



November 07, 2024

**LIMITED INVITATION TO BID**  
**No. UNFPA/MNG/LIB/24/020**

**MANUFACTURE AND/OR SUPPLY OF MEDICAL PRODUCTS AND RELATED SERVICES**  
**INTRODUCTORY LETTER**

Dear Sir/Madam,

1. UNFPA invites sealed bids for the supply of below medical products and related services for its programme in Mongolia. This Limited International Bidding (LIB) is divided into two lots:
  - **LOT 1:** UNFPA previously issued an Invitation to Bid, UNFPA/DNK/ITB/24/014 for the procurement of essential items, which was published on UNGM. Despite a broad outreach, some items did not receive a sufficient number of qualified proposals to meet our requirements. Therefore, UNFPA is now conducting a Limited International Bidding (LIB) process for these items to ensure competitive sourcing and adequate supplier participation.
  - **LOT 2:** Additional items are added to this LIB based on the urgency to meet the country demand to deliver the items to the rural family health centres of Mongolia.

We invite qualified suppliers to submit their proposals in response to this LIB to support UNFPA in fulfilling its mandate.

2. UNFPA invites sealed bids for the supply of the following items for its programme in Mongolia:

Item No (or internal number)	Item short description	Qty
<b>LOT 1</b>		
Item 1 (OR 1).	Activated Clotting Time (ACT) Measuring device	2
Item 3 (OR 3).	Extra Corporeal Circulation (ECC) Machine	1
Item 4 (OR 4).	Hypo-hyperthermia Machine	1
Item 5 (OR 33).	Patient Auto-Transfusion System	1
Item 12 (OR 19).	Brain Monitoring System	1
Item 22 (OR 32).	Portable external pacemaker	3

Item 23 (OR 34).	Patient drainage system	1
Item 25 (OR 38).	Surgeon's headlamp	1
Item 26 (ICU 3).	Dialysis Equipment for Neonate - Peritoneal dialysis system	1
<b>LOT 2</b>		
Item A	Cardiotocograph (CTG)	22
Item B	Portable ultrasound scanner	22

3. Bidding shall be conducted through ONE envelope. The technical bid containing the technical specifications and the financial bid containing price information shall be submitted together.
4. Instructions on partial bids: For both LOT 1 and LOT2, the Bidder shall **not be** required to quote for all items. However, Bidders are encouraged to quote for as many items as possible.
5. To enable you to submit a bid, please read the following attached documents carefully:
 

Section I:	Instructions to Bidders
Section II:	Technical Specifications and Schedule of Requirements
Section III:	UNFPA General Conditions of Contract
Section IV:	UNFPA Special Conditions for Contracts
Section V:	Bidding Forms
Section VI:	Contract Forms
6. The bid shall reach UNFPA's email inbox of [bidtender@unfpa.org](mailto:bidtender@unfpa.org) no later than November 28, 2024, at 23:00 CET Time<sup>1</sup>.
7. The bid shall be opened on November 29, 2024, at 10:00 CET Time<sup>2</sup>. Bidders or their authorized representatives may attend the bid opening. Kindly confirm by email by November 14, 2024, whether your company shall be represented at the bid opening.
8. Bids received after the stipulated date and time shall not be accepted under any circumstances. Bids delivered through courier and posted later than the due date shall not be registered and shall be returned unopened or shall be shredded. Bids submitted to any other email address than [bidtender@unfpa.org](mailto:bidtender@unfpa.org) shall be rejected.
9. Bidders shall acknowledge receipt of this LIB according to the Bid Confirmation Form, Section V, 1 of this solicitation document by email to Natalia Giortz-Behrens, email:

<sup>1</sup> Reference: [www.timeanddate.com/worldclock](http://www.timeanddate.com/worldclock)

<sup>2</sup> Reference: [www.timeanddate.com/worldclock](http://www.timeanddate.com/worldclock)

[behrens@unfpa.org](mailto:behrens@unfpa.org) no later than November 14, 2024 and to indicate whether or not a bid shall be submitted. If you are declining to bid please state the reasons for UNFPA to improve its effectiveness in future invitations.

10. Any questions relating to the attached documents shall be addressed in writing to the following UNFPA personnel:

- Tsetsenbaatar Batsuuri, email: [batsuuri@unfpa.org](mailto:batsuuri@unfpa.org)
- Natalia Giortz-Behrens, email: [behrens@unfpa.org](mailto:behrens@unfpa.org)

Do **not** submit your bid to these contacts, or your bid will be **disqualified**.

11. This letter is not to be construed in any way as an offer to contract with your firm.

12. UNFPA strongly encourages all Bidders to register on the United Nations Global Marketplace (<http://www.ungm.org>). The UNGM is the procurement portal of the United Nations system. By registering on UNGM, vendors become part of the database that UN buyers use when searching for suppliers. Vendors can also access all UN tenders online and, by subscribing to the Bid Tender Service, vendors can be automatically notified via email of all UN business opportunities that match the products and services for which they have registered. Instructions on how to subscribe to the Tender Alert Service can be found in the UNGM Interactive Guide for Suppliers.

[http://www.ungm.org/Publications/UserManuals/Suppliers/UserManual\\_Supplier.pdf](http://www.ungm.org/Publications/UserManuals/Suppliers/UserManual_Supplier.pdf) .

13. Estimated LIB Timeline:

Date	CET Time Zone*	Solicitation stage
07/11/2024	15:00	Bid Release Date
14/11/2024	15:00	Deadline for submission of Questions and Queries
11/11/2024	15:00	Answers and clarifications shared by UNFPA
14/11/2024	15:00	Submission of completed Bid Confirmation Form
<b>28/11/2024</b>	<b>23:00</b>	<b>Deadline for Bid Submission</b>
29/11/2024	10:00	Bid Opening
29/11/2024	10:00	Preliminary Examination
03/12/2024	10:00	Commercial Evaluation
06/12/2024	10:00	Technical Evaluation
20/12/2024	10:00	Final Evaluation
07/01/2025	10:00	UNFPA Internal Review and Approval
14/01/2025	10:00	Contract Award

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

Yours sincerely,

**Natalia Giortz-Behrens**  
**UNFPA**



## **UNITED NATIONS POPULATION FUND**

### **LIMITED INVITATION TO BID**

**NO.: UNFPA/MNG/LIB/24/020**

**Bid document for the manufacture and/or supply of products and related services**

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## SECTION I: Instructions to Bidders

### A. Introduction

#### 1. Scope

- 1.1.** The goods and related services to be procured for UNFPA's Programme located in Mongolia are divided into two different lots and as follows:

Item No (or internal number)	Item short description	Qty
<b>LOT 1</b>		
Item 1 (OR 1).	Activated Clotting Time (ACT) Measuring device	2
Item 3 (OR 3).	Extra Corporeal Circulation (ECC) Machine	1
Item 4 (OR 4).	Hypo-hyperthermia Machine	1
Item 5 (OR 33).	Patient Auto-Transfusion System	1
Item 12 (OR 19).	Brain Monitoring System	1
Item 22 (OR 32).	Portable external pacemaker	3
Item 23 (OR 34).	Patient drainage system	1
Item 25 (OR 38).	Surgeon's headlamp	1
Item 26 (ICU 3).	Dialysis Equipment for Neonate - Peritoneal dialysis system	1
<b>LOT 2</b>		
Item A	Cardiotocograph (CTG)	22
Item B	Portable ultrasound scanner	22

#### 2. Eligible Bidders

- 2.1 This bid is open to International Suppliers of Medical Devices and Equipment holding a valid LTA/BPA with UNFPA SCMU.

#### 3 Eligible Goods and Related Services

- 3.1. All the goods and related services to be supplied under the contract may have their origin in any country.
- 3.2. For purposes of this Clause, the term "origin" means the country where the goods have been produced, manufactured or processed; or, through manufacture, processing, or assembly,

another commercially recognized article results that differs substantially in its basic characteristics from its components.

#### **4 Cost of Bid**

- 4.1. The Bidder shall bear all costs associated with the preparation and submission of the bid, and the procuring UN entity shall in no case be responsible or liable for those costs, regardless of the conduct or outcome of the bid.

#### **5 Fraud and Corruption**

- 5.1. UNFPA's policy regarding fraud and corruption is available at <http://www.unfpa.org/about-procurement#FraudCorruption> and applies fully to this Invitation to Bid. The submission of any offer implies that the Bidder is aware of this policy.

### **B. Solicitation Documents**

#### **6 UNFPA Solicitation document**

- 6.1. Bidders are expected to examine all instructions, forms, specifications, terms and conditions contained within this UNFPA solicitation document. Failure to comply with these documents shall be at the Bidder's risk and may affect the evaluation of the bids, or may result in the rejection of the bid.
- 6.2. Bidding documents consist of the following:
- |              |   |
|--------------|---|
| Section I:   | Instructions to Bidders                               |
| Section II:  | Technical Specifications and Schedule of Requirements |
| Section III: | UNFPA General Conditions of Contract                  |
| Section IV:  | UNFPA Special Conditions for Contracts                |
| Section V:   | Bid Forms   |
| Section VI:  | Contract Forms  |
- 6.3. Bidders are cautioned to read the specifications carefully (see Section II Technical Specifications and Schedule of Requirements), as there may be special requirements. The technical specifications presented herein are not to be construed as defining a particular manufacturer's product. Bidders are encouraged to advise UNFPA if they disagree.
- 6.4. The specifications are the minimum requirements for the products and related services. Products and services offered must meet or exceed all requirements herein. The products shall conform in strength, quality and workmanship to the accepted standards of the relevant industry. Modifications of or additions to basic standard products of less size or capability to meet these requirements will not be acceptable.



## **7 Clarifications of solicitation document**

- 7.1. A prospective Bidder requiring any clarification on the bid solicitation documents may notify UNFPA in writing no later than November 14, 2024, at 15:00 CET Time<sup>3</sup> as per Section 10 above. UNFPA shall respond in writing to any request for clarification received and circulate its response (including an explanation of the query but without identifying the source of enquiry) to all prospective Bidders who have received the bid solicitation documents. A copy of UNFPA's answer shall also be posted on the UN Global Marketplace, <http://www.ungm.org/>.

## **8 Amendments to UNFPA bid solicitation document**

- 8.1. At any time prior to the deadline for submission of bids, UNFPA may for any reason, whether at its own initiative or in response to a clarification requested by a prospective Bidder, modify the bidding documents by amendment.
- 8.2. All prospective Bidders that have received the bidding documents shall be notified in writing of all the amendments to the bidding documents. In order to give prospective Bidders reasonable time to take the amendments into account in preparing their bids UNFPA may, at its discretion, extend the deadline for the submission of bids.

### **C. Preparation of Bids**

## **9 Language of the bid**

- 9.1. The bid prepared by the Bidder and all correspondence and documents relating to the bid shall be written in English.

## **10 Documents to be submitted with the bid**

### **10.1. Documents Establishing the Eligibility of the Bidder**

- 10.1. To establish their eligibility, Bidders shall complete the following forms:
- 1) Bid Submission Form, Section V, 2.
  - 2) Joint Venture Partner Information Form, Section V, 7 and provide all documents as required in the Form in the event that the bid is submitted by a Joint Venture.

### **10.2. Documents Establishing the Qualifications of the Bidder**

To establish its qualifications, the Bidder shall submit to UNFPA's satisfaction the following documents:

- a. Copy of valid manufacturing license from the country of manufacturing and/or a copy of company registration in the country of operation demonstrating that is duly authorized to supply these goods to the country of destination.
- b. In the case of a Bidder not doing business within the country of destination, the Bidder is or will be represented by an Agent in the country that is equipped and able to carry out the supplier's maintenance, training, repair and spare parts-stocking obligations prescribed in the Section II, Technical Specifications and Schedule of Requirements.

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<sup>3</sup> Reference: [www.timeanddate.com/worldclock](http://www.timeanddate.com/worldclock)

Failure to furnish all the information required for submission shall be at the Bidder's risk as it may then be determined that the bid does not substantially respond to the UNFPA bid document in every respect. This may result in a rejection of the bid.

### **10.3. Documents Establishing the Eligibility and Conformity of the Goods and Related Services**

Bidders shall submit:

- a. Documentary evidence that the goods conform to the Technical Specifications and standards specified in Section II Technical Specifications and Schedule of Requirements.
- b. Completed Product Item Overview Form, Section V, 5.
- c. Product catalogues containing pictures of the product(s).
- d. Manufacturer's technical product specifications or datasheets.
- e. Results of any testing carried out on the products.
- f. Copies of current certificates such as:
  - GMP/quality,
  - FSC/CPP,
  - valid manufacturer's ISO certificate per declared product,
  - proof of compliance with EU Council Directive 93/42/EEC (MDD) or EU Regulations 2017/745 (MDR) with valid EC Certificate, based on the risk of the devices,
  - USFDA 510k registration authorization,
  - Japan QS standard, or other market authorization issued by a Stringent Regulatory Authority member of the IMDRF (Australia or Canada),
  - proof of compliance with other relevant applicable safety, electrical and performance standards (test reports), as stated in the Technical Specifications and Schedule of Requirements Section II
- g. The Bidder shall also furnish a list giving full particulars, including available sources and current prices of spare parts, special tools, etc., necessary for the proper and continuing functioning of the goods during **5 years** following commencement of the use of the goods by UNFPA. Bidders must complete and submit with their bid the Excel table containing the individual item details, as per Form in Section V.5. Bidding Forms.
- h. Manufacturer's warranty letter indicating the time of the warranty duration.
- i. A copy of the user, service, spare parts manual and installation (when applicable), if not provided with the submission of the documents, a commitment letter to deliver such documents, is applicable.
- j. Training program with the details of the activities and duration of the training, relevant topics. The training must be delivered to users and the technical service team
- k. Items requiring pre-installation (such as the operating light): the workshop layout for the installation of the light must be provided, and a commitment letter to ensure at least one field visit prior to the installation of the light will be performed by the potential bidder, to assure and confirm that operating theater fulfill all the requirements for the proper installation of the device: e.g: verification of ceiling support, sufficient space for the light arm's motions, connection to the electrical and safety protection system (emergency system support).

