United Nations Population Fund (UNFPA)
UNFPA Bangladesh
IDB Bhaban (15th Floor)
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Date: 01 April 2020

Invitation to Bid (ITB) No. UNFPA/BGD/2020/001 - PPE Items

Dear Sir/Madam,

We hereby solicit your Bid for the supply of the following items with the following technical specifications:

Sl No.	Type of Item	Item Description	Quantity	Unit of Measure
1	PPE	Gloves: examination, nitrile, powder free, non-sterile	66,080	Pack of 100
2	PPE	Gown: Isolation, non-woven, disposable	110,088	Each
3	PPE	Mask: Surgical Mask, type IIR, disposable	161,093	Each
4	PPE	Goggle: Panoramic, regular nose, indirect ventilation	1,268	Each
5	PPE	Face Shields reusable	728	Each
6	PPE	Head cover, waterproof, disposable, non-sterile	884	Pack of 100
7	PPE	Shoe Cover waterproof, disposable	1,700	Pack of 100

If you are interested in submitting a bid for these items/services, kindly fill in the attached submission form and send to the **secure email address** indicated below, ***not later than* 7th April 2020, 14:00 hours Bangladesh standard time**. Please ensure to mark your email subject with the ITB reference number.

Secure email address for bid submission:

procurement.bangladesh@unfpa.org

Email address of Contact Person: mshams@unfpa.org

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

Instruction for electronic submission:

A. 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: ITB No. UNFPA/BGD/2020/001, Bidder's Name.

B. The bid shall be submitted to procurement.bangladesh@unfpa.org. Bids received at the procurement.bangladesh@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.

C. E-mail submission shall not exceed 10 MB, including the size of the cover email. 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.

D. It shall be the Bidder's responsibility to ensure that bids sent by e-mail are received by the deadline. All Bidders shall receive an auto-reply acknowledging the receipt of their email. Bidders shall not receive responses to questions sent to procurement.bangladesh@unfpa.org since it is a secure mailbox.

E. In order to avoid last minute internet congestion it is recommended to send your bid as early as possible before the deadline.

Documents to be submitted with the bid:

a. Completed and signed Bid Submission Form
b. Bidders Identification Form
c. Evidence of Bidder's previous experience and clients
d. Product Item Overview Form
e. Technical bid, please submit below documents:

QA FTP Guidelines: Medical devices and equipment
incl. Personal Protective Equipment (PPE)

1	Fast Track Procurement Questionnaire for Medical Devices completed by bidder/supplier. (Attached with the ITB)
2	Minimum documentation as per below table corresponding to classification of Medical Devices (ref. European Commission, MEDDEV 93/42/EEC).
3	Photos of the medical device product and packaging (*preferably in a format where the dimensions and features can be visually verified*).

Product class **(as per EC MEDDEV)**	**Minimum documentation required for Medical Devices**
class I (non-measuring, non- and/or non-reusable instrument, rsi)	1. Copy of ISO 13485 or ISO 9001 QMS certificate. 2. A signed and dated Declaration of Conformity (DoC) according to ISO 17050 stating compliance to the relevant ISO standards and directives (e.g. CE self-declaration 93/42/EEC), and which has a reference to the offered product.

class I **class I sterile** **class I rsi** **class IIa**	1. EC certificate (referencing the name/number of the notifying body), and/or 510k (FDA clearance), and/or approval letter or certificate from national regulatory body. 2. A signed and dated DoC according to ISO 17050 stating compliance to critical ISO standards (e.g. for sterilization, ISO 13485 QMS) and directives, and which has a reference to the offered product. **Note**: If a sterilization activity is subcontracted to a third party, ISO 13485 QMS compliance is also required from the subcontracting company.
class IIb **class III**	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.

Examples of products in each of the Medical Device EC MEDDEV class:

Class I (non-measuring, non-sterile and/or non-reusable surgical instrument)

Aprons, bags, baskets, bowls, etc. (largest item class group in UNFPA procurement catalog).

