

Template Emergency ITB document



United Nations Population Fund (UNFPA)
 Palestine Country Office
 26 Nablus Road, Khan ElOmdan Building
 Tel: +972 2 581 7167
 Website: <https://palestine.unfpa.org/en>

Date: 08th November 2024

Invitation to Bid (ITB) No. UNFPA-PAL-ITB-2024-011

RH Medical Equipment

Dear Sir/Madam,

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

Item No.	Item	UoM	Estimated Quantity
1	Examination Table	Each	15
2	Sterilizer,steam,40L,electric,w/access	Each	20
3	Sphygmomanometer, aneroid, adult	Each	76
4	Stethoscope, binaural, complete	Each	76
5	Stethoscope, obstetrical, Pinard, monoaural	Each	152
6	Thermometer, clinical, digital, 32–43°C	Each	304
7	Resuscitator, hand operated, child/newborn	Each	104
8	Scale, infant, spring type, 5 kg × 25 g	Each	76
9	Timer, mechanical, battery less, respiration rate measurement	Each	228
10	Vacuum extractor, Bird, anterior + posterior cups, manual, set	Each	28

Item No.	Item	UoM	Estimated Quantity
11	Pump, suction, foot operated, aspirator	Each	28
12	Resuscitator, hand operated, neonate, set	Set	28
13	Resuscitator, hand operated, adult, set	Set	28

Notes:

- *UNFPA preserves the right to adjust (increase/decrease) quantities without incurring any additional charges.*

Bid Submission:

If you are interested in submitting a bid for these items, kindly fill in the attached submission forms and send to the secure email address not later than **24th November 2024 at 14:00 Palestine local time**

Please ensure to mark your email with the ITB reference number and the words “Do not open before {**24 Nov. 2024 at 14:00 Palestine local time**}”.

Secure email address for bid submission: palestine.proc@unfpa.org

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

Questions or Clarifications related to the Bid:

Any questions or clarifications relating to the Bid process and/or to the attached documents shall be sent to: **Nibal Qundos** and **Razan Khalilieh** at emails: gundos@unfpa.org / khalilieh@unfpa.org no later than **15th November 2024**

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

Documents to be submitted with the bid:**DOCUMENT CHECKLIST - Please remember to submit the following documents:**

Note: Bidders are requested to name files clearly and organize documents by category to streamline the review process.

No.	DOCUMENT NAME	<input type="checkbox"/>
1	Annex 1 - Bid Submission Form - Completed and Signed	<input type="checkbox"/>
2	Annex 2 - Bidders Identification Form - Completed	<input type="checkbox"/>
3	Annex 3 - Product Item Overview Form - Completed	<input type="checkbox"/>
4	Annex 5 - Price Schedule Form - Completed and Signed	<input type="checkbox"/>
5	A statement whether any import or export licenses are required in respect of the goods to be purchased including any restrictions on the country of origin, use/dual use nature of goods or services, including and disposition to end users;	<input type="checkbox"/>
6.1	- Latest Business Registration Certificate.	<input type="checkbox"/>
6.2	- Latest Internal Revenue Certificate / Tax Clearance.	<input type="checkbox"/>
6.3	- Manufacturer's Authorization of the Company as a Sales Agent (if Bidder is not the manufacturer);	<input type="checkbox"/>
7	Certificate of Exclusive Distributorship in the country (if applicable, and if Bidder is not the manufacturer);	<input type="checkbox"/>
8	Complete documentation, information and declaration of any goods classified or may be classified as "Dangerous Goods"	<input type="checkbox"/>
9	Patent Registration Certificates (if any of technologies submitted in the quotation is patented by the Supplier)	<input type="checkbox"/>
10	Written Self-Declaration of not being included in the UN Security Council 1267/1989 list, UN Procurement Division List or other UN Ineligibility List	<input type="checkbox"/>
11	Complete Technical bid submission, including detailed Technical Specifications, product catalogue, technical data sheets and schematic drawings (when applicable) to demonstrate that specification and quality of the products are in line with the requirements listed in the bidding document.	<input type="checkbox"/>

No.	DOCUMENT NAME	<input type="checkbox"/>
12	<p>Quality Assurance Documents to be submitted: Below are Guidelines describing the minimum documentation required to be submitted by the bidders and can be found in the tables below as per each product group: Pharmaceuticals, medical devices and IVDs.</p> <p>All certificates and approvals must be valid at the time of bid submission.</p>	
12.1	<p>Documents to be submitted for Medical Devices:</p> <ul style="list-style-type: none"> ● Annex 4 - Fast Track Procurement Questionnaire for Medical Devices - duly completed by bidder and signed for <u>each of the items included in the submission.</u> ● Minimum documentation as per below table corresponding to classification of Medical Devices (ref. European Commission, MEDDEV 93/42/EEC). ● Photos of the medical devices product and packaging (preferably in a format where the dimension and features can be visible). 	<input type="checkbox"/>

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

No.	DOCUMENT NAME	<input type="checkbox"/>
<p>Examples of products in each of the Medical Device EC MEDDEV class:</p> <ul style="list-style-type: none"> • Class I (non-measuring, non-sterile and/or non-reusable surgical instrument) Aprons, bags, baskets, bowls, etc. (largest item class group in UNFPA procurement catalog). • Class I (measuring, sterile and/or reusable surgical instrument) Thermometers, scales, catheters, cytobrushes, sterile surgical and gynecological instruments, sterile gloves and supplies, reusable surgical and gynecological instruments, etc. • Class IIa: Cannulas, needles, blades, pumps (manual, electrical), resuscitators, etc. (Many of the class IIa products are also sterile products.) • Class IIb and III: Anaesthesia machines, cryosurgical units, sutures, baby warmers and incubators, infusion pumps etc. 		