## **11 Bid Currency and Prices**

### **11.1. All prices shall be quoted in US Dollars (USD).**

**11.2.** The Bidder shall indicate the unit prices (where applicable) and total bid price of the goods or services it proposes to supply under the contract. This price information shall be indicated on the Price Schedule Form, Section V, 6.

**11.3.** Bidders are requested to provide price proposals as follows, based on INCOTERMS 2020:

**LOT 1**

- Price of goods FCA Point of Departure and
- DAP to National Center for Maternal and Child Healthcare (NCMCH), “Huvisgalchdiin” street, Bayangol district, Ulaanbaatar 16060, Mongolia. Please note:
  - a. The supplier is responsible for arranging import customs clearance.
  - b. The supplier is responsible for unloading and off-loading the goods into the specified rooms.
  - c. Insurance costs should be excluded when completing the Price Schedule Form.

**LOT 2**

- Price of goods FCA Point of Departure and
- DAP to Local representative/Supplier’s warehouse in Ulaanbaatar. The supplier is responsible for:
  - a. The supplier is responsible for arranging import customs clearance.
  - b. The supplier is responsible for unloading and offloading the goods in the Ulaanbaatar warehouse.
  - c. 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.
  - d. Insurance costs should be excluded when completing the Price Schedule Form.

**11.4.** The terms FCA, DAP and other similar terms shall be governed by the rules prescribed in the INCOTERMS 2020, published by the International Chamber of Commerce.

**11.5.** Where installation, commissioning, training or other similar services are required to be performed by the Bidder, the Bidder shall include an itemized list of the prices for the requested.

**12 Validity of Bid**

**12.1.** 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 on the grounds that it is non-responsive.

**12.2.** In exceptional circumstances, UNFPA may solicit the Bidder's consent for an extension of the period of validity under exceptional circumstances. The request and the responses shall be made in writing.

## **D. Submission of Bids and Bid Opening**

### **13 Partial Bids**

- 13.1. **For both LOT 1 and LOT 2:** Partial bids are **allowed**. Bidders can quote for all or some medical devices, however bidders must quote for full quantities per each item requested. UNFPA reserves the right to select and accept a part or parts of any bid. Bidders that will submit Bids for the majority of items may get priority at the bid evaluation and the contract awards stages.

### **14 Alternative Bids**

- 14.1. Alternative bids will not be accepted. In the event of a supplier submitting more than one bid, the following shall apply:
- a. All bids marked alternative bids will be rejected and only the base bid will be evaluated.
  - b. All bids will be rejected if no indication is provided as to which bids are alternative bids.

### **15 Bids**

- 15.1. Bids shall be submitted in one envelope or transmitted in an email to a secure email address designated by UNFPA.
- 15.2. The technical portion of the bid shall be prepared in accordance with Section II: Schedule of Requirements and Technical Specifications and shall include the requested documentation as per Instructions to Bidders Clause 10.
- 15.3. The financial portion of the bid shall be prepared in accordance with the Price Schedule Form in Section V, 6 of the bid forms.
- 15.4. Bids shall be signed by the Bidder or a person or persons duly authorized to bind the Bidder to the contract. A bid shall contain no interlineations, erasures, or overwriting except as necessary to correct errors made by the Bidder. In that case such corrections shall be initialled by the person or persons signing the bid.

### **16 Electronic Submissions**

Bids shall be submitted electronically and as follows:

- 16.1. Bidders shall make clear reference to the specific bid in the subject field as instructed, otherwise bids may be rejected. Clearly specify the following text in the subject line:  
**UNFPA/MNG/LIB/24/020, Bidder's Name.**
- 16.2. The bid shall be submitted to **bidtender@unfpa.org**. Bids received at the **bidtender@unfpa.org** mailbox are kept undisclosed and shall not be opened before the scheduled opening date. Sending to any other email address will violate confidentiality and invalidate the bid.
- 16.3. Email submission shall not exceed 10MB, including the size of the cover email and attachment. It is recommended that all the bidding documents are consolidated into as few attachments as possible which shall be in commonly used file formats. If the bid consists of large electronic files, it is recommended to send these files separately before the deadline

indicating the order of emails (email 1, email 2, etc.) after the bid reference number and the Bidder's name in the subject line of each email.

It shall be the Bidder's responsibility to ensure that bids sent by email are received by the deadline. All Bidders shall receive an auto-reply acknowledging the receipt of their email. Bidders will receive an auto-reply acknowledging receipt of the first email. In the body of this first email, bidders are requested to list the number of messages which make up their technical offer and the number of messages which make up their financial offer. If you do not receive any auto-reply from UNFPA's email system, please inform TNatalia Giortz-Behrens, email: [behrens@unfpa.org](mailto:behrens@unfpa.org).

Submission documents should be converted to PDF, submissions containing links to the files which need to be downloaded will not be considered. Bidders shall not receive responses to questions sent to [bidtender@unfpa.org](mailto:bidtender@unfpa.org) since it is a secure mailbox.

- 16.4. In order to avoid last minute internet congestion it is recommended to send your bid as early as possible before the deadline.
- 16.5. Please do not add any passwords to the submitted documents, as this will prevent UNFPA from opening them.

## **17 Bid Submission Deadline/Late Bids**

- 17.1. Bid Submission Deadline is November 28, 2024, at 10:00 CET Time<sup>4</sup>.
- 17.2. Bids must be submitted on or before the date and time specified in the introductory letter of this solicitation document. If any doubt exists as to the time zone in which the bid should be submitted please refer to [www.timeanddate.com/worldclock](http://www.timeanddate.com/worldclock), or contact the bid focal point.
- 17.3. UNFPA may, under special and exceptional circumstances, extend the bid submission deadline and such changes shall be notified in UNGM before the expiration of the original period.
- 17.4. Any bid received by UNFPA after the bid submission deadline shall be rejected. UNFPA shall not be legally responsible for bids that arrived late due to the Bidder's problems with transmission of bid submissions via email and/or with the courier company.

## **18 Withdrawal, Substitution and Modification of Bids**

- 18.1. A Bidder may withdraw, substitute, or modify its bid after it has been submitted by sending a written notice prior to the bid submission deadline. The modification shall be submitted in a sealed envelope or to the dedicated secured email.
- 18.2. The Bidder may withdraw its bid after submission, provided that written notice of the withdrawal is received by UNFPA prior to the bid submission deadline requested to be withdrawn shall be shredded or shall be returned unopened to the Bidder.

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<sup>4</sup> Reference: [www.timeanddate.com/worldclock](http://www.timeanddate.com/worldclock)

- 18.3. No bid may be withdrawn, substituted, or modified in the interval between the deadline for submission of bids and the expiration of the period of bid validity specified by the Bidder on the Bid Submission Form or any extension thereof.

## **19 Storage of Bids**

- 19.1. Bids received prior to the deadline of submission and the time of opening shall be securely kept unopened until the specified bid opening date stated in the UNFPA's solicitation document. No responsibility shall be attached to UNFPA for prematurely opening an improperly addressed and/or identified bid.

## **20 Bid Opening**

- 20.1. UNFPA shall conduct the bid opening in public via online Teleconferencing on November 29, 2024, at 10:00 CET Time<sup>5</sup>.
- 20.2. Bids received electronically by the required deadline will be printed and a copy of the bids will be put in a sealed envelope that will be opened at the time and date specified in the bid document. Only the last received bid will be opened if multiple bids are sent by a same Bidder.
- 20.3. UNFPA shall open all bids in the presence of at least two witnesses from UNFPA or another UN agency. The bids shall be opened publicly at the time and place specified in the LIB and an immediate record made thereof.
- 20.4. Only those who have submitted bids may attend the bid opening. However, the Bidders may authorize a local agent, embassy or trade commission (also referred to as observers) to represent them. In order to be able to attend bid opening, agents representing Bidders must provide reasonable evidence (business cards, letter of authorization, etc.) confirming the name of the Bidder they represent.
- 20.5. The report shall be available for viewing by Bidders for a period of thirty days from the date of the opening. No information that is not included in the bid opening report can be given to Bidders.
- 20.6. No bid shall be rejected at bid opening, except for late bids. Bids that are not opened and read out at the bid opening shall not be considered further for evaluation, irrespective of the circumstances. Withdrawn bids will be shredded except for any bank securities, which will be returned to the Bidder.

### **E. Evaluation and Comparison of Bids**

## **21 Confidentiality**

- 21.1. Information relating to the examination, evaluation, comparison, and recommendation of contract award shall not be disclosed to Bidders or any other persons not officially concerned with such process until the contract award is published.

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<sup>5</sup> Reference: [www.timeanddate.com/worldclock](http://www.timeanddate.com/worldclock)

- 21.2. Any effort by a Bidder to influence UNFPA in the examination, evaluation, and comparison of the bids or contract award decisions may result in the rejection of its bid.
- 21.3. Notwithstanding from the time of bid opening to the time of contract award, if any Bidder wishes to contact UNFPA on any matter related to the bidding process, it should do so in writing.

## **22 Clarification of Bids**

- 22.1. To assist in the examination, evaluation and comparison of bids, UNFPA may ask Bidders for clarification of their bids. The request for clarification and the response shall be in writing by UNFPA and no change in price or substance of the bid shall be sought, offered or permitted.

## **23 Responsiveness of bids**

- 23.1. UNFPA's determination of a bid's responsiveness is to be based on the contents of the bid itself.
- 23.2. 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.
- 23.3. UNFPA considers material deviation to include, but to not to be limited to the following situations:
- a. During preliminary examination of bids (verification of formal criteria):
    - Absence of bid form(s), change in the wording or lack of signature on key portions of the bid form when this is clearly specified in the tender document as a requirement. Any change in wording that is consistent with the standard format of the bid form(s) is not a material deviation;
    - The Bidder indicates in the bid that they do not accept important contract conditions, i.e. related to Warranty, Force Majeure Applicable Law, Delivery Schedule, Payment Terms, General Conditions and Limitation of Liability;
    - Non historical documents required in the solicitation document have not been provided, such as documents specifically related to the bidding process and that the Bidder could not be expected to possess before the solicitation document was issued;
  - b. During technical evaluation of bids and qualification of Bidders:
    - Specifications of the item quoted vary in one or more significant respect(s) from the minimum required technical specifications.
    - The Bidder does not meet the minimum conditions for qualification.
  - c. During financial evaluation of bids:

- The Bidder does not accept the required price correction as Instructions to Bidders Clause 24.1, c.
  - Required price components are missing.
  - The Bidder offers less quantity than what is required.
- 23.4. If a bid is not substantially responsive to the bidding documents, it shall be rejected by UNFPA and may not subsequently be made responsive by the Bidder by correction of the material deviation, reservation, or omission.

## **24 Nonconformities, Errors, and Omissions**

- 24.1. Provided that a bid is substantially responsive:
- a. UNFPA may waive any non-conformities or omissions in the bid that do not constitute a material deviation.
  - b. UNFPA may request that the Bidder submit the necessary information or documentation within a reasonable period of time to rectify nonmaterial nonconformities or omissions in the bid related to documentation requirements. Such omission shall not be related to any aspect of the price of the bid. Failure of the Bidder to comply with the request may result in the rejection of its bid.
  - c. UNFPA shall correct arithmetical errors on the following basis:
    - If there is a discrepancy between the unit price and the line item total that is obtained by multiplying the unit price by the quantity, the unit price shall prevail and the line item total shall be corrected, unless in the opinion of UNFPA there is an obvious misplacement of the decimal point in the unit price. In that case the line item total as quoted shall govern and the unit price shall be corrected;
    - if there is a discrepancy between words and figures, the amount in words shall prevail;
    - if there is an error in a total corresponding to the addition or subtraction of subtotals, the subtotals shall prevail, and the total shall be corrected.
- 24.2. If the Bidder that submitted the lowest evaluated bid does not accept the correction of errors, its bid shall be rejected.

## **25 Preliminary examination of Bids**

- 25.1. UNFPA shall examine the bids to determine whether they are complete, that all documents and technical documentation requested as per Instructions to Bidders Clause 10 have been provided and to determine the completeness of each document submitted. UNFPA will also examine whether any computational errors have been made, whether the documents are properly signed, and whether the bids are generally in order.

## **26 Examination of Terms and Conditions and Technical Evaluation**

- 26.1. UNFPA shall examine the bid to confirm that it does not contain any material deviations, reservation, or omission related to the conditions and requirements specified in the Section II Technical Specifications and Schedule of Requirements, Section III UNFPA General Conditions of Contract and Section IV UNFPA Special Conditions for Contracts.
- 26.2. If after the examination of the terms and conditions and the technical evaluation UNFPA determines that the bid is not substantially responsive in accordance with Instructions to Bidders Clause 23 "Responsiveness of bids", the bid shall be rejected.



## **27 Conversion to Single Currency**

- 27.1. To facilitate evaluation and comparison, UNFPA will convert all bid prices expressed in the amounts in various currencies in which the bid prices are payable to US dollars at the official UN exchange rate on the last day for submission of bids.

## **28 Domestic Preference**

- 28.1. Domestic preference shall not be a factor in bid evaluation.

## **29 Evaluation of Bids**

- 29.1. UNFPA shall evaluate each bid that has been determined, up to this stage of the evaluation, to be substantially responsive.
- 29.2. UNFPA's evaluation of a bid will exclude and not take into account:
- a. Customs duties and other import taxes, sales and other similar taxes, which will be payable on the goods if the contract is awarded to the Bidder;
  - b. Any allowance for price adjustment during the period of execution of the contract, if provided in the bid.

