

Name/Surname	
Telephone Number (direct)	
Email address (direct)	

P.S.: This person must be available during the next two weeks following receipt of bid

Annex 3 - Product Item Overview Form
Invitation to Bid (ITB) No. UNFPA/ YEM/2024/004

Product's adherence with specifications

The product supplied from manufacturers (and Supplier, if different from manufacturer) shall conform with the UNFPA technical specifications or be similar. Bidders are to state clearly in the below table, whether each criteria of the technical specifications matches or not and clearly state the Bidder's specifications in the below field for each item. It is essential that the full specifications are provided.

The bidder SHOULD NOT copy and paste UNFPA's specifications.

Item No.	Description and minimum /mandatory specifications *[Detailed description to be completed by UNFPA]*	Description of items offered and Bidder's statements on deviations (To be completed by the bidder)	Compliant? (Y/N) (To be completed by UNFPA during evaluation)
1	**[...]**		
2	**[...]**		
3	**[...]**		
...			

(Use the spreadsheet "Product Item Overview Form.xls" if a large number of items need to be compared.)

Annex 4 - FTP Questionnaires

Invitation to Bid (ITB) No. UNFPA/ YEM/2024/004

Bidders to complete and submit the below Questionnaires:

➔ **Annex 4.1 - Fast Track Procurement Questionnaire for Pharmacuticles**

UNFPA Questionnaire for

Pharmaceutical Products under FTP

Please complete all the fields in the questionnaire as required and attach the requested supporting documents. Please fill out one form separately for each pharmaceutical product.

1) MANUFACTURER DETAILS

Name of manufacturer:

Physical address (include Block number, line number etc.):
Postal address:

City:	Country:
Telephone:	Fax:
E-mail:	Website:

A. Include a copy of registration certificate or evidence that the product is registered in the country of intended use.

2) FINISHED DRUG PRODUCT

2.1. IDENTIFICATION

Content	Active Pharmaceutical Ingredient	Amount in dosage form or amount per unit (Strength)
Active Ingredient 1		
Active Ingredient 2 (if applicable)		

Inactive Ingredients (excipients) of medical/pharmaceutical relevance (e.g. sugar, allergens such as preservatives, lactose) amount in dosage form or per dosage unit (e.g. Contains Alcohol 10%):

Brand/trade name (if any):

Dosage form (select below):

- □ **Tablets**
  - ○ Uncoated
  - ○ Sugar coated
  - ○ Film coated
  - ○ Enteric coated
- □ **Capsules**
- □ **Syrup/oral liquids**

- □ **Injection**
  - ○ Microcrystalline suspension
  - ○ Oily solution
  - ○ Aqueous solution
  - ○ Powder for injection
- □ **Implants**

Route of administration (select below):

☐ Oral ☐ I.M. ☐ I.V. ☐ S.C. ☐ Other (Please specify)

2.2PACKAGING

Number of dosage units per unit packs:

Description of primary packaging materials:

B. Attach package insert and/or patient information leaflet (PIL).

C. Picture/photo of the finished pharmaceutical product and labelling.

D. Certificate of analysis for at least one recently released batch (not more than 1 year old).

2.3SHELF LIFE and STORAGE CONDITIONS

Shelf life as it appears on the packaging:

Temperature:

Light:

Humidity:

Other (Specify):

2.4. REGULATORY STATUS

Registration Number of Pharmaceutical Product: Valid until:

Regulatory issued by (Name of Agency): Country:

E. Valid GMP certificate for Finished Pharmaceutical Products (FPP).

3) DECLARATION BY BIDDER/MANUFACTURER

F. Filled out declaration from bidder/manufacturer.

[*Company letterhead*]

Declaration by bidder/manufacturer

I, the undersigned certify that all the information in this declaration and all accompanying documentation is correct and updated. I further certify that I have examined the following statements and I attest to their accuracy.