Partial Bids:

Partial bids are **allowed** under this ITB. Partial bids mean that the bidder does not have to offer all requested items in order to submit a complete bid. However, within each item, full quantities must be offered.

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

UNFPA reserves the right to select and accept a part or parts of any Bid submitted.

Pre-Bid Meeting:

A pre-bid meeting will be held on **13th November 2024** via Google Meet. This meeting aims to provide potential bidders with an opportunity to seek clarification on the tender requirements, ask questions, and discuss the submission process. Attendance is strongly encouraged to ensure a comprehensive understanding of the tender specifications.

Google Meet info:

RH Medical Equipment (UNFPA-PAL-ITB-2024-011)

Wednesday, November 13, 2024 at 11:00 – 12:00 / Time zone: Asia/Hebron

Video call link: <https://meet.google.com/dkt-mygc-tnq>

Or dial: (US) +1 414-909-5259 PIN: 818 369 746#

More phone numbers: <https://tel.meet/dkt-mygc-tnq?pin=2328484417094>

INCOTERMS 2020 & Delivery Destination:

Delivery Options are as follows:

1. DAP Al Arish, Egypt / Port Said

2. DAP Cairo Airport

3. DAP Ashdod Port

4. DAP Amman warehouse, Jordan

5. DAP Kerem Shalom Crossing

6. DDP Ramallah, Palestine

For deliveries to **Gaza**, the assigned delivery end point will be selected from Options 1–5, as determined by logistical requirements.

For deliveries to the **West Bank**, the delivery end point will be restricted to Option 6.

Currency:

Prices shall be quoted in **USD**

- For Bidders with Palestinian Registration: **Prices must be EXCLUSIVE OF VAT. (UNFPA will provide Tax Exemption to the Supplier)**
- For International Bidders: **Prices must be INCLUSIVE OF VAT/TAX. (UNFPA will **NOT** provide Tax Exemption to the Supplier)**

Validity of Bid:

The prices of the bid shall be valid for **180 days** after the closing date of bid submission as specified by UNFPA. A bid valid for a shorter period shall be rejected by UNFPA.

Delivery Time:

Bidders are requested to fill the delivery lead time in “Annex 5 - Price Schedule Form”.

Technically accepted offers will be evaluated on unit cost and delivery lead times, with preference given to offers that combine competitive pricing and lead times.

Evaluation of Bids:

UNFPA shall compare all substantially responsive bids to determine the lowest priced substantially responsive bid considering the delivery lead time.

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

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

Contract Award:

UNFPA shall award multiple Long-Term Agreements (LTAs) to the lowest priced bidder(s) for each designated delivery destination, provided the bid has been determined to be substantially responsive with the bidding documents. Note: The technically acceptable lowest priced offer will be evaluated Item by Item per each delivery destination.

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

Name: Farah Altarifi

Title: Humanitarian Supplies Logistics Specialist Team Lead
Palestine Country Office

DocuSigned by:

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Attachments:

- **Annex 1 - Bid Submission Form**
- **Annex 2 - Bidders Identification Form**
- **Annex 3 - Product Item Overview Form**
- **Annex 4 - Fast Track Procurement Questionnaire (Attached)**
- **Annex 5 - Price Schedule Form (Attached)**
- **Annex 6 - Technical Specification**

Annex 1 - Bid Submission Form

Invitation to Bid (ITB) No. UNFPA-PAL-ITB-2024-011

Name of Bidder:	
Contact Person:	
Title:	
Email Address:	
Telephone Number:	
Date of Bid:	
Bid No:	
Currency of Bid price:	
Delivery time <i>(days from receipt of order till dispatch):</i>	
Expiration of Validity of Bid/Proposal <i>(The bid shall be valid for a period of at least 180 days after the Closing date.):</i>	

<i>Vendor's Comments:</i>

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

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

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

Name and title

Date and Place

Annex 2 - Bidders Identification Form
Invitation to Bid (ITB) No. UNFPA-PAL-ITB-2024-011

1. Organization

Company/Institution Name	
Address, City, Country	
Telephone/FAX	
Website	
Date of establishment	
Legal Representative: Name/Surname/Position	
Legal structure: natural person/Co.Ltd, NGO/institution/other (please specify)	
Organizational Type: Manufacturer, Wholesaler, Trader, Service provider, etc.	
Areas of expertise of the organization	
Current Licenses, if any, and permits (with dates, numbers and expiration dates)	
Years supplying to UN organizations	
Years supplying to UNFPA	
Production Capacity	

Subsidiaries in the region (please indicate names of subsidiaries and addresses, if relevant to the bid)	
Commercial Representatives in the country: Name/Address/Phone (for international companies only)	

2. Quality Assurance Certification

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

3. Expertise of Staff

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

4. Client Reference List

Please provide references of main client details.