## **30 Comparison of Price Bids**

- 30.1. UNFPA shall compare all substantially responsive bids to determine the lowest-priced substantially responsive bid and considering the proposed delivery time.
- 30.2. Bid comparison will be made on the total cost, delivered to final destination. UNFPA reserves the right to compare freight prices of Bidders with rates of reputable freight forwarders and to consider such rates for the purpose of bid evaluation. In the event that Bidder's freight prices are found to be less competitive than the rates offered by freight forwarders, UNFPA may issue a contract on FCA basis to the Supplier instead of DAP, depending on the LOT, and issue a separate contract for freight to a freight forwarder if deemed in the best financial interest of UNFPA.

## **31 UNFPA's Right to Accept Any Bid and to Reject Any or All Bids**

- 31.1. A bid that is rejected by UNFPA may not be made responsive by the Bidder by correction of the non-conformity. A responsive bid is defined as one which conforms to all the terms and conditions of the UNFPA's bid solicitation documents without material deviations. UNFPA shall determine the responsiveness of each bid against the UNFPA solicitation documents.
- 31.2. UNFPA reserves the right to reject any bid if a Bidder has previously failed to perform properly or complete on time in accordance with contracts or the Bidder who in UNFPA's perspective is not in a position to perform the contract.
- 31.3. The Bidders waive all rights to appeal against the decision made by UNFPA.

## **32 UNFPA's Right to Annul a Bidding Process**

- 32.1. UNFPA reserves the right to annul the bidding process and reject all bids at any time prior to award of purchase order, without thereby incurring any liability to the affected Bidder(s) or any obligation to provide information on the grounds for UNFPA's action.

## **F. Award of Contract**

### **33 Award Criteria**

- 33.1. In the event of a contract award, UNFPA will award the Purchase Order to the lowest-priced Bidder(s) whose bid is determined to be substantially responsive to the bidding documents and offers the most favorable delivery time.
- 33.2. If required, the Bidder shall permit UNFPA representatives' access to their facilities at any reasonable time to inspect the premises that shall be used for the production, testing and packaging of the products. The Bidder shall also provide reasonable assistance to the representatives for such inspection, including copies of any test results or quality control reports as may be necessary. UNFPA may inspect the manufacturing facilities of the lowest evaluated responsive Bidder to assess his capability to successfully perform the contract as per the terms and conditions specified in the LIB.
- 33.3. UNFPA reserves the right to make multiple arrangements for any item(s) where, in the opinion of UNFPA, the lowest priced substantially responsive Bidder cannot fully meet the delivery requirements or if it is deemed to be in UNFPA's best interest to do so. Any arrangement under this condition shall be made on the basis of the lowest priced substantially responsive, the second lowest priced substantially responsive, the third lowest priced substantially responsive , etc. Further, UNFPA reserves the right to prioritize higher priced substantially responsive options over lower priced substantially responsive options based on critical factors such as productions and delivery lead times proposed by the bidders in order to satisfy the best interest of UNFPA and partners.

### **34 Right to Vary Requirements at Time of Award**

- 34.1. 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.

### **35 Signing of the contract**

- 35.1. Prior to the expiration of the period of bid validity, UNFPA shall send the successful Bidder the Contract/Purchase Order, which constitute the notification of award. The successful Bidder shall sign, date the contract and return it to UNFPA within 10 days of receipt of the contract. After receipt of the contract, the successful Bidder shall deliver the commodities in accordance with the quantity, quality and delivery schedule outlined in its bid in conjunction with UNFPA terms and conditions.

### **36 Publication of Contract Award**

- 36.1. UNFPA shall publish the contract award on United Nations Global Marketplace <http://www.ungm.org>, with the information of the awarded Bidder company name, contract amount or LTA and the date of the contract.
- 36.2. Suppliers perceiving that they have been unjustly treated in connection with the solicitation or award of a contract may lodge a complaint directly to the Chief, Supply Chain Management Unit at [procurement@unfpa.org](mailto:procurement@unfpa.org), who will then make an assessment of the complaint and provide a reply to the Supplier within a week and, if required, advise the Supplier on further recourse.

## SECTION II: Technical Specifications and Schedule of Requirements

### 2.1. Technical Specifications

Item No	Item name	Requirement	Quantity
<b>LOT 1</b>			
<b>Item 1 (OR 1)</b>	<b>Activated Clotting Time (ACT) Measuring device</b>	<p><b>Product Description:</b></p> <p>Activated clotting time (ACT) device is intended for in vitro diagnostic testing in point-of-care and it is designed for a quick testing and monitoring the whole blood coagulation time of patients undergoing heparin therapy.</p> <p><b>Electrical Requirements:</b></p> <ul style="list-style-type: none"> <li>• Power requirements according to Mongolia standards: 220 VAC, 50 Hz. Power cord with plug type E.</li> <li>• Rechargeable batteries with autonomy of at least 45 test cycles at 150 sec per test.</li> </ul> <p><b>Technical specifications:</b></p> <ul style="list-style-type: none"> <li>• Portable system for point-of-care use.</li> <li>• Multiple test types available, at least: <ul style="list-style-type: none"> <li>o Activated Clotting Time (ACT+ and ACT-LR),</li> <li>o Activated Partial Thromboplastin Time (APTT and APTT Citrate),</li> <li>o Prothrombin Time (PT and PT Citrate).</li> </ul> </li> <li>• Clotting times measurement system: through disposable single-use cuvettes.</li> <li>• One cuvette per specific test.</li> <li>• Screen display of at least: <ul style="list-style-type: none"> <li>o Time and date.</li> <li>o Type of test running.</li> <li>o Test result.</li> <li>o Battery status.</li> <li>o Operating and configuring menus.</li> </ul> </li> </ul>	<b>2</b>

		<ul style="list-style-type: none"> <li>● Barcode Reader for cuvette lot information, and quality control lot information.</li> <li>● Keypad for manual entry information.</li> <li>● Internal memory for at least 500 patient results and 500 quality control results.</li> <li>● Data port to be connected to a PC or a printer.</li> <li>● Test Precision: <math>\leq 10\%</math> C.V. for whole blood samples.</li> <li>● Test Chamber: 1</li> <li>● Timing Range: up to 1020 seconds</li> <li>● Incubation Temperature: <math>37\text{ }^{\circ}\text{C} \pm 1.0\text{ }^{\circ}\text{C}</math></li> <li>● Incubation Warm-Up Time: 30 seconds to 90 seconds</li> <li>● Self-test.</li> <li>● All materials resistant to hospital-use disinfectants.</li> </ul> <p><b>Accessories:</b></p> <ul style="list-style-type: none"> <li>● One (1) Rechargeable battery</li> <li>● One (1) Battery charger for 1 battery</li> <li>● One (1) PC and printer cable.</li> <li>● Set of start-up consumables</li> </ul> <p><i>NOTE: All the necessary accessories for the correct operation of the product, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included.</i></p> <p><i>Accessories should be reusable when an option is available.</i></p> <p><b>Documentation requirement:</b></p> <ul style="list-style-type: none"> <li>● User manual must be provided (including operation instructions, maintenance and/or procedures for decontamination, storage conditions, safe disposal). In English, French and preferably also in Mongolian.</li> <li>● Service manual must be provided (including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits). In English, French and preferably also in Mongolian.</li> </ul>	
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		<ul style="list-style-type: none"> <li>• List of common spares parts and accessories with part numbers must be provided.</li> <li>• Manufacturer authorization.</li> <li>• Commitment Manufacturer letter, including: <ul style="list-style-type: none"> <li>o at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause "Warranty").</li> <li>o at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause "Post-sale Services").</li> <li>o training on use, cleaning, disinfecting for healthcare staff and basic maintenance technical staff, in English and Mongolian. (according to the general requirements in the bid document under the clause "Training").</li> </ul> </li> </ul> <p><b>Regulatory approvals required:</b></p> <ul style="list-style-type: none"> <li>• Valid Mongolian official Import license from the main manufacturer for receiving, installing, and maintaining medical equipment in Mongolia.</li> <li>• And at least one of the following regulatory approvals and certificates: <ul style="list-style-type: none"> <li>o European Certificate of Conformity (CE) with Regulation 2017/746 or Directive 98/78 EC and Agreement Letter signed with the NB demonstrating the on-going IVDR application, for IVD devices, or</li> <li>o FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or</li> <li>o Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan.</li> </ul> </li> </ul> <p><b>Safety &amp; product Standards:</b></p> <p>Bidder shall furnish the <b>documentary evidence</b> to demonstrate that the good it offers meet the international safety &amp; regulatory standards, providing in addition a signed and dated Declaration of Conformity (DoC) according to ISO 17050 stating compliance to the follow standards:</p> <ul style="list-style-type: none"> <li>• ISO 13485: Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes.</li> </ul>	
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		<ul style="list-style-type: none"> <li>• IEC 61010-1: Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements</li> <li>• IEC 61010-2-101: Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment</li> <li>• IEC 61326-1: Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements</li> </ul>	
<b>Item 3 (OR 3)</b>	<b>Extra Corporeal Circulation (ECC) Machine</b>	<p><b>Product Description</b></p> <p>A device designed to support the Heart-Lung perfusion practice.</p> <p><b>Electrical Requirements:</b></p> <ul style="list-style-type: none"> <li>• Power requirements according to Mongolia standards: 220 VAC, 50 Hz. Power cord with plug type E.</li> <li>• UPS with autonomy of at least 20 minutes of continuous use at maximum power.</li> </ul> <p><b>Technical specifications:</b></p> <ul style="list-style-type: none"> <li>• Modular Design</li> <li>• Each module must work independently from one another: no central control, no central failure or breakdown of the whole machine.</li> <li>• Low maintenance pumps without belts and gearbox.</li> <li>• Panel displays must be exchanged during HLM function without compromising the procedure.</li> <li>• Timer: Counting range 0 - 999 min 59 sec</li> <li>• System Panel: 3 Display and Control Modules</li> <li>• Pumps <ul style="list-style-type: none"> <li>o 3 Roller Pump: <ul style="list-style-type: none"> <li>▪ Diameter of pump raceway <math>\varnothing</math>: 150 mm</li> <li>▪ Diameter of occlusion roller <math>\varnothing</math>: 30.5 mm</li> <li>▪ rotate in, at least 15° increments.</li> </ul> </li> <li>o Double Roller Pump: <ul style="list-style-type: none"> <li>▪ Two roller pumps with a in a single housing. Both roller pumps must be operated independently.</li> <li>▪ Each pump must be operated in continuous or pulse mode.</li> </ul> </li> </ul> </li> </ul>	<b>1</b>

		<ul style="list-style-type: none"> <li>▪ Diameter of pump raceway Ø: 85 mm</li> <li>▪ Diameter of occlusion roller Ø: 15 mm</li> <li>▪ Speed Range: 0 to 250 rpm (clockwise, counterclockwise)</li> </ul> <ul style="list-style-type: none"> <li>● Mast System: <ul style="list-style-type: none"> <li>o Modular, it must allow at least 3 roller pumps to be mounted.</li> <li>o It must allow an oxygenator and tubing set to be mounted.</li> <li>o Swivel telescope, with infusion rack and castor.</li> <li>o At least 2 swivel arms</li> <li>o At least 2 horizontal masts</li> <li>o Transport locking arm.</li> </ul> </li> <li>● Cardioplegia Module: To deliver cardioplegic solutions or blood cardioplegia during an operation. <ul style="list-style-type: none"> <li>o Manual and automatic operation modes.</li> </ul> </li> <li>● Sensors <ul style="list-style-type: none"> <li>o Pressure - The system must measure and displays the pressure in the cardiopulmonary bypass circuit: <ul style="list-style-type: none"> <li>▪ Measurement range mmHg -200 mmHg to +800</li> <li>▪ Resolution 1 mmHg</li> </ul> </li> <li>o Cardioplegia</li> <li>o Temperature - The system must measure and display up to four temperatures: Display range 0 °C to +50 °C.</li> <li>o Level - Regulate and stop the arterial pump flow whether the blood level in the reservoir reaches the target volume. Level sensor pad small, flexible, and transparent to fit and stick on every reservoir and allow a clear view of the blood level.</li> <li>o Bubble - Sensor to detect different bubble air sizes in the extracorporeal circuit. The system must have at least three alarm thresholds to be set up (4 mm, 5 mm, and 6.5 mm Ø).</li> </ul> </li> </ul> <p><b>Accessories:</b></p> <ul style="list-style-type: none"> <li>● One (1) set of transducers, cable, and holders for the pressure module.</li> <li>● One (1) temperature probe the temperature module.</li> </ul>	
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		<ul style="list-style-type: none"> <li>• One (1) Complete level controller module with one set of cells.</li> <li>• One (1) Plexiglass pump protection</li> <li>• Six (6) Cover for quick fixing</li> <li>• Two (2) Cable retention system</li> <li>• Two (2) Cable retention system</li> <li>• One (1) DRP 85 double head roller pump with red, yellow, and black inserts.</li> <li>• One (1) CP5 Transonic flow sensor (3/8")</li> <li>• One (1) 3/8" air bubble detector sensor module with 620 mm articulated support</li> <li>• One (1) Level sensor support</li> <li>• One (1) Venous clamp with mechanical control for coarse and fine adjustments.</li> <li>• Four (4) Self-Adhesive Cells for Generation II Level Sensor</li> <li>• One (1) Thermal generator 3 tanks 220V with remote control on control panel, maintenance kit and connections</li> <li>• Two (2) Hansen female elbow fitting</li> <li>• One (1) Hansen male straight fitting</li> <li>• Two (2) Hansen female straight fitting</li> <li>• Set of start-up consumables.</li> </ul> <p><i>NOTE: All the necessary accessories for the correct operation of the product, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included.</i></p> <p><i>Accessories should be reusable when an option is available.</i></p> <p><i>The accessories will be used for both neonates and pediatric patients.</i></p> <p><b>Documentation requirement:</b></p> <ul style="list-style-type: none"> <li>• User manual must be provided (including operation instructions, maintenance and/or procedures for decontamination, storage conditions, safe disposal) in English and French. Preferably also in Mongolian.</li> <li>• Service manual must be provided (including preventive maintenance and calibration procedures, equipment necessary for preventive</li> </ul>	
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		<p>maintenance and repair, diagrams, and circuits) in English and French. Preferably also in Mongolian.</p> <ul style="list-style-type: none"> <li>• List of common spares and accessories with part numbers must be provided.</li> <li>• Manufacturer authorization.</li> <li>• Commitment Manufacturer letter, including: <ul style="list-style-type: none"> <li>o at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause "Warranty").</li> <li>o at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause "Post-sale Services").</li> <li>o training on use, cleaning, disinfecting for healthcare staff and basic maintenance technical staff, in English and Mongolian. (according to the general requirements in the bid document under the clause "Training").</li> </ul> </li> </ul> <p><b>Regulatory approvals required:</b></p> <ul style="list-style-type: none"> <li>• Valid Mongolian official Import license from the main manufacturer for receiving, installing, and maintaining medical equipment in Mongolia.</li> <li>• And at least one of the following regulatory approvals and certificates: <ul style="list-style-type: none"> <li>o European Certificate of Conformity (CE) with Regulation 2017/745 or Directive 93/42 EC and Agreement Letter signed with the NB demonstrating the on-going MDR application, for Class IIb devices, or</li> <li>o FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or</li> <li>o Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan.</li> </ul> </li> </ul> <p><b>Safety &amp; product Standards:</b></p> <p>Bidder shall furnish the <b>documentary evidence</b> to demonstrate that the good it offers meet the international safety &amp; regulatory standards, providing in addition a signed and dated Declaration of Conformity (DoC) according to ISO 17050 stating compliance to the follow standards:</p>	
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		<ul style="list-style-type: none"> <li>• ISO 13485: Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes.</li> <li>• IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance</li> <li>• 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</li> <li>• ISO 10993-1 Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process.</li> </ul>	
<b>Item 4 (OR 4)</b>	<b>Hypo-hyperthermia Machine</b>	<p><b>Product Description</b></p> <p>A device used to circulate water through heat exchangers to warm or cool a patient during cardiopulmonary bypass procedures lasting 6 hours or less. <u>The brand and model offered must be compatible with the Extracorporeal Machine (Item 03) to work together in cardiopulmonary bypass procedures.</u></p> <p><b>Electrical Requirements:</b></p> <ul style="list-style-type: none"> <li>• Power requirements according to Mongolia standards: 220 VAC, 50 Hz. Power cord with plug type E.</li> <li>• UPS with autonomy of at least 20 minutes of continuous use at maximum power.</li> </ul> <p><b>Technical specifications:</b></p> <ul style="list-style-type: none"> <li>• The system must be based on three water tanks: <ul style="list-style-type: none"> <li>o Cold and Warm tanks: to control the warming and cooling cardioplegia.</li> <li>o Patient tank with two circuits.</li> </ul> </li> <li>• Temperature Ranges: <ul style="list-style-type: none"> <li>o Cold Cardioplegia Tank: 2 °C to 10 °C</li> <li>o Warm Cardioplegia Tank: 15 °C to 40 °C</li> <li>o Patient Tank: 2 °C to 40 °C</li> </ul> </li> <li>• Temperature control with accuracy of 0.1 °C for settings.</li> <li>• Circuits for the patient and the circuit for cardioplegia can be switched off separately.</li> <li>• Flow indicator.</li> <li>• Vacuum gauge with scale</li> </ul>	<b>1</b>