1. The holder of the national registration follows national requirements for handling adverse reactions to its products.
2. The holder of the national registration follows national requirements for handling batch recalls of its products.
3. The formula to be supplied is the same as the formula approved by the National Regulatory Authority (NRA), …… *(insert name of NRA)*. The strength, specifications (API, excipients, and FPP), etc. are exactly the same as the formula approved by NRA.
4. The primary packaging is exactly the same in all aspects, including specifications, as the primary packaging is approved for use in the same product as approved by the NRA.
5. The secondary packaging is exactly the same in all aspects, including specifications, as the primary packaging approved for use in the same product as approved by the NRA.
6. The information in the questionnaire/dossier submitted to UNFPA contains information which is the same as the information in the dossier which is approved by the NRA.
7. The package insert, summary of product characteristics, patient information leaflet submitted in the submission are the same as those approved by the NRA.
8. Where there are any differences in any aspect of the product including formula, manufacturing site of API, manufacturing site of FPP, specifications of primary packaging, specifications of secondary packaging, package insert, summary of product characteristics, patient information leaflet, I have stipulated these and the justification for the changes in a separate document and submitted to UNFPA.

Name: Signature:

Position in Company: Date:

Annex: Checklist of attachments required

Please ensure that all documents necessary to enable objective evaluation of your product are attached. This checklist may not be exhaustive.

☐ A. Copy of the registration certificate or evidence that the product is registered in the country of intended use.

☐ B. Package insert and patient information leaflet (PIL).

☐ C. Picture/photo of the finished pharmaceutical product and labelling.

☐ D. Certificate of analysis for at least one recently released batch (not more than 1 year old).

☐ E. Valid GMP certificate for Finished Pharmaceutical Product (FFP).

☐ F. Filled out declaration from bidder/manufacturer.

Annex 4.2 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

<table>
<tr><td rowspan="2">3.1 Is the product CE marked?

Certification body and number:
Click here to enter text.</td><td>□ Yes</td><td>Start Date: Click here to enter text.
Expiry Date: Click here to enter text.</td></tr>
<tr><td colspan="2">□ No</td></tr>
<tr><td rowspan="2">3.2 Is the product FDA approved?

510k clearance #: Click here to enter text.
PMA clearance #: Click here to enter text.</td><td>□ Yes</td><td>Start Date: Click here to enter text.
Expiry Date: Click here to enter text.</td></tr>
<tr><td colspan="2">□ No</td></tr>
</table>

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 <u>any other</u> 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 ☐

a. Certification body and number: Click here to enter text.

b. 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/or non-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 measuring **class I sterile** **class I rsi** **class 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.

➔ **Annex 4.3 - Fast Track Procurement Questionnaire for IVD products**

Fast Track Procurement Questionnaire

for *In vitro* Diagnostic Products (IVD)

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

2.1 Product name and product code

2.1.1 Product name: Click here to enter text.	
2.1.2 Manufacturer's **product code** as it appears in the label and catalog (reference number): Click here to enter text.	
2.1.3 Product details, or individual contents of the IVD kit[1], including accessories	2.1.4 Number of tests per box/kit (if different kit sizes are available, complete one form per each kit)
Insert name of one component per line, add more rows if needed. Click here to enter text.	*Indicate units, X tests/vials/devices/ bottles (a volume)* Click here to enter text.

[1] [**ATTACHMENT:** Attach photographs of all kit components (packaged and individually.]

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

2.1.5 If reagents are supplied in more than one box, provide the reagent name, product code/catalogue number, and number of tests for each box of reagents: Click here to enter text.

2.1.6 Does this product require dedicated instrumentation? If so, please provide the instrument or component name, product code/catalogue number, and other relevant information.
Click here to enter text.

2.2 Disease category, type of analyte and IVD method of analysis

2.2.1 Name of the disease, category	Click here to enter text.
2.2.2 Analyte - (Name and type of analyte molecule: Antibody, Antigen, DNA, RNA, etc.)	Click here to enter text.
2.2.3 IVD method of analysis (e.g. PCR, POCT, immunoassay, ELISA,etc.)	Click here to enter text.
2.2.4 Other information	Click here to enter text.

2.3 Specimen/sample type

2.3.1 Select the specimen type(s) to be used with the product	
□ Serum	□ Plasma
□ Venous whole blood	□ Capillary whole blood
□ Oral fluid	□ Dried blood spot
□ Urine	□ Stool

2.3.2 Other information (e.g. sample volume or quantity, requirements for sample collection, specify acceptable blood sample anticoagulants, etc.):
Click here to enter text.

2.4 Transport, storage and operating temperatures

2.4.1. List transport, storage and operating temperatures and shelf life (add more rows if needed).

Product name (If more than one box, provide the name for each reagent box)	Transport temperature range (min °C - max °C)	Storage temperature range (min °C -max °C)	Operating temperature range (min °C - max °C)	Shelf-life upon manufacture (months)	Indicative shelf life upon delivery (months)

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.