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

5. Previous Experience and Similar main projects

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

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

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

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

Annex 3 - Product Item Overview Form
Invitation to Bid (ITB) No. UNFPA-PAL-ITB-2024-011

Product’s adherence to specifications

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

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

Note: For any items not included in your bid, please leave the relevant fields blank or enter "N/A" (Not Applicable) to indicate no bid for that item.

Item No.	Description and Minimum* / Mandatory Specifications <i>[Please refer to Annex 6 for detailed description. Click on the item name to navigate directly].</i>	Description of items offered and Bidder’s statements on deviations <i>(To be completed by the bidder)</i>	Compliant? (Y/N) <i>(To be completed by UNFPA during evaluation)</i>
1	Examination Table		
2	Sterilizer,steam,40L,electric,w/access		
3	Sphygmomanometer, aneroid, adult		
4	Stethoscope, binaural, complete		
5	Stethoscope, obstetrical, Pinard, monoaural		

Item No.	Description and Minimum* / Mandatory Specifications <i>[Please refer to Annex 6 for detailed description. Click on the item name to navigate directly].</i>	Description of items offered and Bidder's statements on deviations <i>(To be completed by the bidder)</i>	Compliant? (Y/N) <i>(To be completed by UNFPA during evaluation)</i>
6	Thermometer, clinical, digital, 32–43°C		
7	Resuscitator, hand operated, child/newborn		
8	Scale, infant, spring type, 5 kg × 25 g		
9	Timer, mechanical, battery less, respiration rate measurement		
10	Vacuum extractor, Bird, anterior + posterior cups, manual, set		
11	Pump, suction, foot operated, aspirator		
12	Resuscitator, hand operated, neonate, set		
13	Resuscitator, hand operated, adult, set		

**Click on the links associated with each item to read the full specifications.*

Annex 4 - FTP Questionnaires
Invitation to Bid (ITB) No. UNFPA-PAL-ITB-2024-011

(Attached)

Bidders to complete and submit the below Questionnaires:

→ Annex 4 - Fast Track Procurement Questionnaire for Medical Devices (Attached)

Note: The Questionnaire must be completed by the bidder and signed for each of the items included in the submission.

Annex 5 - Price Schedule Form

Invitation to Bid (ITB) No. UNFPA-PAL-ITB-2024-011

(Attached)

Note: The Price Schedule Form must be submitted in both Excel and PDF formats, signed and stamped by the bidder.

Annex 6 – Technical Specifications**ITB No. UNFPA-PAL-ITB-2024-011****1. Examination Table****Intended use:** Non-mobile table for medical examinations of patients.**Technical specifications:**

- Examination table, 2 sections.
- Mounted on 4 sturdy supports, all finished with height adjustable feet.
- Both sections fitted with non-removable padded upholstery.
- Backrest angle adjustable via secured pawl and gear ratchet, safe for patient and operator.
- When fully extended, both sections align to perfectly flat surface.
- Transfer bars connect all lower distal portions of the 4 supports, providing maximal structural strength.

Materials:

- High resistance to corrosion (tropical environment)
- Frame: epoxy coated tubular steel
- Adjustable feet: rubber or nylon
- Padded upholstery: high-density polyurethane foam, density 28-30 kg/m³
- Cover: plastic, flexible, highly tear resistant, anti-static, flame-retardant, non-absorbing, waterproof and cleanable with hospital-grade disinfection products.

Dimensions:

- Examination table, two sections extended, including upholstery: (185-190) x 55 x 80cm (l x w x h).
- Frame: 3 cm (outside, across), 1.35-1.5 mm thickness.
- Upholstery: 4.5-5 cm (h).
- Carrying capacity: minimum 160 kg.
- Knockdown construction: yes.

Items supplied with:

- 1 x complete set of tools required for assembly
- List of accessories and parts
- Detailed step-by-step instructions for assembly and safe use, text-free pictorial based (i.e. line-drawings only)
- Instructions for use including cleaning and disinfection instructions in English and/ Arabic

Warranty of minimum 2 years.**Quality Management System:** ISO 13485:2016: Medical devices - Quality management systems**Regulation & conformity requirements:** Regulation (EU) 2017/745, **Class I** (or equivalent internationally recognised marketing clearance)**Nomenclature:** GMDN code: 38458 - Examination/treatment table, manual

Annex 6 – Technical Specifications

ITB No. UNFPA-PAL-ITB-2024-011

Environmental compliance and safety:

- All furniture components contain less than 100 parts per million of the below chemical groups, as applicable:
 - Urea formaldehyde
 - Heavy metals including mercury, cadmium, lead, antimony
 - Hexavalent chromium in plated finishes
 - Stain and non-stick treatments derived from Perfluorinated Compounds (PFCs), including Perfluorooctanoic Acid (PFOA)
 - Added antimicrobial treatments

Packaging, labelling, instructions: 1 One (1) unit per box

Compliance with EAN 128 bar code requirements

Annex 6 – Technical Specifications

ITB No. UNFPA-PAL-ITB-2024-011

2. Sterilizer, steam, 40L, electric, w/access

Product Description: <https://supply.unicef.org/s0002022.html>

3. Sphygmomanometer, aneroid, adult

Product description: Device used for the indirect (non-invasive) measurement of arterial blood pressure. The sphygmomanometer is composed of a cloth cuff containing an inflatable bag, connected via a tube to a flexible bulb with valve and integrated manometer needle gauge.