		<ul style="list-style-type: none"> <li>● Control panel must allow separated operation and configuration of the three circuits: Two patient circuits and one cardioplegia circuit.</li> <li>● Aerosol Collection Set.</li> <li>● Alarms: <ul style="list-style-type: none"> <li>○ High-temperature fluid limit: Visual and audible</li> <li>○ Low fluid: Visual and audible</li> </ul> </li> <li>● Water must not come in contact with the patient's or the patient's blood during a procedure.</li> <li>● Compressor-based cooling with refrigerant covered by the Kyoto protocol.</li> <li>● Separate settings for warm cardioplegia, cold cardioplegia and patient temperature.</li> <li>● Independent safety system to prevent the water temperature from reach critical temperatures.</li> <li>● Two-chamber pumps</li> <li>● Castors with brakes for easy lock.</li> <li>● Operating Temperature: 10 °C through 30 °C</li> <li>● Service life expected: 10 years.</li> </ul> <p><b>Accessories:</b></p> <ul style="list-style-type: none"> <li>● One (1) Aerosol collection container holder</li> <li>● One (1) set of tubing connectors for tanks, drain, etc.</li> <li>● One (1) Vacuum extension line with connector</li> <li>● Ten (10) Water filters 0.2 um</li> <li>● Set of start-up consumables.</li> </ul> <p><i>NOTE: All the necessary accessories for the correct operation of the product, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included.</i></p> <p><i>Accessories should be reusable when an option is available.</i></p> <p><i>The accessories will be used for both neonates and pediatric patients.</i></p>	
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		<p><b>Documentation requirement:</b></p> <ul style="list-style-type: none"> <li>• User manuals must be provided (including operation instructions, maintenance and/or procedures for decontamination, storage conditions, safe disposal) in English and French. Preferably also in Mongolian.</li> <li>• Service manual must be provided (including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits) in English and French. Preferably also in Mongolian.</li> <li>• List of common spares and accessories with part numbers must be provided.</li> <li>• Manufacturer authorization.</li> <li>• Commitment Manufacturer letter, including: <ul style="list-style-type: none"> <li>o at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause "Warranty").</li> <li>o at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause "Post-sale Services").</li> <li>o training on use, cleaning, disinfecting for healthcare staff and basic maintenance technical staff, in English and Mongolian. (according to the general requirements in the bid document under the clause "Training").</li> </ul> </li> </ul> <p><b>Regulatory approvals required:</b></p> <ul style="list-style-type: none"> <li>• Valid Mongolian official Import license from the main manufacturer for receiving, installing, and maintaining medical equipment in Mongolia.</li> <li>• And at least one of the following regulatory approvals and certificates: <ul style="list-style-type: none"> <li>o European Certificate of Conformity (CE) with Regulation 2017/745 or Directive 93/42 EC and Agreement Letter signed with the NB demonstrating the on-going MDR application, Class IIb devices,</li> <li>o or</li> <li>o FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or</li> </ul> </li> </ul>	
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		<p>o Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan.</p> <p><b>Safety &amp; product Standards:</b></p> <p>Bidder shall furnish the <b>documentary evidence</b> to demonstrate that the good it offers meet the international safety &amp; regulatory standards, providing in addition a signed and dated Declaration of Conformity (DoC) according to ISO 17050 stating compliance to the follow standards:</p> <ul style="list-style-type: none"> <li>• ISO 13485: Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes.</li> <li>• IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance</li> <li>• 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</li> </ul>	
Item 5 (OR 33)	Patient Auto-Transfusion System	<p><b>Product Description</b></p> <p>A device used for intraoperative recovery of blood, washing of blood collected in the postoperative period, and preoperative sequestration with indirect patient connection.</p> <p><b>Electrical Requirements:</b></p> <ul style="list-style-type: none"> <li>• Power requirements according to Mongolia standards: 220 VAC, 50 Hz. Power cord with plug type E.</li> </ul> <p><b>Technical specifications:</b></p> <ul style="list-style-type: none"> <li>• Automatic machine 4 bowl Sizes.</li> <li>• Color touch Screen user interface with large view: 8" or larger.</li> <li>• Hematocrit indicator of returned blood.</li> <li>• Plasma Free Hemoglobin Indicator</li> <li>• Centrifuge Speed: 1500 - 5600 rpm (steps of 100 rpm) setting in steps of 100 rpm.</li> <li>• Pump Speed: 25 - 1000 ml/min (adjustable)</li> <li>• Wash protocol available for high quality RBC, Heparin, and protein removal.</li> <li>• Specific protocol for fat removal</li> <li>• High RBC recovery rate</li> </ul>	1

		<ul style="list-style-type: none"> <li>● Display Type Graphic color LCD TFT: at least 8" diagonally.</li> </ul> <p><b>Accessories:</b></p> <ul style="list-style-type: none"> <li>● One (1) Vacuum Generator <ul style="list-style-type: none"> <li>o Vacuum Range: -50 to -300 mmHg.</li> <li>o steps of 10 mmHg</li> </ul> </li> <li>● Set of Start-up consumables</li> </ul> <p><i>NOTE: All the necessary accessories for the correct operation of the product, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included.</i></p> <p><i>Accessories should be reusable when an option is available.</i></p> <p><i>The accessories will be used for both neonates and pediatric patients.</i></p> <p><b>Documentation requirement:</b></p> <ul style="list-style-type: none"> <li>● User manuals must be provided (including operation instructions, maintenance and/or procedures for decontamination, storage conditions, safe disposal) in English and French. Preferably also in Mongolian.</li> <li>● Service manual must be provided (including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits) in English and French. Preferably also in Mongolian.</li> <li>● List of common spares and accessories with part numbers must be provided.</li> <li>● Manufacturer authorization.</li> <li>● Commitment Manufacturer letter, including: <ul style="list-style-type: none"> <li>o at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause "Warranty").</li> <li>o at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause "Post-sale Services").</li> <li>o training on use, cleaning, disinfecting for healthcare staff and basic maintenance technical staff, in English and Mongolian. (according to the general requirements in the bid document under the clause "Training").</li> </ul> </li> </ul>	
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		<p><b>Regulatory approvals required:</b></p> <ul style="list-style-type: none"> <li>Valid Mongolian official Import license from the main manufacturer for receiving, installing, and maintaining medical equipment in Mongolia.</li> <li>And at least one of the following regulatory approvals and certificates: <ul style="list-style-type: none"> <li>European Certificate of Conformity (CE) with Regulation 2017/745 or Directive 93/42 EC and Agreement Letter signed with the NB demonstrating the on-going MDR application, for Class IIa devices, or</li> <li>FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or</li> <li>Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan.</li> </ul> </li> </ul> <p><b>Safety &amp; product Standards:</b></p> <p>Bidder shall furnish the <b>documentary evidence</b> to demonstrate that the good it offers meet the international safety &amp; regulatory standards, providing in addition a signed and dated Declaration of Conformity (DoC) according to ISO 17050 stating compliance to the follow standards:</p> <ul style="list-style-type: none"> <li>ISO 13485: Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes.</li> <li>IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance</li> <li>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</li> <li>ISO 10993-1 Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process.</li> </ul>	
Item 12 (OR 19)	Brain Monitoring System	<p><b>Product Description</b></p> <p>Device designed for Brain monitoring. The system analyzes the electrical activity of the brain to provide real-time feedback on the depth of anesthesia during medical procedures.</p> <p><b>Electrical Requirements:</b></p> <ul style="list-style-type: none"> <li>Power requirements according to Mongolia standards: 220 VAC, 50 Hz. Power cord with plug type E.</li> </ul>	1