2.4.2. Describe any other storage conditions that are applicable to this product:

Click here to enter text.

Part III. Regulatory Status

3.1 Is the product WHO prequalified?	□ Yes	Start Date: Click here to enter text. Expiry Date: Click here to enter text.
	□ No	
3.2 Has the product undergone one of the following: 1) a WHO Emergency Use Evaluation and Listing of IVDs (EUAL), 2) an US FDA Emergency Use of Medical Products and Related Authorities (EUA), 3) an approval process from Stringent Regulatory Authority (SRA) designated by Global Harmonization Task Force (GHTF) Competent Authority.	□ Yes	Name of body: Click here to enter text. Start Date: Click here to enter text. Expiry Date: Click here to enter text.
	□ No	
3.3 Is the product for "Research use only" or "For export only"?	□ Yes, specify Click here to enter text.	
	□ No	

3.4 Is the product CE marked (IVDD 98/79/EC)? 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	
3.5 Is 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	
	□ Yes	Start Date: Click here to enter text. Expiry Date: Click here to enter text.

3.6 Is the product approved by National Regulatory Agency or Department? Name of agency and type of approval: Click here to enter text.	☐ No	
3.7 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	

3.8 Manufacturer QMS ISO 9001 Yes ☐ No ☐

a. Certification body and number: Click here to enter text.
b. Expiration date: Click here to enter text.

3.9 Manufacturer QMS ISO 13485 Yes ☐ No ☐

c. Certification body and number: Click here to enter text.
d. Expiration date: Click here to enter text.

Part IV. Checklist of Required Documentation

Documents to be submitted must be true and valid copies. All documents submitted must be in English or be accompanied with a certified English translation.

☐ Copy of ISO 13485* Certificate
☐ A signed and dated Declaration of Conformity according to ISO 17050 stating compliance to critical ISO standards and directives, and which has reference to the offered product.
☐ Approval letter or certificate (National Regulatory Body) and/or EC certificate (European Notifying body), and/or 510k or PMA device letter (FDA).
☐ Proof of WHO prequalification (If product is not prequalified, a proof of approval by one of the other regulatory bodies in section 3.2 is mandatory)
☐ Evidence that the product is registered in the country of intended use.
☐ Certificate of analysis for at least one recently released batch.
☐ Photos of the finished IVD product and labeling.
☐ A certificate of analysis for at least one recently released batch.

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

Annex 5 - Price Schedule Form

Invitation to Bid (ITB) No. UNFPA/ YEM/2024/004

Name of Bidder: _____

Date of Bid: _____

Bid No: _____

Currency of Bid price: _____

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

(Note: maximum number of days is: 3 weeks)

Expiration of Validity of Bid/Proposal *(The bid shall be valid for a period of at least 90 days months after the Closing date.):* _____

You can include an Excel spreadsheet instead of this format. The table columns should be modified as appropriate for the specific case.

Item No.	price/unit	Quantity	Total FCA/FOB (Destination)	Transportation cost to destination (specify mode of transportation)	Total DAP (Destination)	Delivery schedule (days/weeks upon order)

Vendor's Comments:

PROVIDED THAT A PURCHASE ORDER IS ISSUED BY UNFPA **WITHIN THE REQUIRED BID VALIDITY PERIOD**, THE UNDERSIGNED HEREBY COMMITS, SUBJECT TO THE TERMS OF SUCH PURCHASE ORDER, TO FURNISH ANY OR ALL ITEMS AT THE PRICES OFFERED AND TO DELIVER SAME TO THE DESIGNATED POINT(S) WITHIN THE DELIVERY TIME STATED ABOVE.

_____ _____

Name and title **Date and Place**

Annex 6 – Technical Specification

Invitation to Bid (ITB) No. UNFPA/ YEM/2024/004

LOT 1 - Medical supplies

Refer to Sheet attached to this ITB with the detailed Technical Specifications for each item required ''Specifications of Medical Supplies''