Material for cuff: Durable nylon, non-deformable, washable at 30°C. **Material for tube:** Rubber. Very strong cuff with double Velcro fastening, enabling it to be adjusted to fit tightly around the arm. Cuff reinforced at both ends. **Dimensions of cuff:** Approx. 570 x 145 mm.

The bag is inflated by means of a flexible bulb connected via a tube (length 60 cm) with a reliable quick connector. The quick connector can easily be connected to all types of inflation bulbs. Rubber inflation bulb with integrated manometer needle gauge. Glass and metal aneroid pressure gauge with needle. **Dial graduation:** 0 to 300 mmHg, with pressure release valve. Easy-to-grip bulb.

Instructions for use: For the measurement of arterial blood pressure.

Packaging and labeling: One (1) sphygmomanometer (adult) in a box, case, or bag with manufacturer's instructions for use in English and/or Arabic, including spare parts and accessories (when applicable). Symbols used according to ISO 15223. CE mark with Notified Body Number.

Regulation & conformity requirements: CE mark conforming to Council Directive 93/42/EEC on Medical Devices. CE certificate (for Class Im with Notified Body number).

Classification: Class Im – Class I measure (Devices with a measuring function MDD 93/42/EEC).

Safety & product standards: Must comply with the following standards:

- ISO 13485: 2003
- EN 1060-3:1997+A2:2009 Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems
- EN 1060-4:2004 Non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers
- ISO 81060-1:2007 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type
- ISO 10993-1:2009

Environmental requirements: To avoid contaminant paint.

4. Stethoscope, binaural, complete

Product description: Stethoscope of either Littman or Rappaport type for listening to sounds within the body walls, used for pulmonary and cardiac auscultation. Double cup dual-use (adult and pediatric auscultation) chest piece in stainless steel or chromed brass. **Adult diaphragm:** 43 mm. **Pediatric diaphragm:** 28 mm. Adjustable arms in stainless steel or chrome brass with flexible spring, treated for lasting resilience and maximum reliability and comfort.

Sensitivity: 3.2 dB in a range from 50 Hz to 500 Hz for cardiology; 8.1 dB in a range from 600 Hz to 1500 Hz for pneumology. Y tube treated rubber with a large diameter (10 mm), impervious to outside noises, ensuring full transmission of sound and good auditory quality. **Length of tube:** Maximum 400 mm. Removable plastic ear-pieces. Easy to dismantle, clean, and disinfect. Suitable for training health technicians in auscultation.

Supplied with: 1 spare adult diaphragm, 1 spare pediatric diaphragm, and 1 spare pair of removable plastic ear-pieces.

Instructions for use: Instrument for listening to sounds within the body. Easy to dismantle, clean, and disinfect.

Packaging and labeling: One (1) binaural stethoscope in a box, case, or bag with manufacturer's instructions for use in English and/or Arabic, including spare parts and accessories (when applicable). Symbols used according to ISO 15223. CE mark.

Regulation & conformity requirements: CE mark conforming to Council Directive 93/42/EEC on Medical Devices. CE self-declaration, ISO 13485:2003 certificate.

Classification: Class Im – 93/42/EEC Self-declaration / CE certification.

Safety & product standards: Must comply with the following standards:

- ISO 13485: 2003
- ISO 10993-1:2009

5. Stethoscope, obstetrical, Pinard, monoaural

Product description: Foetal Stethoscope Pinard Monoaural for diagnosis and prenatal care of pregnant women to listen to the foetal heart. **Material:** Unbreakable plastic or aluminum. **Type:** Monoaural, 1 piece. **Length:** Approx. 150 mm.

Instructions for use: For diagnosis and prenatal care of pregnant women to listen to the foetal heart.

Packaging and labeling: One (1) foetal stethoscope in a plastic bag with manufacturer's instructions for use in English and/or Arabic. Symbols used according to ISO 15223. CE mark.

Regulation & conformity requirements: CE mark conforming to Council Directive 93/42/EEC on Medical Devices. CE self-declaration, ISO 13485:2003 certificate.

Classification: Class Im – 93/42/EEC Self-declaration / CE certification.

Safety & product standards: Must comply with the following standards:

- ISO 13485: 2003
- ISO 10993-1:2009

Annex 6 – Technical Specifications**ITB No. UNFPA-PAL-ITB-2024-011****6. Thermometer, clinical, digital, 32–43°C**

Product description: Electronic device (without mercury) to measure body temperature of children and adults in Celsius degrees. Safe to use—no glass, no mercury. Digital thermometer with Celsius scale. Liquid crystal display (LCD), easy to read.

Measurement range: 32°C to 43°C.

Accuracy: +/- 0.1°C between 35°C to 41°C.

Measurement time: 30 to 40 seconds. Long-life battery: minimum 200 hours (about 1000 measurements). Automatic shut-off after a few minutes. Beep sound and switch off. Waterproof for ease of cleaning. Resistant to chlorine (high-level disinfection).

Operating ambient temperature: +10° C to 35° C. Battery powered with low battery indicator. Supplied with battery and clear instructions for use/preventive maintenance.

Instructions for use: To measure temperature of children and adults. It is recommended to follow the manufacturer's instructions for use and preventive maintenance.

Packaging and labeling: One (1) thermometer in storage case with manufacturer's instructions for use in English and/or Arabic. Symbols used according to ISO 15223. CE mark with Notified Body number.