		<p><b>Technical specifications:</b></p> <ul style="list-style-type: none"> <li>● Display Features: <ul style="list-style-type: none"> <li>○ BIS number</li> <li>○ Trend graph of BIS values over time</li> <li>○ Real-time raw EEG waveforms</li> <li>○ Signal quality indicators like SQI and EMG</li> <li>○ Alarm indicators and messages.</li> </ul> </li> <li>● Sensor Technology: <ul style="list-style-type: none"> <li>○ Specialized sensor attached to the patient's forehead and temple.</li> <li>○ Records brain's electrical activity through EEG</li> </ul> </li> <li>● Data Analysis: <ul style="list-style-type: none"> <li>○ Proprietary algorithm analyzes EEG data to calculate BIS value.</li> <li>○ Provides real-time information on anesthesia depth.</li> </ul> </li> </ul> <p><b>Accessories:</b></p> <ul style="list-style-type: none"> <li>● One (1) Patient Interface Cable (PIC).</li> <li>● Set of start-up consumables.</li> </ul> <p><i>NOTE: All the necessary accessories for the correct operation of the product, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included.</i></p> <p><i>Accessories should be reusable when an option is available.</i></p> <p><b>Documentation requirement:</b></p> <ul style="list-style-type: none"> <li>● User manual must be provided (including operation instructions, maintenance and/or procedures for decontamination, storage conditions, safe disposal). In English, French and preferably also in Mongolian.</li> <li>● Service manual must be provided (including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits) in English and French. Preferably also in Mongolian.</li> <li>● List of common spares and accessories with part numbers must be provided.</li> <li>● Manufacturer authorization.</li> </ul>	
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		<ul style="list-style-type: none"> <li>● Commitment Manufacturer letter, including: <ul style="list-style-type: none"> <li>o at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause "Warranty").</li> <li>o at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause "Post-sale Services").</li> </ul> </li> </ul> <p><b>Regulatory approvals required:</b></p> <ul style="list-style-type: none"> <li>● Valid Mongolian official Import license from the main manufacturer for receiving, installing, and maintaining medical equipment in Mongolia.</li> <li>● And at least one of the following regulatory approvals and certificates: <ul style="list-style-type: none"> <li>o European Certificate of Conformity (CE) with Regulation 2017/745 or Directive 93/42 EC and Agreement Letter signed with the NB demonstrating the on-going MDR application, for Class IIb devices, or</li> <li>o FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or</li> <li>o Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan.</li> </ul> </li> </ul> <p><b>Safety &amp; product Standards:</b></p> <p>Bidder shall furnish the <b>documentary evidence</b> to demonstrate that the good it offers meet the international safety &amp; regulatory standards, providing in addition a signed and dated Declaration of Conformity (DoC) according to ISO 17050 stating compliance to the follow standards:</p> <ul style="list-style-type: none"> <li>● ISO 13485: Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes.</li> <li>● IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance</li> <li>● IEC 60601-1-2: Medical Electrical Equipment - General Requirements for Basic Safety and Essential Performance</li> <li>● IEC 80601-2-26 Medical electrical equipment: Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs</li> </ul>	
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Item 22 (OR 32)	Portable external pacemaker	<p><b>Product Description</b></p> <p>External pacemaker is a device designed for temporary cardiac pacing, that is the application of an artificial electrical stimulus, in combination with a cardiac pacing lead system.</p> <p><b>Electrical Requirements:</b></p> <ul style="list-style-type: none"> <li>• Operation: Alkaline batteries powered external pacemaker.</li> </ul> <p><b>Technical specifications:</b></p> <ul style="list-style-type: none"> <li>• Dual-chamber device.</li> <li>• To be used with patients of any age.</li> <li>• At least for the following applications: <ul style="list-style-type: none"> <li>o Pre-, intra- and postoperative pacing of patients with heart surgery</li> <li>o Treatment of arrhythmias and heart block</li> <li>o Symptomatic sinus bradycardia</li> <li>o Emergency pacing</li> </ul> </li> <li>• Option with fast atrial stimulation up and atrial overdrive stimulation</li> <li>• Dial for quick parameter adjustment.</li> <li>• Visualization of the programmed settings.</li> <li>• Lead impedance monitoring.</li> <li>• Self-test.</li> <li>• Adjustable parameters range, at least: <ul style="list-style-type: none"> <li>o Pacing modes (NBG code): DDD, D00, VDD, VVI, V00, VVT.</li> <li>o Rate: between 30 to 200 ppm</li> <li>o Sensitivity (A: Atrial): between 0.4 to 10 mV</li> <li>o Sensitivity (V: Ventricular): between 1 to 20 mV</li> <li>o AV delay: between 20 to 300 ms.</li> <li>o Atrial rate (A): between 80 to 800 ppm.</li> </ul> </li> <li>• Pre-setting no-adjustable parameters, at least: <ul style="list-style-type: none"> <li>o Pulse width: 1 ms.</li> <li>o Upper rate: 230 ppm</li> <li>o Atrial refractory period: between up to 500 ms.</li> </ul> </li> </ul>	3
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		<ul style="list-style-type: none"> <li>o In channel blanking: 110 ms.</li> <li>• Alarms acoustic and/or visual at least for: <ul style="list-style-type: none"> <li>o Low battery indication.</li> <li>o Rate set &gt; 180 ppm.</li> <li>o Lead impedance out of range.</li> <li>o Auto-test failure.</li> </ul> </li> <li>• All materials resistant to hospital-use disinfectants.</li> </ul> <p><b>Accessories:</b></p> <ul style="list-style-type: none"> <li>• Two (2) Startup sets of alkaline batteries.</li> <li>• Two (2) Adapter to connect the pacemaker with patient cable, if necessary for the device offered</li> <li>• Two (2) Long patient cable/s for dual chamber, as necessary for the device offered.</li> <li>• One (1) Hook to hang from IV pole.</li> <li>• One (1) Protective cover, if necessary</li> <li>• One (1) Portable case.</li> <li>• Set of start-up consumables, if necessary.</li> </ul> <p><i>NOTE: All the necessary accessories for the correct operation of the product, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included.</i></p> <p>Accessories should be reusable when an option is available.</p> <p><b>Documentation requirement:</b></p> <ul style="list-style-type: none"> <li>• User manual must be provided (including operation instructions, maintenance and/or procedures for decontamination, storage conditions, safe disposal). In English, French and preferably also in Mongolian.</li> <li>• Service manual must be provided (including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits). In English, French and preferably also in Mongolian.</li> <li>• List of common spares and accessories with part numbers must be provided.</li> </ul>	
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		<ul style="list-style-type: none"> <li>● Manufacturer authorization.</li> <li>● Commitment Manufacturer letter, including: <ul style="list-style-type: none"> <li>o at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause "Warranty").</li> <li>o at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause "Post-sale Services").</li> <li>o training on use, cleaning, disinfecting for healthcare staff and basic maintenance technical staff, in English and Mongolian. (according to the general requirements in the bid document under the clause "Training").</li> </ul> </li> </ul> <p><b>Regulatory approvals required:</b></p> <ul style="list-style-type: none"> <li>● Valid Mongolian official Import license from the main manufacturer for receiving, installing, and maintaining medical equipment in Mongolia.</li> <li>● And at least one of the following regulatory approvals and certificates: <ul style="list-style-type: none"> <li>o European Certificate of Conformity (CE) with Regulation 2017/745 or Directive 93/42 EC and Agreement Letter signed with the NB demonstrating the on-going MDR application, for Class IIb devices, or</li> <li>o FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or</li> <li>o Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan</li> </ul> </li> </ul> <p><b>Safety &amp; product Standards:</b></p> <p>Bidder shall furnish the <b>documentary evidence</b> to demonstrate that the good it offers meet the international safety &amp; regulatory standards, providing in addition a signed and dated Declaration of Conformity (DoC) according to ISO 17050 stating compliance to the follow standards:</p> <ul style="list-style-type: none"> <li>● ISO 13485: Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes.</li> <li>● IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance</li> </ul>	
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		<ul style="list-style-type: none"> <li>• 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</li> <li>• IEC 60601-2-31: Medical electrical equipment - Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source.</li> </ul>	
<b>Item 23 (OR 34)</b>	<b>Patient drainage system</b>	<p><b>Product Description</b></p> <p>A device designed for continuous wound and chest drainage, including features like a fine control valve, fistula indicator, and bacterial filter.</p> <p><b>Electrical Requirements:</b></p> <ul style="list-style-type: none"> <li>• N/A</li> </ul> <p><b>Technical specifications:</b></p> <ul style="list-style-type: none"> <li>• Filling volume: At least 700 ml</li> <li>• Max. filling level up to overflow protection: At least 1000 ml.</li> <li>• Scaling in 10 ml steps up to max.</li> <li>• Max. vacuum: At least -10 to 0 kPa (-100 to 0 mbar)</li> <li>• Max. flow: At least 14 l/min</li> <li>• Weight: At most 3 kg (empty)</li> <li>• Dimensions (WxHxD): At most 300 x 350 x 200 mm</li> </ul> <p><b>Accessories:</b></p> <ul style="list-style-type: none"> <li>• Set of start-up consumables</li> </ul> <p>Accessories should be reusable when an option is available.</p> <p><b>Documentation requirement:</b></p> <ul style="list-style-type: none"> <li>• User manual must be provided (including operation instructions, maintenance and/or procedures for decontamination, storage conditions, safe disposal). In English, French and preferably also in Mongolian.</li> <li>• List of common spares and accessories with part numbers must be provided.</li> <li>• Manufacturer authorization.</li> <li>• Commitment Manufacturer letter, including:</li> </ul>	<b>1</b>

		<ul style="list-style-type: none"> <li>o at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause "Warranty").</li> <li>o at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause "Post-sale Services").</li> </ul> <p><b>Regulatory approvals required:</b></p> <ul style="list-style-type: none"> <li>● Valid Mongolian official Import license from the main manufacturer for receiving, installing, and maintaining medical equipment in Mongolia.</li> <li>● And at least one of the following regulatory approvals and certificates: <ul style="list-style-type: none"> <li>o European Certificate of Conformity (CE) with Regulation 2017/745 or Directive 93/42 EC and Agreement Letter signed with the NB demonstrating the on-going MDR application, for Class IIa devices, or</li> <li>o FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or</li> <li>o Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan.</li> </ul> </li> </ul> <p><b>Safety &amp; product Standards:</b></p> <p>Bidder shall furnish the <b>documentary evidence</b> to demonstrate that the good it offers meet the international safety &amp; regulatory standards, providing in addition a signed and dated Declaration of Conformity (DoC) according to ISO 17050 stating compliance to the follow standards:</p> <ul style="list-style-type: none"> <li>● ISO 13485: Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes.</li> <li>● IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance</li> </ul>	
Item 25 (OR 38)	Surgeon's headlamp	<p><b>Product Description</b></p> <p>A device designed to be used as an adjunct light source during clinical or surgical procedures in a medical setting.</p> <p><b>Electrical Requirements:</b></p> <ul style="list-style-type: none"> <li>● Operation: Rechargeable battery-powered.</li> </ul> <p><b>Technical specifications:</b></p>	1

		<ul style="list-style-type: none"> <li>• LED lamp with optic</li> <li>• LED Expected Life Span &gt; 50,000 hours</li> <li>• Illumination Range: 100.000 - 500.000 lux (25 cm)</li> <li>• Color temperature: 4500K. Preferable, adjustable between 4000K and 6100K.</li> <li>• Adjustable illumination spot size: beam angle up to 120 degrees</li> <li>• Uniform light distribution over the surgical field.</li> <li>• Mounting system: Adjustable and secure allowing firm and stable attachment of the lamp to the surgeon's head.</li> <li>• Battery: <ul style="list-style-type: none"> <li>o Autonomy of 8 hs.</li> <li>o Lithium based.</li> <li>o Fast and safe charging system.</li> <li>o Battery Expected Life Span &gt; 300 Charges.</li> </ul> </li> <li>• Material: <ul style="list-style-type: none"> <li>o Lightweight and durable</li> <li>o Main Body: Aluminum alloy recommended.</li> <li>o Adjustable parts: High-quality plastic recommended.</li> </ul> </li> <li>• Water Resistance: IPX7 or higher.</li> <li>• Weight: less than 350 g.</li> </ul> <p><b>Accessories:</b></p> <ul style="list-style-type: none"> <li>• One (1) Charger system at least 2 batteries</li> <li>• One (1) Battery pack</li> <li>• One (1) Charger Wires set.</li> </ul> <p>Accessories should be reusable when an option is available.</p> <p><b>Documentation requirement:</b></p> <ul style="list-style-type: none"> <li>• User manual must be provided (including operation instructions, maintenance and/or procedures for decontamination, storage conditions, safe disposal) in English and French. Preferably also in Mongolian.</li> </ul>	
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	<ul style="list-style-type: none"> <li>• Service manual must be provided (including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits) in English and French. Preferably also in Mongolian.</li> <li>• List of common spares and accessories with part numbers must be provided.</li> <li>• Manufacturer authorization.</li> <li>• Commitment Manufacturer letter, including: <ul style="list-style-type: none"> <li>o at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause "Warranty").</li> <li>o at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause "Post-sale Services").</li> </ul> </li> </ul> <p><b>Regulatory approvals required:</b></p> <ul style="list-style-type: none"> <li>• Valid Mongolian official Import license from the main manufacturer for receiving, installing, and maintaining medical equipment in Mongolia.</li> <li>• And at least one of the following regulatory approvals and certificates: <ul style="list-style-type: none"> <li>o European Certificate of Conformity (CE) with Regulation 2017/745 or Directive 93/42 EC and Agreement Letter signed with the NB demonstrating the on-going MDR application, for Class I devices, or</li> <li>o FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or</li> <li>o Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan.</li> </ul> </li> </ul> <p><b>Safety &amp; product Standards:</b></p> <p>Bidder shall furnish the <b>documentary evidence</b> to demonstrate that the good it offers meet the international safety &amp; regulatory standards, providing in addition a signed and dated Declaration of Conformity (DoC) according to ISO 17050 stating compliance to the follow standards:</p> <ul style="list-style-type: none"> <li>• ISO 13485: Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes.</li> </ul>	
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		<ul style="list-style-type: none"> <li>• IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance</li> <li>• 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</li> </ul>	
<b>Item 26 (ICU 3)</b>	<b>Dialysis Equipment for Neonate - Peritoneal dialysis system</b>	<p><b>Product Description</b></p> <p>A device intended to deliver a neonate peritoneal dialysis system. This sophisticated system offers a variety of therapy options, including hemodialysis, hemodiafiltration, and online hemodiafiltration, catering to a wide range of patient needs.</p> <p><b>Electrical Requirements:</b></p> <ul style="list-style-type: none"> <li>• Power requirements according to Mongolia standards: 220 VAC, 50 Hz. Power cord with plug type E.</li> </ul> <p><b>Technical specifications:</b></p> <ul style="list-style-type: none"> <li>• HighVolumeHDF Capability: Ability to perform pre- and post-dilution hemodiafiltration for efficient removal of middle molecular toxins and cardioprotective hemodialysis.</li> <li>• AutoFlow Technology: Incorporation of AutoFlow for dialysate flow savings without compromising treatment efficacy, ensuring optimal use of resources.</li> <li>• EcoFlow Integration: Implementation of EcoFlow technology for efficient and sustainable workflows, contributing to resource optimization.</li> <li>• Heat Exchanger: Inclusion of a heat exchanger for temperature control during dialysis sessions, enhancing patient comfort and treatment effectiveness.</li> <li>• Service-Friendly Design: Emphasis on service-friendliness with features like interactive hydraulic flow charts for error diagnosis, easy maintenance access to machine components, and snap-lock technology for quick component exchange.</li> <li>• BCM-Body Composition Monitor: bioimpedance spectroscopy</li> <li>• Management of low volumes: <ul style="list-style-type: none"> <li>o Sensitive machine settings and limits</li> <li>o Blood flow limited according to body weight.</li> <li>o Reduced bolus rate according to blood flow</li> </ul> </li> </ul>	<b>1</b>