Class I (measuring, sterile and/or reusable surgical 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.

f. Signed Financial bid including the price schedule

Partial bids are **allowed** under this ITB. Note: Partial bids mean that the bidder does not have to offer all requested commodity types in order to submit a complete bid.

INCOTERMS 2010:

- Price of goods
- Freight cost, Hazrat Shah Jalal International Airport, Dhaka Bangladesh
- For local suppliers/ manufacturers- DAP, Dhaka City.

Validity of Bid:

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

Delivery Time:

The preferred delivery time is 7 (Seven) days (from ready stock) upon issuing of purchase order. However, Bidders may propose partial delivery as per the delivery schedule

form attached herewith. It is also mentionable that all award of contract is subject to pre-delivery inspection at the discretion of UNFPA.

Evaluation of Bids:

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

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

a. affects in any substantial way the scope, quality, or performance of the goods and related services specified in the contract; or

limits in any substantial way, inconsistent with the bidding documents, UNFPA's rights or the bidder's obligations under the contract; or if rectified would unfairly affect the competitive position of other bidders presenting substantially responsive bids.

Contract Award:

UNFPA shall award the contract to the lowest priced bidder(s) whose bid has been determined to be substantially responsive with the bidding documents, including the maximum allowable lead time.

Note: partial bids are allowed, the lowest evaluated bidder will be evaluated by commodity type.

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

Attachments (Annexex):

1. **Bid Submission Form**
2. **Bidders Identification Form**
3. **Technical specification and QA requirements of the product (Product Item Overview Form)**
4. **Fast Track Questionnaire**
5. **Price Schedule Form**
6. **Delivery Schedule form**

1. Bid Submission Form

Name of Bidder: _____

Contact Person: _____

Title: _____

Email Address: _____

Telephone Number: _____

Date of Bid: _____

Bid No: _____

Currency of Bid price: _____

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

(Note: preferred number of days is: 07 days)

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

Vendor's Comments:

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

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

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

_____ _____

Name and title **Date and Place**

2. Bidders Identification Form

Bid No. UNFPA/BGD/ITB/2020/001

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. 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

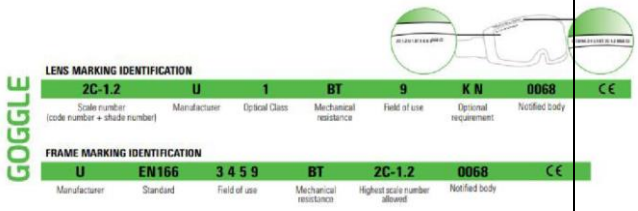
3. Product Item Overview Form

Item No. Name and picture	Item description and technical specifications	Mandatory QA requirements And Packaging / labelling remarks	Description of items offered and Bidder's statements on deviations (To be completed by the bidder)	Bidder's statement on QA Requirement, and Packaging	Compliant? (Y/N) (To be completed by UNFPA during evaluation)
1. Gloves: examination, nitrile, powder free, non-sterile 	Glove for clinical examinations and routine clinical laboratory work. Contains 5 fingers, palm and a sleeve. Disposable, non-powdered and non-sterile nitrile gloves are used to protect both patient, staff and environment from cross-contamination after handling infectious substances. Technical Specifications: Fits either hand (ambidextrous shape). Material: 100% Nitrile. Powder free (non-powdered). Waterproof. Non-sterile. Single-use, disposable. Sizes available: S-50%, L-50% Size Medium dimensions: Total length: minimum 230mm. Width: 95 mm, +/- 10mm. Thickness: fingers: approx. 0.12mm; palm: 0.8mm. **Intended use:** Strictly single use. A non-powdered glove, allowing the use of hydroalcoholic solution as hand cleanser. Wash hands before and after use of gloves. To be worn only on dry hands.	**Conformity requirements (WHO):** • EU MDD Directive 93/42/EEC Class I or IIa, • EU PPE Regulation 2016/425 Category III, • EN 455, • EN 374, • ANSI/ISEA 105, • ASTM D6319, or equivalent set of standards **Packaging and labeling:** Unit presentation: Hundred (100) gloves per box (50 pairs). Symbols used according ISO 15223. CE Mark. Manufacturer name and address. Lot/batch information. Must have words "non-powdered", or equivalent. Must indicate compliance to PPE 2016/425 Category III. Must indicate 'non-sterile, single use'. Must indicate 'latex free'.			