Accessories/spare parts/consumables: Pack of batteries.

Regulation & conformity requirements: CE mark conforming to Council Directive 93/42/EEC on Medical Devices. CE certificate (for Class Im with Notified Body number).

Classification: **Class Im** – Class I measure (Devices with a measuring function MDD 93/42/EEC).

Safety & product standards: Must comply with the following standards:

- ISO 13485: 2003
- EN 12470-3:2000+A1:2009 Clinical thermometers - Part 3: Performance of compact electrical thermometers (non-predictive and predictive) with maximum device
- ISO 80601-2-56:2009 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
- IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-1:2000 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
- IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

Annex 6 – Technical Specifications**ITB No. UNFPA-PAL-ITB-2024-011**

Environmental requirements: Material of batteries should be environmentally safe.

7. Resuscitator, hand operated, child/newborn

Product description: Self-inflating ventilation bag used for manual ventilation assistance in infants or children over 30 kg in cases of respiratory distress or failure. Ventilation can be done with ambient air or oxygen. All parts are manufactured from high-strength, long-life materials and require no special maintenance or storage conditions. Resuscitator can be fully disassembled, easy to clean, disinfect, and autoclavable.

- **Material:** Self-refilling ventilation bag - silicone rubber. Non-rebreathing patient valve - polycarbonate/translucent polysulfone. Masks - silicone rubber/translucent polysulfone. Hooks - silicone rubber. Oxygen reservoir bag - translucent plastic. Airways Guedel - translucent plastic.
- **Features:** Self-inflating bag, compressible (one flexible pouch), with a pressure release valve set at 40 mbar, which can be blocked if higher pressures are indicated. Compressible self-refilling ventilation bag capacity: approx. 500 ml. Intake valve with nipple for O2 tubing.
- **Patient valves:** Removable expiratory outlet. Non-rebreathing patient valve with pressure limiting valve, one-way with single valve leaflet.
- **Oxygen reservoir bag:** Capacity approx. 2000 - 2600 ml.
- **Masks:** Translucent, 3 different sizes: 1 mask size adult small/teenager, 1 mask size adult medium, 1 mask size adult large.
- **Airways Guedel:** Translucent, 3 different sizes: 1 airway Guedel size 00 (approx. 40 mm), 1 airway Guedel size 0 (approx. 50 mm), 1 airway Guedel size 1 (approx. 60 mm).
- **Instructions for assembly, use, maintenance, and list of accessories & spare parts** with product reference code in 2 languages (English and/or Arabic).

Accessories/Spare parts/Consumables: Masks, airways.

Instructions for use: Basic hospital equipment for health structures and emergency situations in wards, emergency rooms, operating theaters, delivery rooms, intensive care units, ambulances, etc. Resuscitator is used to ventilate patients (children/infants over 30 kg). Resuscitator can maintain ventilation or resuscitate in other critical situations and should only be operated by someone with adequate resuscitation training. Both resuscitator and mask must be cleaned and disinfected after each use.

Packaging & Labeling: Unit presentation: 1 (one) Resuscitator in a plastic bag. Symbols used according to ISO 15223, CE mark, and notified body number.

Regulation & conformity requirements: CE mark conforming to Medical Device Directive (MDD) 93/42/EEC, CE certificate (for Class IIa with Notified Body number).

Classification: Class IIb (MDD 93/42/EEC).

Safety & product standards: Must comply with the following standards:

Annex 6 – Technical Specifications

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- ISO 5359:2008 Low-pressure hose assemblies for use with medical gases
- ISO 80369-1:2010 Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements
- ISO/CD 80369-2 Small-bore connectors for liquids and gases in healthcare applications - Part 2: Connectors for breathing systems and driving gases application
- ISO 10651-4: Ventilators - Part 4: Particular requirements for operator-powered resuscitators

Annex 6 – Technical Specifications**ITB No. UNFPA-PAL-ITB-2024-011****8. Scale, infant, spring type, 5 kg × 25 g****Product description:** Scale for weighing babies to monitor growth.

- **Materials:** Hooks - metal; Dial - plastic or metal (stainless steel preferred); Body - metal (stainless steel preferred) or plastic.
- **Measuring range:** 0 to 5 kg.
- **Graduation:** Minimum 25 g increments.
- **Enhanced readability:** Reflecting surface behind the needle for improved visibility. Readable in both kg and lbs.
- **Readability in low light** working conditions; maximum reading time of 15 seconds.
- **Features:** Easy zero adjustment; fitted with two hooks - upper for fixation and lower for attaching weighing trousers or sling. Designed to handle rough conditions with smooth, easy-to-clean surfaces.
- **Durability:** Rust-proof, splash-proof, shock-resistant, lightweight, and suitable for heavy-duty use. Body design allows for easy maintenance and repairs in low-tech settings.

Supplied with:

- Text and pictorial user instructions for operation, preventive maintenance, and troubleshooting in English and/or Arabic.
- Splash-proof carry bag.

Instructions for use: Scale for weighing babies to monitor growth. Use and maintain according to the manufacturer's instructions.**Packaging & Labeling:** One (1) scale, plus user information. Symbols used according to ISO 15223, CE mark, and Notified Body number.**Regulation & conformity requirements:**

- CE mark conforming to Council Directive 93/42/EEC on Medical Devices.
- CE certificate (for Class Im with Notified Body number).
- CE mark conforms to EU 90/384/EEC for non-automatic weighing instruments.

