



January 14, 2025

INVITATION TO BID
No. UNFPA/MNG/ITB/25/001

Amendment

Considering that the answers to the questions were provided later than originally anticipated, UNFPA would like to share the adjusted ITB timeline as follows.

Estimated ITB Timeline:

Date	CET Time Zone*	Solicitation stage
06/Jan/2025		Bid Release Date
10/Jan/2025	11:00	Deadline for submission of Questions and Queries
14/Jan/2025	16:00	Answers and clarifications shared by UNFPA
15/Jan/2025	15:00	Submission of completed Bid Confirmation Form
26/Jan/2025	23:00	Deadline for Bid Submission
27/Jan/2025	10:00	Bid Opening
28/Jan/2025		Preliminary Examination
31/Jan/2025		Commercial Evaluation
7/Jan/2025		Technical Evaluation
24/Feb/2025		Final Evaluation
10/Mar/2025		UNFPA Internal Review and Approval
14/Mar/2025		Contract Award

* Reference: <https://www.timeanddate.com/worldclock/denmark/copenhagen>

Questions & Answers

Nr.	Question by the Bidder	Answer by UNFPA
1.	This bid is open to primary manufacturers, authorized agents and authorized resellers. Can you please advise a wholesaler like xx is allowed to participate in bid - UNFPA/MNG/ITB/25/001 if we are able to share a MAF from the primary manufacturer?	Yes, this ITB is also open to wholesalers, and we highly encourage them to submit a bid.
2.	While attempting to express our interest in participating in this bid, we noticed that the button	Please submit a completed Bid Confirmation Form by January 15, 2025, to behrens@unfpa.org . Kindly note that bids submitted to this email will be

	<p>to proceed is currently disabled on the website. Could you kindly advise on the appropriate steps to submit our materials for this bid?</p>	<p>disqualified.</p> <p>Please follow the instructions provided in Section 16 of the ITB document for submitting your bid to the secure email box: bidtender@unfpa.org</p>
3.	<p>We would like to make sure whether to send the bid only to bidtender@unfpa.org email or send a hard copy? Or both?</p>	<p>Bids must be submitted electronically only. Please refer to Section 16 of the ITB Document, 'Electronic Submissions,' for detailed guidelines.</p>
4.	<p>On the technical specification:</p> <p>Light weight: < 5.0 kg</p> <p>Most of the manufacturer's portable ultrasound weights between 5-8 kgs. Since, there is only few manufacturers and it is giving them the advantages for them. For our device, the main required parameters are superior, but our participation is limited only by the weight parameter. Also, since the weight issue of 1-2kg does not affect the operation of the device, can the weight limit specified as <5kg be changed?</p>	<p>We can accept ± 1 kg. The lightweight is important as the equipment will be used in rural conditions and the provider, usually female, will need to carry the equipment along with other instruments.</p>
5.	<p>On the technical specification:</p> <p>Simultaneous display modes, at least: B/PW, B/CFM or PDI, B/M, Dual B (B/B), Dual B + CFM or PDI</p> <p>This parameter varies in terms of nomenclature and labeling depending on each manufacturer, but its function and operation are the same.</p> <p>For example:</p> <p>for B/PW Sonoscape manufacturer's is B + PW</p> <p>for B/M Sonoscape manufacturer's is B + M</p> <p>So, do we need to enter only your specified name or can we enter our own name?</p>	<p>It is acceptable as long as the function is present.</p> <p>The labeling can be done in either format.</p>
6.	<p>Do we need to send the tender materials from our official website xxxx? Or can we send them from the email of the employee who is preparing the tender documents?</p>	<p>There is no specific requirement for the sender's email address, provided that the signed bids are submitted by official employees of the Bidder to UNFPA's secure email inbox: bidtender@unfpa.org.</p>