	Once removed, the gloves should be disposed of according to waste management rules. Never reuse. Store below 30°C protected from sunlight, heat and humidity.				
2. Gown: Isolation, non-woven, disposable 	Gown, isolation, non-woven, disposable. Non-sterile single use garment intended to be worn by healthcare providers or visitors to protect the patient from the transfer of infectious agents. It may also help to protect the healthcare provider or visitor from a contagious agent which has infected the patient. Technical specifications: Isolation gown (opening at the back), with long sleeves, a waist tie that binds at the back or front. Non-woven material, e.g. SMS, SMMS, polyethylene-coated polypropylene. Outer layer liquid penetration resistant in critical areas (full front and arms). Impermeable but breathable, flexible. Minimum average material density: 30 g/m2 Length (measured at front from middle of neckline to bottom): 110 – 150 cm (length mid-calf). Universal size but coverage of the whole upper body till under the knees is required. Width or circumference (measured at waist): minimum of 130 cm. Sleeves finished with double layer cuff, cotton or synthetic, stretchy (elastic) interlocked jersey band, length: 4 - 8 cm. Non-sterile. Single use, disposable.	**Conformity requirements (WHO):** • EU PPE Regulation 2016/425 and EU MDD directive 93/42/EEC • FDA class I or II medical device, or equivalent; • EN 13795 any performance level, or • AAMI PB70 all levels acceptable, or equivalent **Packaging and labeling:** Packaging: One (1) unit in a plastic bag. Labelling on primary packaging (one unit) must include: - Name and/or trademark of the manufacturer - Manufacturer address - Manufacturer's product reference (product code) - Type of product and main characteristics - If the packaging is not transparent, it must bear a diagram showing the essential parts of the product - Information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate			

	Intended use: To be worn when there is a protection isolation of an immune-depressed patient; or an infectious isolation: contagious diseases transmitting by airborne contact (droplets). Follow the infection control rules of undressing and dressing.	(or equivalent harmonised symbol) - Information for handling, if applicable (or equivalent harmonised symbol) - Words 'Non-sterile, disposable, single use' - Word 'Universal size' - CE mark (+ EC REP), FDA, and equivalent Secondary packaging: Packaging of multiple units Labelling to be the same as primary packaging.			
3. Mask: Surgical Mask, type IIR, disposable 	Mask, surgical, type IIR, tie strap, disposable. Medical mask covering the nose, mouth and chin, designed to limit transmission of infectious agents exhaled by the nose and mouth of the wearer, and additionally to protect the wearer against liquid splashes. Technical specifications: . Splash resistant, type IIR surgical mask. . Bacterial filtering efficiency (BFE): equal to or greater than 98%. . Differential pressure (breathability)/Breathing resistance: equal to or < 49 Pa. . Splash resistance pressure: greater than 120 mmHg (tested in accordance with ASTM F1862 standard). . Fabric, non-woven with outer layer impervious liquid splash resistant material, f.e. polyethylene. . Comprised of 3 or 4 non-woven folded layers, shape completely covering nose, mouth and chin. . Clearly identifiable inner and outer surfaces. . Malleable nose strip, made of aluminum,	**Conformity requirements (WHO):** • EU MDD directive 93/42/EEC Class I or IIa ,or equivalent, • EN 14683 Type IIR (or II or IR) • ASTM F2100 minimum level 1 or equivalent. **Packaging and labeling:** Packaging: One (1) unit in a protective packaging. Manufacturer name and address. ISO 15223 CE mark (+EC REP), FDA and equivalent. Lot/batch, MFD and expiry date. Word 'non-sterile, single use, disposable.' Comes with instructions for use.			