Classification: **Class Im** – Class I measure (Devices with a measuring function under MDD 93/42/EEC).**Environmental requirements:** Designed to avoid contamination.

9. Timer, mechanical, battery-less, respiration rate measurement

Product Description: Mechanical battery-less stopwatch (spring-wound timer) designed to assist medical staff in determining the respiration rate of newborns, particularly in the context of suspected acute respiratory infections. This timer measures newborn breathing by counting the number of breaths within 60 seconds.

- **Observation:** Time count in seconds is easily visible to medical staff.
- **Design:** Pocket-sized for convenience; features a durable, water-resistant construction.
- **Material:** Stainless steel.
- **Functionality:** Count-up or count-down; activated with an easily accessible button.
- **Operating Temperature:** Functions effectively between -15°C and +60°C.

Supplied with: Manufacturer's instructions for use, cleaning, and maintenance in English and/or Arabic.

2- Calibration certificate.

Accessories / Spare Parts / Consumables: N/A (available but not supplied).

Intended Use: Battery-less timer for measuring newborn breathing by counting the number of breaths in 60 seconds.

Packaging and Labeling: One (1) unit in protective packaging, labeled with:

- Device identity and intended purpose.
- Manufacturer's product code or reference number.
- Manufacturer identification and address of the manufacturing site.
- EC Representative identification.
- Instructions on device use, maintenance, and storage.
- Lot/Batch number and Manufacture Date (MFD).
- Any residual device risks, warnings, limitations, or contraindications.
- Symbols used according to ISO 15223, including the CE mark.

Regulation and Conformity Requirements:

- CE mark (conforming to Medical Device Directive MDD 93/42/EEC and MDR 2017/745) or FDA 510(k) approved or equivalent.
- Declaration of Conformity according to ISO 17050.
- ISO 13485 or ISO 9001 certified.

Classification: Class I

Safety and Product Standards: Must comply with current versions of the following standards:

- ISO 3158: Timekeeping instruments - Symbolization of control positions.
- ISO 1112: Horological movement jewels.
- ISO 6426: Horological vocabulary.
- ISO 10552: Timekeeping instruments - Crowns and sealed tubes - Designs and dimensions.

Annex 6 – Technical Specifications**ITB No. UNFPA-PAL-ITB-2024-011****Environmental Requirements:** ISO 14001 certified.**10. Vacuum extractor, Bird, anterior + posterior cups, manual, set**

Description: Vacuum extractor system designed to assist vaginal deliveries in a delivery room setting. The hand-operated suction pump generates the required vacuum, which is adjustable from 0 to -100 kPa (-800 mmHg).

- **Gauge Specifications:**
 - Vacuum range: 0 to -100 kPa
 - Minimal graduation: 5 kPa (40 mmHg)
 - Accuracy of vacuum gauge: ± 2.5 kPa.
- **Maintenance:** All parts can be disassembled for cleaning; relevant components are autoclavable at 121°C. The system requires no more than routine maintenance manageable at the delivery room level.

Supplied as a complete set, including:

- 2 x Bird-type anterior suction/extraction cups (1 x 50 mm & 1 x 60 mm diameter) with rounded edges.
- 1 x Bird-type posterior suction/extraction cup (1 x 50 mm diameter) with rounded edges.
- 2 x Extraction handles for Bird-type anterior cups.
- 2 x Soft suction/extraction cups (1 x 50 mm & 1 x 60 mm opening diameter).
- 1 x Vacuum/collection bottle (plastic, 500 ml).
- 1 x Cover plug for vacuum/collection bottle with 3 holes (2 connectors + 1 vacuum gauge).
- 1 x Connector (angled, chrome-plated).
- 1 x Connector (angled with screw valve for vacuum release, chrome-plated with cap & gasket).
- 1 x Vacuum gauge with straight connector (chrome-plated).
- 1 x Basket (epoxy-coated) to support the vacuum/collection bottle and suction pump, with a large hook for fitting to the delivery table.
- 2 x Silicone tubes (transparent, inner/outer diameter approx. 6/11 mm, lengths 50 cm & 150 cm).

Intended Use: This manual vacuum extractor system is specifically designed to assist vaginal deliveries in a delivery room setting, utilizing stainless steel anterior and posterior cups. It is essential hospital equipment for delivery rooms.

Supplied with:

- 1 x Spare vacuum/collection bottle (500 ml).
- 1 x Spare silicone tube (transparent, inner/outer diameter approx. 6/11 mm, length 300 cm).
- 1 x Spare gasket for the screw valve (vacuum release).

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- 20 x Polypropylene bottom plates for stainless steel suction/extraction cups (10 for each size: 50 mm and 60 mm).
- 1 x List of accessories and parts, each identified with its product reference.
- 1 x Instructions for use and maintenance, including contact details for repair service in English and/or Arabic.

Accessories / Spare Parts / Consumables: Vendor-specific (available but not supplied).

Packaging & Labeling:

- Packaging: One (1) manual Bird vacuum system with accessories in protective packaging.
- Labels include:
 - Name and/or trade name and address of the manufacturer.
 - Manufacturer's product code/reference.
 - Lot number prefixed by "LOT" or equivalent harmonized symbol.
 - Expiry date (month and year).
 - CE marking and Notified Body number.
 - Symbols according to ISO 15223 & EN 980.