LOT 2 – Medicines

No	Row Labels	UoM	NEML
1	Adrenaline HCl 1:10000 (aqueous) 0.1mg/ml Inj	Amp	Yes
2	Aminophylline; injection 25 mg/ml	Amp	Yes
3	Ampicillin (powder) vial 1g	Vial	Yes
4	Ampicillin (powder) vial 500mg	Vial	Yes
5	Anti- D Immunoglobulin 250mic.gr/5ml amp or 300mcg/1ml	Vial	Yes
6	Atropine Injection: 1 mg (sulfate) in 1-mL ampoule.	Amp	Yes
7	Calcium gluconate 100mg/ml inj	Amp	Yes
8	Ceftriaxone pdr/inj 1g vial	Vial	Yes
9	Ceftriaxone pdr/inj 250mg vial	Vial	Yes
10	Chlorohyxidine Digluconate; 7.1% w/v gel	Each	Yes
11	Co-Amoxiclav 500mg+125mg tabs/PAC3x5	Tab.	Yes
12	Dexamethasone 4mg/ml amp	Amp	Yes
13	Dextrose 10%; solution	Bag	Yes
14	Dopamine 40mg/ml , 80mg/ml or Dopamine hydrochloride injection 40mg/ml-200mg/5ml	Amp	Yes
15	Erythromycin eye ointment 0.5%	Tube	Yes
16	Ferrous sulphate 200mg+folicacid 0.4mg tab or 150 mg+0.5mg	Tab.	Yes
17	Folic acid 5mg tab	Tab.	Yes
18	Gentamycin sulfate; 40 mg/ml amp 2 ml	Amp	Yes
19	Heparin sodium s.c 25000IU/5ml inj	Amp	Yes
20	Hydralazine HCl, scored; 20 mg amp 1 ml	Amp	Yes

21	Hydrocortisone Powder 100 mg (as sodium succinate) in vial.	Vial	Yes
22	Methyldopa 250mg tablet	Tab.	Yes
23	Metronidazole; 500 mg/100ml inj	Bottle	Yes
24	Sodium Bicarbonate; injection 8.3% or 8.4%-50 ml	Amp	Yes
25	Vancomycin 0.5 g inj	Amp	Yes
26	Vitamin K 10mg/ml inj	Amp	Yes

Annex 7 – Distribution List

Invitation to Bid (ITB) No. UNFPA/ YEM/2024/004

LOT 1 Medical Supplies

No	Item Name	Sana'a	Aden	Total
1	Apron Reusable for Adult	3400	124	3524
2	Blood Bag 500 cc with IV Set	7828	3383	11211
3	Cotton Wool 100g Roll	8899	322	9221
4	Cotton Wool 500g Roll	3417	759	4176
5	Disposable Face Mask with Ear loops	4433	144	4577
6	Disposable Gown	22138	15615	37753
7	Disposable Head Cover	1563	886	2449
8	Disposable Hospital Bed Sheet	31812	3630	35442
9	Disposable Shoe Cover	2137	1092	3229
10	Endotracheal 2.5 w/o cuff Tube	845	474	1319
11	Endotracheal 3 w/o cuff Tube	944	474	1418
12	Endotracheal 6.5 w/ cuff Tube	3074	652	3726
13	Endotracheal 7 w/ cuff Tube	2979	784	3763
14	Examination Gloves Pre-Powdered Large Size	5391	219	5610
15	Examination Gloves Pre-Powdered Medium Size	5822	380	6202
16	Examination Gloves Pre-Powdered Small Size	5085	219	5304
17	Feeding CH05 Tube	7842	1604	9446
18	Feeding CH08 Tube	7759	1274	9033
19	Gauze Swab Sterile 10x10cm	8118	2266	10384
20	Hand Antiseptic Gel 500 ml	1679	264	1943
21	IV Cannula 18 G	17611	4208	21819
22	IV Cannula 20 G	20350	4125	24475
23	IV Cannula 22 G	153368	29700	183068
24	IV Cannula 24 G	117106	13613	130719
25	Medical Disposable Gloves Plastic Powder Free	5647	377	6024
26	Medical Gauze 36 * 100 Roll	2897	540	3437
27	Medical shoes / crocs	234	0	234
28	Oxygen Mask for Adult	6960	219	7179
29	Oxygen Mask for Infant	7257	433	7690