	allowing a snug fit. . With attached 2 x 2 tie-straps, allowing correct fixation and securing at the back of the head. . Size (indicative): 15-19 cm x 9-11 cm (l x w). Unfolded 175 x 175 mm. . Latex-free, glass fibre-free . Non-sterile . Single use, disposable . Conform requirements of EU Medical Devices Directive 93/42 (or equivalent internationally recognized marketing clearance). . In specific, compliant with the EN 14683 standard for type IIR (or equivalent international standard). **Intended use:** Worn by the medical staff or most typically by the contagious patient. The surgical mask prevents the contamination spread to the people surrounding and the environment (air, surface, products…) around the wearer and protects the wearer against liquid splashes. Not to be reused after removing from the face. The mask must be replaced at least every 3 hours. Always wash hands before fitting and after removing the mask. Note! A surgical mask does not protect the wearer against airborne infectious agents (coronavirus, TB, viral haemorrhagic fever, measles, varicella, SARS, avian influenza, etc.). In such cases, it is advisable to wear a respiratory protective mask rated FFP2 (complies with european standards) or N95 (complies with american standards).				

4. Goggle: Panoramic, regular nose, indirect ventilation 	Goggle, panoramic, regular nose, indirect ventilation. Goggles, or safety glasses, are forms of protective eyewear that usually enclose or protect the area surrounding the eye in order to prevent particulates, water or chemicals from striking the eyes. In haemorrhagic fever contexts it is recommended to use safety wrap around goggles: they protect the eyes from dust and splashing. **Technical specifications:** Good seal with the skin of the face. Reusable. Markings written on the goggles (frame and lenses) according to the EN 166 specifications: Mechanical class = F = Minimum mechanical resistance (resistance to shocks of low-energy particles): withstands a bead of 6 mm and 0.85 g at 45m/s impact. Optic class 1 or 2 = applicable for intermittent use, for activities with medium visual requirements. K = Anti-Scratch N = Anti-Fog Frame Protection class = 3 Protection against liquid doplets.  Lens:	**Conformity requirements (WHO):** • EU PPE Regulation 2016/425, • EN 166, • ANSI/ISEA Z87.1, or equivalent PPE class 3 EN 166 : 2002 Personal eye-protection – Specification EN 167 : 2002 Personal eye-protection - optical test methods EN 168 : 2002 Personal eye-protection - non-optical test methods **Packaging and labeling:** Packaging: One (1) unit in a protective packaging. Manufacturer name and address. ISO 15223 CE mark (+EC REP), FDA and equivalent. Lot/batch, MFD and expiry date.			

	Material: mechanically strong but less flexible polycarbonate (PC) or a better chemical resistant acetate type (PA) are equivalent options. Clear lens for protection against UV light. Panoramic view 180° The optical zone for every eye must be at least 32 mm horizontally and 25 mm vertically. Replaceable. Treated against fogging and against scratching. Must be easy to disinfect and resistant to chlorine à.5% solution. Frame: Shape of nose bridge: regular (or alternatively wide) Covers big part of the cheek (important in VHF context: between hood and respirator). Parts that touch the skin are not allergenic or irritating. Easy to combine with personal spectacles/ corrective glasses. Made of thermoplastic elastomer. Flexible PVC frame to easily fit with all face contours with even pressure. Broad and fully adjustable headband. Adjustable band to secure firmly so as not to become loose during clinical activity. Must be easy to disinfect and resistant to chlorine à.5% solution. Indirect ventilation: a venting system that does not allow for direct contact of particles to the interior of the goggles. this is achieved by adding angled vents, (prefereably at the bottom), which face away from the front lens that the wearer looks through.				