Regulation & Conformity Requirements:

- CE mark (conforming to Medical Device Directive MDD 93/42/EEC, MDR 2017/745) or FDA 510(k) approved or equivalent.
- Declaration of Conformity according to ISO 17050.
- ISO 13485 certified.

Classification: Class IIa - Rule 5: Invasive accessory device for short-term use (MDD 93/42/EEC, MDR 2017/745).

Safety & Product Standards: Compliance with current versions of the following standards:

- ISO 14971: Medical Devices - Application of risk management to medical devices.
- ISO 10079-2: Medical suction equipment — Part 2: Manually powered suction equipment.
- ISO 3529-1: Vacuum technology - Vocabulary — Part 1: General terms.
- ISO 3529-2: Vacuum technology — Vocabulary — Part 2: Vacuum pumps and related terms.
- ISO 21360-1: Vacuum technology - Standard methods for measuring vacuum-pump performance - Part 1: General description.
- ISO 17664: Sterilization devices -- Information to be provided by the manufacturer for processing of re-sterilizable medical devices.
- ISO 14001: Environmental management systems.

11. Pump, suction, foot operated, aspirator

Product Description: To aspirate fluids secretions or other foreign materials from a patient's airway by means of suction. Used typically during patient transport or for emergency situations. High performance suction pump for pharyngeal and tracheal suction. Can be hand or foot-operated. Pump chassis is complete with valve diaphragms manifold pipe bottom cover cylinder with draw link and valve diaphragm piston ring O-ring pedal with retaining springs. Unit surface is to be hard and corrosion resistant. Pump handle/pedal to be spring loaded to return to 'up' position after each stroke. Supplied mounted on robust board with carrying handle.

Material: Parts made of transparent plastic: polycarbonate. Seals O-rings and valve diaphragm: silicone rubber. Piston rings: Teflon. Aspirating tube: silicone rubber. Easily portable by hand. Pump can be disassembled entirely is easy to clean disinfect and sterilize. (All parts can be autoclaved at 121°C). All parts are manufactured from high-strength durable material that does not require specific maintenance or storage conditions. Knock-down construction. Vacuum maximum: approx. 0.70 bar. Maximum Airflow/suction power: approx. 40 lt/min. Capacity of collection container: 600-1000ml. Supplied with 2 long silicone tubes with 10mm internal diameter 135-150cm long; and 2 short silicone tubes with 6mm internal diameter 40 cm long. (note: all dimensional values are approximate only). Supplied with angled connector and combination suction tip. Operating temperature range: -20 °C to +50 °C.

Supplied with: Two (2) conical connectors and a set of disposable suction catheters (3 pcs). Instructions for assembly use and maintenance and list of accessories and spare parts with product reference code in 2 languages (English and/or Arabic).

Accessories/Spare parts/Consumables: 10 x sets of spare filters. 1 x spare suction bottle. 2 x spare seals for each storage jar. List to be provided of other spare parts anticipated during one year's operation with costs. Supplier to specify any accessories required for normal operation stating any extra cost.

Instructions for use: Basic hospital equipment for health structures and emergency situations in wards emergency room operating theater delivery room intensive care unit ambulance etc. High performance suction pump hand or foot-operated for pharyngeal and tracheal suction. The suction pump and the aspirating tube must be cleaned and disinfected after each use. All parts can be sterilized in a steam sterilizer. Surgical suction pump must be used and maintained properly according manufacturers instructions. Recommendation: Use suction tubes (sterile and disposable) for pharyngeal and tracheal suction.

Packaging & Labelling: Unit presentation: 1 (one) Pump suction hand or foot-operated in a plastic bag + box with manufacturers instruction for use spare parts and accessories. Symbols used according ISO 15223. CE mark.

Regulation & conformity requirements: CE mark conforming to Medical Device Directive (MDD) 93/42/EEC. Meets the applicable provisions of Regulation 2017/745 EU (MDR).

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Classification: Class IIb

Safety & product Standards: Must comply with following standards ISO 10079-2:1999 Medical suction equipment -- Part 2: Manually powered suction equipment. ISO 5359:2008 Low-pressure hose gases.

Environmental requirements: RoHS compliance.

12. Resuscitator, hand operated, neonate, set

Product description: Self-inflating ventilation bag used for manual ventilation assistance in preterm newborn small infants with a body weight between 0-7kg in case of respiratory distress or failure. Ventilation can be done with ambient air or with oxygen using one hand only performing regular inflations. All parts must be manufactured from high-strength long-life materials and require no special maintenance or storage conditions. Resuscitator can be totally disassembled, easy to clean, disinfect, and be autoclavable.

Material: Latex-free. Compressible self-refilling ventilation bag: silicone rubber. Non-rebreathing patient valve with pressure limiting valve: polycarbonate/polysulfone/silicone. Inlet valve with nipple for O2 tubing: polycarbonate/polysulfone/silicone. Masks: transparent silicone rubber.

Self-inflating bag: Compressible (one single flexible pouch). Pressure release valve set at 40mbar, which can be blocked if higher pressures are indicated. Compressible self-refilling ventilation bag capacity approx.: 200-250 ml. Inlet valve with nipple for O2 tubing.