		<ul style="list-style-type: none"> <li>o Reduced blood flow of 50ml/min for a gentle start of dialysis</li> <li>o Adapted air and microbubble detection sensitivity.</li> <li>o Pediatric User setup</li> <li>o Pediatric AV blood line set with reduced fill volume of 114 ml.</li> </ul> <p><b>Accessories:</b></p> <ul style="list-style-type: none"> <li>● One (1) Online Clearance Monitor, if applicable.</li> <li>● One (1) Blood Temperature Monitor, if applicable.</li> <li>● One (1) Blood Volume Monitor, if applicable.</li> <li>● Set of start-up consumables.</li> </ul> <p><i>NOTE: All the necessary accessories for the correct operation of the product, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included.</i></p> <p>Accessories should be reusable when an option is available.</p> <p><i>The accessories will be used for both neonates and pediatric patients.</i></p> <p><b>Documentation requirement:</b></p> <ul style="list-style-type: none"> <li>● User manual must be provided (including operation instructions, maintenance and/or procedures for decontamination, storage conditions, safe disposal). In English, French and preferably also in Mongolian.</li> <li>● Service manual must be provided (including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits) in English and French. Preferably also in Mongolian.</li> <li>● List of common spares and accessories with part numbers must be provided.</li> <li>● Copy of the agreement between the bidder and the local service center for the provision of services</li> <li>● Manufacturer's authorization issued to the local service center for the right to provide maintenance services for the declared medical equipment (copy certified by the seal of the bidder and the local service center)</li> <li>● Commitment Manufacturer letter, including:</li> </ul>	
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		<ul style="list-style-type: none"> <li>o at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause "Warranty").</li> <li>o at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause "Post-sale Services").</li> <li>o training on use, cleaning, disinfecting for healthcare staff and basic maintenance technical staff, in English and Mongolian. (according to the general requirements in the bid document under the clause "Training").</li> </ul> <p><b>Regulatory approvals required:</b></p> <ul style="list-style-type: none"> <li>● Valid Mongolian official Import license from the main manufacturer for receiving, installing, and maintaining medical equipment in Mongolia.</li> <li>● And at least one of the following regulatory approvals and certificates: <ul style="list-style-type: none"> <li>o European Certificate of Conformity (CE) with Regulation 2017/745 or Directive 93/42 EC and Agreement Letter signed with the NB demonstrating the on-going MDR application, for Class IIb devices, or</li> <li>o FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or</li> <li>o Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan.</li> </ul> </li> </ul> <p><b>Safety &amp; product Standards:</b></p> <p>Bidder shall furnish the <b>documentary evidence</b> to demonstrate that the good it offers meet the international safety &amp; regulatory standards, providing in addition a signed and dated Declaration of Conformity (DoC) according to ISO 17050 stating compliance to the follow standards:</p> <ul style="list-style-type: none"> <li>● ISO 13485: Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes.</li> <li>● IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance</li> <li>● 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</li> </ul>	
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		<ul style="list-style-type: none"> <li>• ISO 23500: Preparation and quality management of fluids for haemodialysis and related therapies — Part 1: General requirements.</li> <li>• ISO 11663: Quality of dialysis fluid for haemodialysis and related therapies.</li> </ul>	
LOT 2			
Item A	Cardiotocograph (CTG)	<p><b>Product Description</b></p> <p>Cardiotocograph (CTG) system is used to monitor the baby and the mother for any signs of distress during the prenatal, intra and postpartum period.</p> <p>CTG provides graphic and numeric information on fetal heart rate (FHR) and maternal uterine activity (UA) and physiological parameters to help clinical personnel assess fetal well-being.</p> <p><b>Electrical Requirements:</b></p> <ul style="list-style-type: none"> <li>• Power requirements according to Mongolia standards: 220 VAC, 50 Hz. Power cord with plug type E</li> <li>• Rechargeable battery with autonomy of at least 4 hours of continuous operation.</li> </ul> <p><b>Technical specifications:</b></p> <ul style="list-style-type: none"> <li>• Continuous monitoring of fetal heart rate (FHR) by ultrasonic pulsed doppler mode.</li> <li>• Dual Ultrasonic Heart Rate channels for Twins Monitoring (FHR1, FHR2).</li> <li>• Uterine activity (TOCO) acquired using a tocodynamometer (a pressure sensitive transducer).</li> <li>• Touchscreen LCD or TFT color screen of at least 6".</li> <li>• Display shows at least: FHR1, FHR2, UCs, TOCO, Pulse rate (MHR), Maternal blood pressure (NIBP), patient data and alarms.</li> <li>• Automatically detects transducers when they are plugged in.</li> <li>• Detection of heartbeat coincidence between both fetal channels and maternal heartbeat. Signals overlap verification and separation.</li> <li>• Ultrasound frequency: 1 MHz +/- 10%.</li> <li>• Remote switch for event marking.</li> <li>• Automatic self-test</li> <li>• At least one (1) communication port to transfer the patient information to the hospital network and for teleconsultation.</li> <li>• Parameters and measurement ranges: <ul style="list-style-type: none"> <li>◦ Monitoring of fetal heart rate (FHR): at least 50-230 bpm, with a resolution of 1 bpm, and accuracy +/- 2 bpm or better.</li> <li>◦ TOCO: at least 0 - 100 units, with a resolution of 1 unit.</li> <li>◦ Maternal heart rate and electrocardiogram: <ul style="list-style-type: none"> <li>▪ at least 30-230 bpm, with a resolution of 1 bpm, and accuracy +/- 2 bpm or better.</li> <li>▪ Single lead ECG.</li> </ul> </li> <li>◦ Maternal non-invasive blood pressure (NIBP), at least: <ul style="list-style-type: none"> <li>▪ Systolic: 50 – 240 mmHg.</li> <li>▪ Mean: 25 – 200 mmHg.</li> <li>▪ Diastolic: 15 – 180 mmHg.</li> </ul> </li> </ul> </li> </ul>	22

		<ul style="list-style-type: none"> <li>● Audible and visual for at least: <ul style="list-style-type: none"> <li>◦ FHR1 high / low</li> <li>◦ FHR2 high / low</li> <li>◦ Low battery</li> <li>◦ NIBP high / low</li> <li>◦ Pulse rate high / low</li> <li>◦ Technical alarms</li> </ul> </li> <li>● The results may be displayed via print-out and electronically with telemetry features by DICOM image processing.</li> <li>● Integrated thermal printer: <ul style="list-style-type: none"> <li>◦ Print at least: FHR1, FHR2, TOCO, MHR, ECG, Reports.</li> <li>◦ Print speeds 1, 2 and 3 cm/min</li> </ul> </li> <li>● All materials resistant to hospital-use disinfectants.</li> <li>● Indications and messages on the equipment must be in English language as mandatory, preferably also in Mongolian language.</li> </ul> <p><b>Accessories:</b></p> <ul style="list-style-type: none"> <li>● One (1) Toco UC transducer.</li> <li>● Two (2) FHR ultrasound transducers</li> <li>● One (1) Remote switch event marker with cable.</li> <li>● Five (5) reusable adjustable large belts for transducers.</li> <li>● Two (2) packs of thermal recording paper (type depending on the paper use with the printer).</li> <li>● Two (2) MECG reusable transducer with cable and adapter for electrode, if necessary.</li> <li>● One hundred (100) self-adhesive ECG disposable electrodes, adult size.</li> <li>● Three (3) adult NIBP reusable cuffs, in different sizes with tube included.</li> <li>● Two (2) bottles of ultrasound gel approximately 250ml each.</li> <li>● Trolley for the CTG and accessories. Chassis and external components must be built of materials, and/or have a finish/coating resistant to corrosion and the application of disinfectants commonly used in healthcare premises.</li> </ul> <p><i>NOTE: If there are other/s necessary/ies reusable/s accessory/ies for the correct operation of the product, they must be included, even if they are not included in the technical specification.</i></p> <p><b>Documentation requirement:</b></p> <ul style="list-style-type: none"> <li>● Manufacturer brochure or data sheet including at least all technical specifications required. In English.</li> <li>● User manual must be provided (including operation instructions, maintenance and/or procedures for decontamination, storage conditions, safe disposal). In English, French and preferably also in Mongolian.</li> <li>● Service manual must be provided (including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits). In English, French and preferably also in Mongolian.</li> </ul>	
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		<ul style="list-style-type: none"> <li>List of common spare parts and accessories with part numbers must be provided.</li> <li>Manufacturer authorization letter.</li> <li>Commitment Manufacturer letter, including: <ul style="list-style-type: none"> <li>at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause "Warranty").</li> <li>at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause "Post-sale Services").</li> <li>training on use, cleaning, disinfecting for healthcare staff and basic maintenance technical staff, in English and Mongolian. (according to the general requirements in the bid document under the clause "Training").</li> </ul> </li> </ul> <p><b>Regulatory approvals required:</b></p> <ul style="list-style-type: none"> <li>Valid Mongolian official Import license from the main manufacturer for receiving, installing, and maintaining medical equipment in Mongolia.</li> <li>And at least one of the following regulatory approvals and certificates: <ul style="list-style-type: none"> <li>European Certificate of Conformity (CE) with Regulation 2017/745 or Directive 93/42 EC and Agreement Letter signed with the NB demonstrating the on-going MDR application, for Class IIb devices, or</li> <li>FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or</li> <li>Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan.</li> </ul> </li> </ul> <p><b>Safety &amp; product Standards:</b></p> <p>Bidder shall furnish the following documents:</p> <ul style="list-style-type: none"> <li>Valid ISO 13485 certificate.</li> <li>Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety &amp; regulatory standards: <ul style="list-style-type: none"> <li>IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance</li> <li>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</li> <li>IEC 60601-2-37 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.</li> </ul> </li> </ul>	
<b>Item B</b>	<b>Portable ultrasound scanner</b>	<p><b>Product Description</b></p> <p>Portable ultrasound scanner designed to allow clinical personnel to perform basic ultrasound examinations to pregnant women to detect</p>	<b>22</b>

		<p>pregnancy complications, fetal conditions, and gynecological issues at early stage.</p> <p><b>Electrical Requirements:</b></p> <ul style="list-style-type: none"> <li>• Power requirements according to Mongolia standards: 220 VAC, 50 Hz. Power cord with plug type E</li> <li>• Rechargeable batteries with autonomy of at least 30 minutes of continuous use.</li> </ul> <p><b>Technical specifications:</b></p> <ul style="list-style-type: none"> <li>• Portable ultrasound scanner, laptop type.</li> <li>• Displays images on screen and remotely, equipped with DICOM 3.0 compatibility to process, storage and transfer image capabilities.</li> <li>• Light weight: &lt; 5.0 kg</li> <li>• High resolution monitor: LCD or TFT LCD color screen of at least 14".</li> <li>• Brightness Adjustment</li> <li>• Integrated Speakers with adjust of volume</li> <li>• Internal Hard Drives: At least 40GB</li> <li>• Alphanumeric Keyboard with special functions.</li> <li>• Trackball or similar.</li> <li>• Connection probes: at least 1 probe port</li> <li>• Cine memory.</li> <li>• USB port at least 2.</li> <li>• Earphone port.</li> <li>• Wireless compatibility.</li> <li>• With handle for transportation.</li> <li>• External Color thermal printer, included.</li> <li>• At least the following operating modes: <ul style="list-style-type: none"> <li>◦ B-Mode</li> <li>◦ M-Mode</li> <li>◦ Anatomical M-mode</li> <li>◦ Color Flow Mode (CFM)</li> <li>◦ Power Doppler Imaging (PDI)</li> <li>◦ Pulse Wave Doppler (PWD)</li> </ul> </li> <li>• Zoom of the live image or the frozen image.</li> <li>• Measure and calculation packages included, at least: <ul style="list-style-type: none"> <li>◦ Standard.</li> <li>◦ Doppler, including auto doppler.</li> <li>◦ Vascular.</li> <li>◦ Obstetrical.</li> <li>◦ Gynecological.</li> </ul> </li> <li>• Simultaneous display modes, at least: <ul style="list-style-type: none"> <li>◦ B/PW</li> <li>◦ B/CFM or PDI</li> <li>◦ B/M</li> <li>◦ Dual B (B/B)</li> <li>◦ Dual B + CFM or PDI</li> </ul> </li> <li>• All materials resistant to hospital-use disinfectants.</li> <li>• Indications and messages on the equipment must be in English language as mandatory, preferably also in Mongolian language.</li> </ul>	
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		<p><b>Accessories:</b></p> <ul style="list-style-type: none"> <li>Probes to be included in the offer: <ul style="list-style-type: none"> <li>One (1) Convex Array (General/OB/GYN)</li> <li>One (1) Transvaginal array (OB/GYN)</li> <li>One (1) Linear array (Vascular)</li> </ul> </li> <li>Two (2) packs of paper for the color printer, adequate to the printer offered.</li> <li>Two (2) bottles of ultrasound gel approximately 250ml each.</li> <li>Trolley for the CTG and accessories. Chassis and external components must be built of materials, and/or have a finish/coating resistant to corrosion and the application of disinfectants commonly used in healthcare premises.</li> </ul> <p><i>NOTE: If there are other/s necessary/ies reusable/s accessory/ies for the correct operation of the product, they must be included, even if they are not included in the technical specification.</i></p> <p><b>Documentation requirement:</b></p> <ul style="list-style-type: none"> <li>Manufacturer brochure or data sheet including at least all technical specifications required. In English.</li> <li>User manual must be provided (including operation instructions, maintenance and/or procedures for decontamination, storage conditions, safe disposal). In English, French and preferably also in Mongolian.</li> <li>Service manual must be provided (including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits). In English, French and preferably also in Mongolian.</li> <li>List of common spare parts and accessories with part numbers must be provided.</li> <li>Manufacturer authorization letter.</li> <li>Commitment Manufacturer letter, including: <ul style="list-style-type: none"> <li>at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause "Warranty").</li> <li>at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause "Post-sale Services").</li> <li>training on use, cleaning, disinfecting for healthcare staff and basic maintenance technical staff, in English and Mongolian. (according to the general requirements in the bid document under the clause "Training").</li> </ul> </li> </ul> <p><b>Regulatory approvals required:</b></p> <ul style="list-style-type: none"> <li>Valid Mongolian official Import license from the main manufacturer for receiving, installing, and maintaining medical equipment in Mongolia.</li> <li>And at least one of the following regulatory approvals and certificates: <ul style="list-style-type: none"> <li>European Certificate of Conformity (CE) with Regulation 2017/745 or Directive 93/42 EC and Agreement Letter signed</li> </ul> </li> </ul>	
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		<p>with the NB demonstrating the on-going MDR application, for Class IIa devices, or</p> <ul style="list-style-type: none"> <li>◦ FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or</li> <li>◦ Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan.</li> </ul> <p><b>Safety &amp; product Standards:</b>  Bidder shall furnish the following documents:</p> <ul style="list-style-type: none"> <li>● Valid ISO 13485 certificate.</li> <li>● Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety &amp; regulatory standards: <ul style="list-style-type: none"> <li>◦ IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance</li> <li>◦ 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</li> <li>◦ IEC 60601-2-37 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.</li> <li>◦ IEC 61157 Declaration of acoustic output parameters.</li> </ul> </li> </ul>	
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**General condition for all items:**

Whether it is included specifically in the technical specification or not, the installation, commissioning and training of personnel should be carried out by the supplier for all items.