30	Penguin Newborn Suction	729	104	833
31	Povidone Iodine 5 Liter	747	195	942
32	Povidone Iodine 500ml	1517	41	1558
33	Pregnancy Rapid Test	43313	2955	46268
34	Safety Box	2224	158	2382
35	Scalpel Blade, Sterile no. 10	392	71	463
36	Scalpel blade, sterile no. 11	345	102	447
37	Scalpel blade, sterile no. 15	350	133	483
38	Scalpel blade, sterile no. 20	393	240	633
39	Silicone Foley Catheter CH14	6930	6848	13778
40	Silicone Foley Catheter CH16	6991	1668	8659
41	Spinal Needle 22G	2632	990	3622
42	Spinal Needle 23G	2703	330	3033
43	Spinal Needle 24G	4745	330	5075
44	Spinal Needle 25G	5082	330	5412
45	Spirit Solution 5 Liter	1368	175	1543
46	Steam Sterilization Indicator Tape	754	363	1117
47	Sterile Surgical Gloves 6.5	648	331	979
48	Sterile Surgical Gloves 7	969	377	1346
49	Sterile Surgical Gloves 7.5	782	305	1087
50	Suction CH06 Tube	7755	3385	11140
51	Suction CH08 Tube	9625	623	10248
52	Surgical Disposable Face Mask able to tie	2259	760	3019
53	Suture Prolene # 0 Cutting	691	37	728
54	Suture Prolene # 2/0 Cutting	1327	842	2169
55	Suture Prolene # 3/0 Cutting	466	45	511
56	Suture Vicryl # 0 Round	2545	87	2632
57	Suture Vicryl # 1 Round	2022	182	2204
58	Suture Vicryl # 2 Round	419	916	1335
59	Suture Vicryl # 2/0 Round	2424	186	2610
60	Syringe with needle 10cc	1955	261	2216
61	Syringe with needle 1cc	820	247	1067
62	Syringe with needle 3cc	3522	169	3691
63	Syringe with needle 5cc	8456	519	8975
64	Ultrasound gel 5 liter	1153	211	1364
65	Ultrasound Paper Roll	1886	234	2120

66	Umbilical Cord Clamp	40737	23100	63837
67	Urine bag with drain 2000ml	14927	3176	18103
68	Wound adhesive dressing 10cm*25cm	36590	9950	46540
69	Zinc Oxide Adhesive Plaster 2.5cm	20140	7227	27367

LOT 2 Medicines

No	Row Labels	UoM	Sana'a	Aden	Total
1	Adrenaline HCl 1:10000 (aqueous) 0.1mg/ml inj	Amp	7777	4472	12249
2	Aminophylline; injection 25 mg/ml	Amp	7599	223	7822
3	Ampicillin (powder) vial 1g	Vial	99269	2010	101279
4	Ampicillin (powder) vial 500mg	Vial	16500	0	16500
5	Anti- D Immunoglobulin 250mic.gr/5ml amp or 300mcg/1ml	Vial	1290	310	1600
6	Atropine Injection: 1 mg (sulfate) in 1-mL ampoule.	Amp	16593	800	17393
7	Calcium gluconate 100mg/ml inj	Amp	13470	1518	14988
8	Ceftriaxone pdr/inj 1g vial	Vial	128733	19388	148121
9	Ceftriaxone pdr/inj 250mg vial	Vial	47583	7623	55206
10	Chlorohyxidine Digluconate; 7.1% w/v gel	Each	407	371	778
11	Co-Amoxiclav 500mg+125mg tabs/PAC3x5	Tab.	308676	62700	371376
12	Dexamethasone 4mg/ml amp	Amp	38559	2120	40679
13	Dextrose 10%; solution	Bag	25975	7884	33859
14	Dopamine 40mg/ml , 80mg/ml or Dopamine hydrochloride injection 40mg/ml-200mg/5ml	Amp	13779	169	13948
15	Erythromycin eye ointment 0.5%	Tube	25817	157	25974
16	Ferrous sulphate 200mg+folicacid 0.4mg tab or 150 mg+0.5mg	Tab.	1187927	108405	1296332
17	Folic acid 5mg tab	Tab.	1176038	194700	1370738
18	Gentamycin sulfate; 40 mg/ml amp 2 ml	Amp	54567	891	55458
19	Heparin sodium s.c 25000IU/5ml inj	Amp	9364	590	9954
20	Hydralazine HCl, scored; 20 mg amp 1 ml	Amp	9805	342	10147

21	Hydrocortisone Powder 100 mg (as sodium succinate) in vial.	Vial	32489	1262	33751
22	Methyldopa 250mg tablet	Tab.	169092	12623	181715
23	Metronidazole; 500 mg/100ml inj	Bottle	96829	1592	98421
24	Sodium Bicarbonate; injection 8.3% or 8.4%-50 ml	Amp	2430	83	2513
25	Vancomycin 0.5 g inj	Amp	4008	726	4734
26	Vitamin K 10mg/ml inj	Amp	57104	31020	88124