7.	<p>Must the goods be delivered to the UNFPA warehouse in UB or would it be acceptable to change this point of delivery?</p>	<p>We understand that the question relates to the conditions of the DAP Price. As specified in Section 11 “Bid Currency and Prices” of the ITB, the goods must be delivered to the Local representative’s or Supplier’s warehouse in Ulaanbaatar, as specified in Section 11 “Bid Currency and Prices” of the ITB. Changing the point of delivery is <u>not</u> acceptable for this ITB.</p>
8.	<p>The tender specifies DAP Incoterms. However, the following bullet points include requirements that fall outside the scope of DAP Incoterms. According to the ICC definition, DAP does not include customs clearance, payment of import duty, or unloading of goods at the warehouse. Could you kindly confirm the Incoterms?</p> <p>11.3. Bidders are requested to quote the following based on INCOTERMS 2020:</p> <ol style="list-style-type: none"> Price of goods FCA Point of Departure <u>and</u> Price of goods <u>DAP</u> to Local representative/Supplier’s warehouse in Ulaanbaatar. The supplier is responsible for: <ol style="list-style-type: none"> The supplier is responsible for arranging import customs clearance. The supplier is responsible for unloading and offloading the goods in the Ulaanbaatar warehouse. The supplier shall also provide local transportation service as per the schedule of service to transport items from Ulaanbaatar to 22 family health centers in rural areas, including repacking, loading and off-loading the goods into the specified rooms. Insurance costs should be <u>excluded</u> when completing the Price Schedule Form. <p>https://iccwbo.org/business-solutions/incoterms-rules/incoterms-2020/#block-accordion-6</p>	<p>You are correct that under the ICC definition, DAP Incoterms do not include customs clearance, payment of import duties, or unloading of goods at the warehouse. However, the tender specifies DAP Incoterms with additional requirements to align with the specific needs of this procurement.</p> <p>To clarify, while the Incoterm remains DAP, the mentioned responsibilities outside the typical DAP scope are indeed part of the supplier's obligations for this tender. Kindly ensure these are accounted for in your bid submission.</p>
9.	<p>A. Regulatory approvals required:</p> <p>Valid Mongolian official Import license from the main manufacturer for receiving, installing, and maintaining medical equipment in Mongolia.</p> <p>Could you clarify it more? What is the official Import license from the manufacturer? Is it okay to provide the authorization letter stating we have the right to import and offer for tender the manufacturer’s product?</p>	<p>A. As per the ITB Document, to ensure that the supplier has the right to comply with the regulatory national requirements, the bidder should submit the following documents together with their bids:</p> <ul style="list-style-type: none"> The special permit issued by the Ministry of Health of Mongolia authorizing the company to import, supply, and sell medical equipment in Mongolia. Manufacturer’s authorization letter to sell their product for this tender in Mongolia.