## 2.2. Schedule of Requirements for LOT 1

The Bidder shall also furnish a list giving full particulars, including available sources and current prices of spare parts, special tools, etc., necessary for the proper and continuing functioning of the goods for **5 years** following commencement of the use of the goods by UNFPA.

a. List of Goods and Delivery Schedule				
Line Item	Description of Goods	Quantity	Unit of measure	Desired Delivery Schedule from date of Contract
Item 1 (OR 1)	Activated Clotting Time (ACT) Measuring device	2	Each	As soon as possible.  Note that the Delivery time will also serve as an additional evaluation criterion
Item 3 (OR 3)	Extra Corporeal Circulation (ECC) Machine	1	Each	
Item 4 (OR 4)	Hypo-hyperthermia Machine	1	Each	
Item 5 (OR 33)	Patient Auto-Transfusion System	1	Each	
Item 12 (OR 19)	Brain Monitoring System	1	Each	
Item 22 (OR 32)	Portable external pacemaker	3	Each	
Item 23 (OR 34)	Patient drainage system	1	Each	
Item 25 (OR 38)	Surgeon's headlamp	1	Each	
Item 26 (ICU 3)	Dialysis Equipment for Neonate - Peritoneal dialysis system	1	Each	

b. Consignee Address and Consignee-wise Quantity Distribution				
Line Item	Consignee Address	Contact person	Quantity	Unit of measure
Item 1 (OR 1).	National Center for Maternal and Child Healthcare (NCMCH), "Huvisgalchdiin" street, Bayangol district, Ulaanbaatar 16060, Tel: 976-11 362205	Tsetsenbaatar Batsuuri, Procurement associate, UNFPA Mongolia, Tel: 976-11-353503 (ext3355), <a href="mailto:batsuuri@unfpa.org">batsuuri@unfpa.org</a>	2	Each
Item 3 (OR 3).			1	Each
Item 4 (OR 4).			1	Each
Item 5 (OR 33).			1	Each
Item 12 (OR 19).			1	Each
Item 22 (OR 32).			3	Each
Item 23 (OR 34).			1	Each
Item 25 (OR 38).			1	Each
Item 26 (ICU 3).			1	Each

**c. List of Related Services and Completion Schedule**

<b>No</b>	<b>Description of Service</b>	<b>Qty</b>	<b>Place where Services shall be performed</b>	<b>Final Completion Date(s) of Services</b>
<b>1</b>	<b>Installation and commissioning.</b> The supplier performs the installation and commissioning for all items.	1	NCMCH	Within 1 weeks upon completion of delivery
<b>2</b>	<b>Training</b> on use, cleaning, disinfecting for healthcare staff and basic maintenance technical staff, in English and Mongolian for all items.  Please also review the requirement included in the technical specification of each item.	1	NCMCH	Within 2 weeks upon completion of delivery and installation
<b>3</b>	<b>After sale service.</b> A minimum of two years of in-country after-sale services by an authorized local service provider.	1	NCMCH	2 years

### 2.3. Schedule of Requirements for LOT 2

The Bidder shall also furnish a list giving full particulars, including available sources and current prices of spare parts, special tools, etc., necessary for the proper and continuing functioning of the goods for 5 years following commencement of the use of the goods by UNFPA.

a. List of Goods and Delivery Schedule				
Line Item	Description of Goods	Quantity	UOM	Desired Delivery Schedule from date of Contract
Item A	Cardiotocograph (CTG)	22	Each	As soon as possible.  Note that the Delivery time will also serve as an additional evaluation criterion
Item B	Portable ultrasound scanner	22	Each	

b. Consignee Address and Consignee-wise Quantity Distribution					
Line Item	Consignee Address	Contact person	Quantity		Unit of measure
			Item A	Item B	
Item A & Item B	Family Health Center of Sukhbaatar district, Ulaanbaatar city	Jargalsaikh an Buzmaa, ICT/Logistics associate, UNFPA Mongolia country office Cell phone: 990 90761 Email: buzmaa@unfpa.org	1	1	Each
	Family Health Center of Bayanzurkh district, Ulaanbaatar city		1	1	Each
	Family Health Center of Bayanlig soum, Bayankhongor province		1	1	Each
	Family Health Center of Bayangovi soum, Bayankhongor province		1	1	Each
	Family Health Center of Bulgan soum, Bayan-Ulgii		1	1	Each
	Family Health Center of Nogoongnuur soum, Bayan-Ulgii		1	1	Each
	Family Health Center of Rashaant soum, Bulgan province		1	1	Each
	Family Health Center of Teshig soum, Bulgan province		1	1	Each
	Family Health Center of Sharingol soum, Darkhan-Uul province		1	1	Each
	Family Health Center of Chuluunkhoroot soum, Dornod province		1	1	Each
	Family Health Center of Dashbalbar soum, Dornod province		1	1	Each
	Family Health Center of Bulgan soum, Khovd province		1	1	Each
	Family Health Center of Zereg soum, Khovd province		1	1	Each

	Family Health Center of Renchinlumbe soum, Khuvsgul province		1	1	Each
	Family Health Center of Tsagaannuur soum		1	1	Each
	Family Health Center of Bat-Ulzii soum, Uvurkhangai province		1	1	Each
	Family Health Center of Bogd, Uvurkhangai province		1	1	Each
	Family Health Center of Khujirt, Uvurkhangai province		1	1	Each
	Family Health Center of Gurvantes soum, Umnugobi province		1	1	Each
	Family Health Center of Tsogttsetsii soum, Umnugobi province		1	1	Each
	Family Health Center of Ikh-Uul soum, Zavkhan province		1	1	Each
	Family Health Center of Tudevtei soum, Zavkhan province		1	1	Each

**c. List of Related Services and Completion Schedule**

No	Description of Service	Quantity	Physical Unit	Place where Services shall be performed	Final Completion Date(s) of Services
1	Local freight service for delivery of the supplied items from UB to the end users located in 22 soums/districts in 10 provinces and Ulaanbaatar (please see the consignee address above)	1	22	In Mongolia	14 days
2	Installation, configuration and calibration	1	22	22 named places (please see consignee address above)	14 days
3	User training in Mongolian	1	22	22 named places (please see consignee address above)	14 days
4	On site warranty and after sales service for item	1	22	22 named places (please see consignee address above)	2 years

### **SECTION III: UNFPA General Conditions of Contract**

UNFPA General Conditions of Contract can be found at:

<http://www.unfpa.org/resources/unfpa-general-conditions-contract>

#### SECTION IV: UNFPA Special Conditions for Contracts

<b>CONTRACT PRICE</b>	The prices charged for the Goods supplied and the related Services performed shall not be adjustable.
<b>PERFORMANCE SECURITY</b>	<p>A Performance Security "Shall" be required.</p> <p>"The Performance Security in original shall be submitted within ten working days from the date of the contract"</p> <p>The amount of the Performance Security shall be 10 % of the Contract Price.</p> <p>The Performance Security shall be unconditional and irrevocable and in the form of either:</p> <ul style="list-style-type: none"> <li>• An unconditional Bank Guarantee</li> <li>• A Demand Draft</li> <li>• A Cashier's Cheque</li> <li>• A Certified Cheque</li> </ul> <p>In the event of Suppliers submitting the Performance Security in the form of a Cheque or Demand Draft in favour of UNFPA, such documents shall be accompanied by a signed statement from the issuing bank on its letterhead indicating the validity period and confirming irrevocability of the Cheque or Demand draft during the required period.</p> <p>Banks issuing Performance Securities must be acceptable to the UNFPA Comptroller, i.e. they have to be banks certified by the Central bank of the country to operate as commercial bank.</p> <p>The Performance Security shall be denominated in the currencies of payment of the Contract, in accordance with their portions of the Contract Price, and shall have a validity period of forty-five (45) days after the date of delivery indicated in the Contract days. UNFPA reserves the right to request an extension of the Performance Security.</p> <p>Discharge of the Performance Security shall take place upon expiry of the Performance Security or upon confirmation of receipt of the Goods by the Consignee. The Performance Security shall then be returned to the Supplier by UNOPS.</p>
<b>WARRANTY</b>	The warranty period shall be <b>24</b> months. Details on Warranty Services required are included in Section II: Technical Specifications and Schedule of Requirements.

<b>GOODS AND SERVICES DEFINED</b>	<p>Goods are hereinafter deemed to include, without limitation, equipment, spare parts, commodities, raw materials, components, customized and standard software as required, intermediate products and products which the Supplier is required to supply under the Purchase Order.</p> <p>Services are to include design, installation and commissioning, training services, technical assistance and warranty services as required to supply in the Purchase Order.</p>
<b>AFTER SALES SERVICES</b>	A minimum of two years of in-country after-sale services by an authorized local service provider.
<b>TRANSPORTATION AND FREIGHT</b>	<p>Responsibility for transportation of the Goods shall be as specified in the INCOTERMS.</p> <p>Partial shipment <i>is</i> allowed. Transshipment <i>is</i> allowed.</p>
<b>LIQUATED DAMAGES</b>	In the event of a Contract being issued and in case the Vendor fails to deliver all the goods by the date or dates of delivery specified in the Purchase Order, UNFPA reserves the rights to claim liquidated damages from the Vendor and deduct 1% of the value of the goods pursuant to the Purchase Order per additional week of delay, up to a maximum of 10% of the value of the Purchase Order. The payment or deduction of such liquidated damages shall not relieve the Vendor from any of its other obligations or liabilities pursuant to any current Long-Term Agreement or Purchase Order.



## SECTION V: Bidding Forms

The following checklist is provided as a courtesy to Bidders. Please use this checklist while preparing the bid to ensure that your bid contains all required information. This checklist is for the Bidder's internal reference and does not need to be submitted with the bid.

ACTIVITY	LOCATION	YES / NO/ NOT APPLICABLE	REMARKS
Have you read and understood all of the Instructions to Bidders in Section I of the bidding documents?	Section I		
Have you reviewed and agreed to the UNFPA General Conditions of Contract?	Section III		
Have you reviewed and agreed to the UNFPA Special Conditions for Contracts?	Section IV		
Have you completed the Bid Confirmation Form?	Section V, 1		
Have you completed the Bid Submission Form?	Section V, 2		
Have you completed the Product Item Overview Form?	Section V, 5		
Have you completed and signed the Price Schedule Form?	Section V, 4		
Have you reviewed all of the relevant contract form(s)?	Section VI		
<i>[Delete if not applicable]</i> Have you prepared a copy of your valid manufacturing license from the country of manufacturing?	Section 1, Sub-Clause 10.2, b.		
Have you prepared documentary evidence that the goods conform to the technical specifications and standards specified in Section II Technical Specifications and Schedule of Requirements?	Section I, Sub-Clause 10.3, a.		

Have you prepared product catalogues containing pictures of the product(s)?	Section I, Sub-Clause 10.3, c.		
Have you prepared the manufacturer's technical product specifications or data sheets?	Section I, Sub-Clause 10.3, d.		
Have you provided the results of any testing carried out on the products?	Section I, Sub-Clause 10.3, a.		
Have you provided any copies of current certificates such as GMP/Quality, FSC/CPP, manufacturer's ISO certificate for the product, manufacturer's CE certificate, USA510k, Japan QS standard, etc. as stated in the Technical Specifications and Schedule of Requirements, in Section II?	Section I, Sub-Clause 10.3, g.		
Have you provided a copy of the valid authorization letter issued by the manufacturer for each product, if you are not the manufacturer?	Section I, Sub-Clause 10.3, h.		
Have you furnished a list of <u>full</u> particulars, regarding the available sources and current prices of space parts, special tools, etc., necessary for the proper and continuing functions of the goods within the Product Item Overview Form, Section V, 3?	Section I, Sub-Clause 10.3, i.		
Have you sealed and marked the bids according to Instructions to Bidders Clause 16 Electronic Submission?	Section I, Clause 16		
Is the file size of the bid less than 10MB? (If the file size is above 10MB, refer to Instructions to Bidders Sub-Clause 16.3)	Section I, Sub-Clause 16.3		

Have you noted the bid closing deadline?	Cover letter and Section I, Clause 17		
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### 1. Bid Confirmation Form

*[Complete this page and return it prior to bid opening]*

		Date:
To:	<b>UNFPA</b> <b>Natalia Gioertz-Behrens</b>	email: <a href="mailto:behrens@unfpa.org">behrens@unfpa.org</a>
From:	<i>[Company name]</i>	
	<i>[Contact person]</i>	
	<i>[Telephone]</i>	
	<i>[Email address]</i>	
	<i>[Postal address]</i>	
Subject:	LIB No.: UNFPA/MNG/LIB/24/020	

YES, we intend to submit a bid.

NO, we are unable to submit a bid in response to the above mentioned Invitation to Bid due to the following reason(s):

- ☐ The requested products and services are not within our range of supply
- ☐ We are unable to submit a competitive bid for the requested products at the moment
- ☐ The requested products are not available at the moment
- ☐ We cannot meet the requested specifications
- ☐ We cannot offer the requested type of packing
- ☐ We can only offer FCA prices
- ☐ The information provided for quotation purposes is insufficient
- ☐ Your LIB is too complicated
- ☐ Insufficient time is allowed to prepare a quotation
- ☐ We cannot meet the delivery requirements
- ☐ We cannot adhere to your terms and conditions (please specify: payment terms, request for performance security, etc)
- ☐ We do not export
- ☐ Our production capacity is currently full
- ☐ We are closed during the holiday season
- ☐ We had to give priority to other clients' requests
- ☐ We do not sell directly, but through distributors
- ☐ We have no after-sales service available in the recipient country
- ☐ The person handling bid is away from the office
- ☐ Other (please specify)

If UNFPA has questions to the Bidder concerning this NO BID, UNFPA should contact Mr./Ms. \_\_\_\_\_, phone/email \_\_\_\_\_, who will be able to assist.