Patient valves: With removal expiratory outlet. Non-rebreathing patient valve with pressure limiting valve 40±5 cmH2O patient connector outside/inside diameter (OD/ID): 22/15mm. One way with single valve leaflet.

Supplied with:

- Non-rebreathing patient valve.
- Compressible self-refilling ventilation bag capacity approx.: 200-250 ml.
- Inlet valve with nipple for O2 tubing.
- Masks translucent 3 different sizes: 1 mask one piece round shape type size preterm, 1 mask one piece round shape type size newborn, 1 mask one piece round shape type size infant small.

Instructions for use: Basic hospital equipment for health structures and emergency situations in wards, emergency room, operating theater, delivery room, intensive care unit, ambulance, etc. Resuscitator is used to ventilate patients: preterm newborn small infant (body weight 0-7 kg). Resuscitator can be used to efficiently maintain ventilation or as resuscitation in other critical situations. Resuscitator should only be operated by a person who has received adequate training in resuscitation technique. The resuscitator and the mask must be cleaned and disinfected after each use.

Recommendation: After dismantling and cleaning, the resuscitator must be reassembled and tested to make sure that it works correctly. In view of its use, the item is considered an emergency resuscitation item. This means that it must always be readily available and in good working condition. It is recommended to follow the manufacturer's instructions manual.

Packaging & Labelling: Unit presentation: 1 (one) Resuscitator in a plastic bag. Symbols used according to ISO 15223. CE mark and notified body number.

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Regulation & conformity requirements: CE mark conforming to Medical Device Directive (MDD) 93/42/EEC CE certificate (for class IIa with Notified body number).

Classification: Class IIb (MDD 93/42/EEC).

Safety & product Standards: Must comply with the following standards ISO 5359:2008 Low-pressure hose assemblies for use with medical gases. ISO 80369-1:2010 Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General healthcare applications -- Part 2: Connectors for breathing systems and driving gases application. ISO 10651-4: 2002 Lung ventilators - Part 4: Particular requirements for operator-powered resuscitators

13. Resuscitator, hand operated, adult, set

Product Description: Self-inflating ventilation bag used for manual ventilation assistance in patients with body weight over 30kg in case of respiratory distress or failure. Ventilation can be done with ambient air or with oxygen. All parts must be manufactured from high-strength long-life materials & require no special maintenance or storage conditions. Resuscitator can be totally disassembled, easy to clean, disinfect & be autoclavable.

Material: Self-refilling ventilation bag: silicone rubber. Non-rebreathing patient valve: polycarbonate / translucent polysulfone. Masks: silicone rubber / translucent polysulfone. Hooks made of silicon rubber. Oxygen reservoir bag: translucent plastic. Airways Guedel: translucent plastic. Self-inflating bag. Compressible (one single flexible pouch). Pressure release valve set at 40mbar which can be blocked if higher pressures are indicated. Compressible self-refilling ventilation bag capacity approx.: 1500 - 2000ml. Intake valve w/nipple for O2 tubing.

Patient valves: w/removal expiratory outlet. Non-rebreathing patient valve. One way w/single valve leaflet. Oxygen reservoir bag. Oxygen reservoir bag capacity approx.: 2000 - 2600ml. Masks translucent 3 different sizes: 1 mask size adult small/teenager, 1 mask size adult medium, 1 mask size adult large. Airways Guedel translucent 3 different sizes: 1 airway Guedel size 2 approx. 70mm, 1 airway Guedel size 3 approx. 80mm, 1 airway Guedel size 4 approx. 90mm.

Instructions for assembly use & maintenance: & list of accessories & spare parts with product reference code in 2 languages (Eng, Fre & Spa).

Accessories/Spare parts/Consumables: Masks, airways.

Instructions for use: Basic hospital equipment for health structures & emergency situations in wards, emergency room, operating theater, delivery room, intensive care unit, ambulance, etc. Resuscitator is used to ventilate patients: children (with body weight over 30 kg) & adults. Resuscitator can be used to efficiently maintain ventilation or as resuscitation in other critical situations. Resuscitator should only be operated by a person who has received adequate training in resuscitation technique. Resuscitator & mask must be cleaned & disinfected after each use.

Recommendation: After dismantling & cleaning, resuscitator must be reassembled & tested to make sure that it works correctly. Item is considered an emergency resuscitation item. It must always be readily available & in good working condition. It is recommended to follow manufacturers' instructions manual.

Packaging & Labelling: Unit presentation: 1 (one) Resuscitator in a plastic bag. Symbols used according to ISO 15223. CE mark & notified body number.

Regulation & conformity requirements: CE mark conforming to Medical Device Directive (MDD) 93/42/EEC. CE certificate (for class IIa with Notified body number).

Classification: Class IIb (MDD 93/42/EEC).

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Safety & product Standards: Must comply with the following standards: ISO 13485:2003 Medical devices -- Quality management systems -- Requirements for regulatory purposes. ISO 10993-1:2009. ISO 5359:2008 Low-pressure hose assemblies for use with medical gases. ISO 80369-1:2010 Small-bore connectors for liquids & gases in healthcare applications -- Part 1: General requirements. ISO/CD 80369-2 Small bore connectors for liquids & gases in healthcare systems & driving gases application. ISO 10651-4: 2002 Lung ventilators - Part 4: Particular requirements for operator-powered resuscitators.