<p>B. And at least one of the following regulatory approvals and certificates ◦ European Certificate of Conformity (CE) with Regu 2017/745 or Directive 93/42 EC and Agreement Letter si with the NB demonstrating the on-going MDR application, Class IIb devices, or ◦ FDA (Food and Drug Administration) of the USA that cer marketing permission in the United States, ◦ Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan. Safety & product Standards: Bidder shall furnish the following documents: ● Valid ISO 13485 certific ● Signed and dated Declaration of Conformity (DoC) according to I 17050 to demonstrate that, the good offered, meet at least the foll international safety & regulatory standard ◦ IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performan ◦ IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance Collateral Standard: Electromagnetic disturbances - Requirements and tests ◦ IEC 60601-2-37 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essen performance of ultrasonic medical diagnostic and monitoring equipment.</p> <p>Our item only has the ISO13485 /don't have CE and FDA, DoC/. Is it still okay to compete with tender?</p> <p>C. In the Price Schedule Form, we must fill FCA price? We are not manufacturer, but trader. Can we only fill DAP price? If need to fill FCA price, can we put out the price until Ulaanbaatar?</p> <p>D. Bidder's delivery data: What is the FCA points?</p> <p>E. We must provide QMS?</p>	<p>B. As to the product's eligibility, among the requirements outlined in Section 10.3 of the ITB document, the quoted Section 10.3.f shall be interpreted as follows:</p> <p>"Copies of the following current certificates must be provided for each declared product:</p> <ul style="list-style-type: none"> ● GMP/Quality certification. ● FSC/CPPI certification. ● A valid manufacturer's ISO certificate. ● Proof of compliance with either the EU Council Directive 93/42/EEC (MDD) <u>or</u> EU Regulations 2017/745 (MDR), including a valid EC Certificate based on the device's risk classification. ● USFDA 510(k) registration authorization, Japan QS standard certification, <u>or</u> other market authorizations issued by a Stringent Regulatory Authority (SRA) that is a member of the IMDRF, such as Australia or Canada. ● Proof of compliance with other relevant applicable safety, electrical, and performance standards, supported by test reports." <p>Items with ISO 13485 but without CE mark or FDA approval are accepted. Bidders should provide any other regulatory approval which may be available.</p> <p>C. In the Price Schedule Form, the bidder must provide both the FCA and DAP prices. Traders are still required to quote the FCA price, which specifies that the seller/bidder is responsible for delivering the goods, cleared for export, to a carrier or another party nominated by the buyer/UNFPA at a specified location.</p> <p>D. Please refer to the answer to question 14 of this document and the official guidance to Incoterms 2020: link.</p> <p>E. Evidence of a functional QMS system such as ISO 9001 and/or ISO 13485 certification or an</p>
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		equivalent certification should be provided.
10.	<p>While reviewing the Performance Statement Form requirements, we would like to confirm if it is mandatory to provide experience specifically from previously awarded tenders, or if contracts based on supply agreements can also be considered.</p>	<p>Yes, contracts based on supply agreements can also be considered for the Performance Statement Form requirements. It is not mandatory to provide experience exclusively from previously awarded tenders.</p> <p>Please ensure that the submitted information clearly demonstrates your relevant experience and aligns with the requirements outlined in the tender documents.</p>
11.	<p>Is it necessary to include all clients from the past five years, or is it acceptable to list only key representative clients?</p> <p>If representative clients are acceptable, how many would be considered suitable to meet the requirements?</p>	<p>As this is an ITB, there will be no scoring of each evaluation criterion of the technical proposal; however, an evaluation of technical compliance and overall experience will be conducted. While it is not necessary to include all clients from the past five years, it is important to provide enough information to demonstrate your relevant experience. Listing key representative clients is acceptable, provided they sufficiently illustrate your capacity and alignment with the requirements outlined in the ITB.</p> <p>If you choose to list representative clients, we recommend including at least 3 to 5 clients with relevant project details to support your submission.</p>
12.	<p>If our company does not have a joint venture, is it acceptable to leave this form blank?</p> <p>Would leaving this form blank have any impact on the evaluation process or tender eligibility?</p>	<p>If your company does not have a joint venture, it is acceptable to leave this form blank. Leaving the form blank will not have any negative impact on the evaluation process or your tender eligibility, provided all other required documents and forms are properly completed and submitted as per the tender requirements.</p>

13.	<p>Is it correct to include the transportation cost to the local destination and the cost of handing over the goods to the client at their specified location in the DAP price? Or is it price to our warehouse in Ulaanbaatar city?</p>	<p>As the ITB is based on two Incoterms including the DAP Incoterms, the DAP price should include the transportation cost to the local destination and the cost of handing over the goods to the client at their specified location. It is not limited to the price at the warehouse in Ulaanbaatar city.</p> <p>Please ensure all associated costs for delivery to the specified destination are factored into your DAP pricing.</p> <p>Kindly note that both FCA and DAP prices are required under this ITB.</p>
14.	<p>FCA price- Point of departure /Our Ultrasound manufactured in Point A.</p> <p>So should write the price from Point A or FCA to Point B (a Mongolian city at the border)? Please provide us with more detailed clarification.</p>	<p>When your company is quoting an FCA price, it should reflect the price of the goods, including delivery to the designated departure point where the goods will be handed over to the carrier. In your case, since the Ultrasound equipment is manufactured in Point A, the FCA price should typically be quoted from Point A (e.g., your factory or warehouse). Hence, the FCA point should be a point where the manufacturer hands over the goods to the freight forwarder selected by the buyer/UNFPA.</p> <p>Kindly note that both FCA and DAP prices are required under this ITB.</p>
15.	<p>QUOTE: "Post qualification documentaon outlined in Instrucons to Bidders, Secon 32." UNQUOTE</p> <p>However, Section 32 refers to: QUOTE: "UNFPA's Right to Accept Any Bid and to Reject Any or All Bids [...]" UNQUOTE</p> <p>Please clarify which documents we have to submit at this stage (before post-qualification).</p>	<p>For the post-qualification instructions please refer to Section 31 "Post-qualification of the Bidder".</p>