## 2. Bid Submission Form

*[The Bidder shall fill in this form in accordance with the instructions indicated. No alterations to its format shall be permitted and no substitutions shall be accepted.]*

**Date:** *[insert date (as day, month and year) of Bid Submission]*

**LIB No.:** UNFPA/MNG/LIB/24/020

To: Natalia Giortz-Behrens, UNFPA

Dear Sir / Madam,

We the Undersigned have examined and have no reservations to the Bidding Documents No. UNFPA/CC/YY/NNN and amendments We hereby offers to supply, in conformity with the Bidding Documents and in accordance with the Delivery Schedules specified in the Schedule of Requirements, the following goods and related services \_\_\_\_\_ which are subject to UNFPA General Conditions of Contract and other terms and conditions as specified in the document.

We agree to abide by this bid for a period of *[Select between 30-90 days depending on the type of good/commodity]* days from the date fixed for opening of bids in the Invitation to Bid, and it shall remain binding upon us and may be accepted at any time before the expiration of that period.

We have no conflict of interest in accordance with Instructions to Bidders Sub-Clause 2.3;

Our firm, its affiliates or subsidiaries—including any subcontractors or suppliers for any part of the contract—have not been declared ineligible by UNFPA, in accordance with Instructions to Bidders Sub-Clause 2.4;

We understand that you are not bound to accept the lowest evaluated bid or any other bid that you may receive.

Dated on .....day of .....[year].

Signature:	..... <i>[insert signature of person whose name and capacity are shown]</i>
In the capacity of:	..... <i>[insert legal capacity of person signing the Bid Submission Form]</i>
Name:	..... <i>[insert complete name of person signing the Bid Submission Form]</i>

Company:	<p>.....</p> <p><i>[insert name of company]</i></p>
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**1. 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)	

**2. Expertise of Staff**

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

**3. 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

### 3. Product Item Overview Form

Item No.	Description and minimum /mandatory specifications	Description of items offered and Bidder's statements on deviations  (To be completed by the bidder)  <b>Please note that bidders should provide their own technical specifications rather than copying and pasting the specifications provided by UNFPA.</b>	Compliant? (Y/N)  (To be completed by UNFPA during evaluation)
1	[Bidder is asked to copy here technical specifications from Section II which is offered]	[Bidder is asked to write here technical specifications from Section II for each offered item and statements on deviations]	



#### 4. Price Schedule Form

[The Bidder shall fill in these Price Schedule Forms in accordance with the instructions indicated. The list of line items in column 1 of the **Price Schedules** shall coincide with the list of goods and related services specified by UNFPA in the Schedule of Requirements.]

##### LOT 1.

LOT 1. BIDDER'S TOTAL PRICES (Price & Currency to be entered by Bidder):	
TOTAL FIRM FCA PRICE	
TOTAL FIRM DAP PRICE	
TOTAL PRICE FOR SERVICES <i>(if applicable)</i>	
FREIGHT COST PER 20/40 FT CONTAINER <i>(if applicable)</i>	

LOT 1. BIDDER'S PRICES FOR GOODS (Price & Currency to be entered by Bidder):						
PLEASE PROVIDE A COMPLETE LIST OF SPARE PARTS, SPECIAL TOOLS, AND OTHER ITEMS NECESSARY FOR THE PROPER AND CONTINUOUS OPERATION OF THE ITEMS OVER A 5-YEAR PERIOD.						
ITEM	DESCRIPTION OF THE GOODS	QTY (a)	CURRENCY:			
			UNIT PRICE FCA (b)	UNIT PRICE DAP (c)	TOTAL PRICE FCA (a)x(b)	TOTAL PRICE DAP (a)x(c)
1.						
2.	<i>Insert more rows if necessary</i>					
3.	<i>or delete if too many</i>					
4.						
5.						

BIDDER'S PRICES FOR SERVICES (Price & Currency to be entered by Bidder):					
ITEM/ LOT	DESCRIPTION OF THE SERVICES	COUNTRY OF ORIGIN	QUANTITY AND PHYSICAL UNIT (a)	UNIT PRICE (b)	TOTAL PRICE PER SERVICE (a)x(b)

1.	e.g. Comprehensive Annual Maintenance Contract				
2.	<i>Insert more rows if necessary</i>				
3.	<i>or delete if too many</i>				
4.					
5.					

BIDDER'S DELIVERY DATA					
Country of origin of offered products:	Item 1				
	Item 3	<i>Insert more rows in each section if necessary</i>			
	Item 4	<i>or delete if too many</i>			
	Item 5				
	Item 12				
FCA point(s) of delivery for offered products:	Item 1				
	Item 3				
	Item 4				
	Item 5				
	Item 12				
Delivery time (FCA from date of order):	Item 1				
	Item 3				
	Item 4				
	Item 5				
	Item 12				
Shipment dimensions of offered products (including package):		Gross weight	Total volume	<i>Containers (if applicable):</i>	
				<i>Number</i>	<i>Size</i>
	Item 1				
	Item 3				
	Item 4				

	Item 5				
	Item 12				
	Total				

**BIDDER'S SIGNATURE AND CONFIRMATION OF THE LIB**

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.

*Exact name and address of company*

COMPANY NAME \_\_\_\_\_

\_\_\_\_\_

ADDRESS \_\_\_\_\_

\_\_\_\_\_

PHONE NO. \_\_\_\_\_ FAX NO. \_\_\_\_\_

EMAIL ADDRESS OF CONTACT PERSON \_\_\_\_\_

OTHER EMAIL ADDRESSES \_\_\_\_\_

\_\_\_\_\_  
**AUTHORIZED SIGNATURE**

\_\_\_\_\_  
**DATE**

\_\_\_\_\_  
NAME OF AUTHORIZED SIGNATORY (TYPE OR PRINT)

\_\_\_\_\_  
FUNCTIONAL TITLE OF SIGNATORY

\_\_\_\_\_  
**WEB SITE**

\_\_\_\_\_

**LOT 2.**

<b>LOT 2. BIDDER'S TOTAL PRICES (Price &amp; Currency to be entered by Bidder):</b>	
TOTAL FIRM FCA PRICE	
TOTAL FIRM CPT PRICE	
TOTAL PRICE FOR SERVICES <i>(if applicable)</i>	
FREIGHT COST PER 20/40 FT CONTAINER <i>(if applicable)</i>	

<b>LOT 2. BIDDER'S PRICES FOR GOODS (Price &amp; Currency to be entered by Bidder):</b>						
<b>PLEASE PROVIDE A COMPLETE LIST OF SPARE PARTS, SPECIAL TOOLS, AND OTHER ITEMS NECESSARY FOR THE PROPER AND CONTINUOUS OPERATION OF THE ITEMS OVER A 5-YEAR PERIOD.</b>						
ITEM	DESCRIPTION OF THE GOODS	QTY (a)	CURRENCY:			
			UNIT PRICE FCA (b)	UNIT PRICE CPT (c)	TOTAL PRICE FCA (a)x(b)	TOTAL PRICE CPT (a)x(c)
Item A						
Item B						

<b>BIDDER'S PRICES FOR SERVICES (Price &amp; Currency to be entered by Bidder):</b>					
ITEM	DESCRIPTION OF THE SERVICES	COUNTRY OF ORIGIN	QUANTITY AND PHYSICAL UNIT (a)	UNIT PRICE (b)	TOTAL PRICE PER SERVICE (a)x(b)
Item A & B	Local freight service for delivery of the supplied items from UB to the end users located in 22 soums/districts in 10 provinces and Ulaanbaatar (please see the consignee address above)				
Item A & B	Installation, configuration and calibration				

Item A & B	User training in Mongolian				
Item A & B	On site warranty and after sales service for item				

BIDDER'S DELIVERY DATA					
Country of origin of offered products:	Item A				
	Item B				
FCA point(s) of delivery for offered products:	Item A				
	Item B				
Delivery time (FCA from date of order):	Item A				
	Item B				
Shipment dimensions of offered products (including package):		Gross weight	Total volume	Containers (if applicable):	
				Number	Size
	Item A				
	Item B				
	Total				

BIDDER'S SIGNATURE AND CONFIRMATION OF THE LIB
<p>PROVIDED THAT A PURCHASE ORDER IS ISSUED BY UNFPA <b>WITHIN THE REQUIRED BID VALIDITY PERIOD</b>, 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.</p>

<p><i>Exact name and address of company</i></p> <p>COMPANY NAME _____</p> <p>_____</p> <p>ADDRESS _____</p> <p>_____</p> <p>PHONE NO. _____ FAX NO. _____</p> <p>EMAIL ADDRESS OF CONTACT PERSON _____</p> <p>OTHER EMAIL ADDRESSES _____</p>	<p>_____</p> <p><b>AUTHORIZED SIGNATURE</b> <b>DATE</b></p> <p>_____</p> <p>NAME OF AUTHORIZED SIGNATORY (TYPE OR PRINT)</p> <p>_____</p> <p>FUNCTIONAL TITLE OF SIGNATORY</p> <p>_____</p> <p><b>WEB SITE</b> _____</p>
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## SECTION VI: Contract Forms

### 1. Bank Guarantee for Advance Payment

*[Insert one of the following: No advance payment shall be made. / The bank, as requested by the successful Bidder, shall fill in this form in accordance with the instructions indicated.]*

Date: *[insert date (as day, month, and year) of Bid Submission]*

No: UNFPA/MNG/LIB/24/020

*[bank's letterhead]*

**Beneficiary:** *[insert legal name and address of UNFPA]*

**ADVANCE PAYMENT GUARANTEE No.:** *[insert Advance Payment Guarantee no.]*

We, *[insert legal name and address of bank]*, have been informed that *[insert complete name and address of Supplier]* (hereinafter called "the Supplier") has entered into Contract No. *[insert number]* dated *[insert date of Agreement]* with you, for the supply of *[insert types of goods to be delivered]* (hereinafter called "the Contract").

Furthermore, we understand that, according to the conditions of the contract, an advance is to be made against an advance payment guarantee.

At the request of the supplier, we hereby irrevocably undertake to pay you any sum or sums not exceeding in total an amount of *[insert amount(s)]*<sup>6</sup> *in figures and words* upon receipt by us of your first demand in writing declaring that the supplier is in breach of its obligation under the Contract because the supplier used the advance payment for purposes other than toward delivery of the goods.

It is a condition for any claim and payment under this guarantee to be made that the advance payment referred to above must have been received by the Supplier on its account *[insert number and domicile of the account]*. This guarantee shall remain valid and in full effect from the date of the advance payment received by the supplier under the contract until *[insert date]*<sup>7</sup>.

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*[signature(s) of authorized representative(s) of the bank]*

<sup>6</sup> The bank shall insert the amount(s), either in the currency(ies) of the contract or a freely convertible currency acceptable to UNFPA.

<sup>7</sup> Insert the delivery date stipulated in the contract delivery schedule. UNFPA should note that in the event of an extension of the time to perform the contract, UNFPA would need to request an extension of this guarantee from the bank. Such request must be in writing and must be made prior to the expiration date established in the guarantee. In preparing this guarantee, UNFPA might consider adding the following text to the Form, at the end of the penultimate paragraph: "We agree to a one-time extension of this guarantee for a period not to exceed [six months/one year], in response to UNFPA's written request for such extension, such request to be presented to us before the expiry of the guarantee."

## 2. Performance Security

*[Insert one of the following: No Performance Security shall be requested.*

*Or*

*The bank, as requested by the successful Bidder, shall fill in this form in accordance with the instructions indicated]*

Date: *[insert date (as day, month, and year) of Bid Submission]*

No. and title: No: UNFPA/MNG/LIB/24/020

Bank's Branch or Office: *[insert complete name of Guarantor]*

Beneficiary: *[insert legal name and address of UNFPA]*

PERFORMANCE GUARANTEE No.: *[insert Performance Guarantee number]*

We have been informed that *[insert complete name of Supplier]* (hereinafter called "the Supplier") has entered into Contract No. *[insert number]* dated *[insert day and month]*, *[insert year]* with you, for the supply of *[description of Goods and related Services]* (hereinafter called "the Contract"). Furthermore, we understand that, according to the conditions of the Contract, a Performance Guarantee is required.

At the request of the Supplier, we hereby irrevocably undertake to pay you any sum(s) not exceeding *[insert amount(s)]*<sup>8</sup> *in figures and words* upon receipt by us of your first demand in writing declaring the Supplier to be in default under the Contract, without cavil or argument, or your needing to prove or to show grounds or reasons for your demand or the sum specified therein.

This Guarantee shall expire no later than the *[insert number]* day of *[insert month]* *[insert year]*,<sup>9</sup> and any demand for payment under it must be received by us at this office on or before that date. This guarantee is subject to the Uniform Rules for Demand Guarantees, ICC Publication No. 458, except that subparagraph (ii) of Sub-article 20(a) is hereby excluded.

*[signatures of authorized representatives of the bank and the Supplier]*

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<sup>8</sup> The Bank shall insert the amount(s) specified in the SCG and denominated, as specified in the SCG, either in the currency(ies) of the Contract or a freely convertible currency acceptable to UNFPA.

<sup>9</sup> UNFPA should note that in the event of an extension of the time to perform the Contract, UNFPA would need to request an extension of this Guarantee from the Bank. Such request must be in writing and must be made prior to the expiration date established in the Guarantee. In preparing this Guarantee, UNFPA might consider adding the following text to the Form, at the end of the penultimate paragraph: "We agree to a one-time extension of this Guarantee for a period not to exceed [six months] [one year], in response to UNFPA's written request for such extension, such request to be presented to us before the expiry of the Guarantee."



### **3. Contract Forms**

The following sample contract form is available on the UNFPA procurement website:

[1. Purchase Order](#)

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