	Intended use: Worn during procedures that may expose personnel to eye contamination by infectious or hazardous chemicals. The reusable goggles must be disinfected with chlorine solution and be easy to remove. The ocular should be cleaned regularly. It can be cleaned with water and soap, or cleaning fluid for glasses. In case the goggles should be cleaned with a chlorine solution, it is necessary to clean it afterwards with water and soap, and rinse it thoroughly with clear water. No traces of chlorine should be left over because these traces will quickly result in fogging. Scratched ocular should be replaced. If the elastic strap is damaged, the entire goggle needs to be replaced.				
5. Face Shields reusable 	Durable full face length safety shield, fog-resistant. Encloses a wide area of the face ear-to-ear and forehead to chin. Can be worn with glasses or goggles, and with a N95 type respirator. **Technical specifications:** Durable full face length safety shield, fog-resistant. Encloses a wide area of the face ear-to-ear and forehead to chin. Can be worn with glasses or goggles. Made of clear plastic and provides good visibility to both the wearer and the patient. Material, shield part: clear polycarbonate, thickness approx. 1 mm. Made of robust material which can be cleaned	**Conformity requirements (WHO):** • EU PPE Regulation 2016/425, • EN 166, • ANSI/ISEA Z87.1, or equivalent set of standards **Packaging and labeling:** Packaging: One (1) unit in a protective packaging. Manufacturer name and address. ISO 15223 CE mark (+EC REP), FDA and equivalent. Lot/batch, MFD and expiry date. Word ‘non-sterile, single use,			

	and disinfected. Impermeable to liquids. Antistatic. Flexible. Size shield, from headband down approx.: 25 x 30 cm (w x h) Adjustable length headband, integrated with the shield. Adjustable band to attach firmly around the head and fit snuggly against the forehead. Width headband, approx.: 3 cm Front part of the headband is foam padded (length approx. 25 cm) Shield is anti-fog treated/coated (preferred). Outside is coated to prevent glare from reflection. Non sterile. Reusable.	disposable.' Comes with instructions for use, cleaning, decontamination from viral agents.			
6. Head cover, waterproof, disposable, non-sterile 	A non-sterile head covering designed as a cap to completely cover the hair and is intended to be worn by surgical staff during an operation to protect both the patient and themselves from the transfer of microorganisms, body fluids, and particulate material. It is an elasticated cap made of non-woven materials. **Technical specifications:** Non-woven (polypropylene, viscose, etc.) Non-permeable to liquid. Waterproof. For medical use. Weight: 10 to 30 g/m2 (e.g. cap of 6 g = 28 g/m2). Elastic opening permitting complete coverage of all hairstyles (Ø ± 50 cm). Latex-free. One-size-fits-all.	**Conformity requirements:** • EU PPE Regulation 2016/425, • EU MDD Directive 93/42/EEC • EN 343 for water and breathability or equivalent **Packaging**: Unit presentation: Hundred (100) Head Covers per box Manufacturer name and address. ISO 15223. CE mark (+EC REP), FDA and equivalent. Lot/batch, MFD and expiry date. Word 'non-sterile, single use,			

	Non sterile, single use. **Intended use:** It is mandatory for all operating theatre staff to wear a surgical cap. Non-woven surgical caps are intended for situations where sterilization is problematic. Dispose after use.	disposable.'			
7. Shoe Cover waterproof, disposable 	A non-sterile device made of a non-conductive material intended to be used as a physical barrier on a shoe to prevent cross-contamination between the shoe and the environment. This is a single-use device. Material: PVC Non-conductive. Disposable. Non-woven. One-size-fits-all. Elastic in hem at ankle. Non-permeable to liquid. Waterproof. **Intended use:** Any protective clothing used in the contaminated area must not be worn in the other areas of the facility. After use discard into infectious waste container.	**Conformity requirements:** • EU PPE Regulation 2016/425, • EU MDD Directive 93/42/EEC • EN 343 for water and breathability or equivalent Packaging & labeling: Manufacturer name and address. ISO 15223 **Packaging:** Unit presentation: Hundred (100) Shoe Covers per box CE mark (+EC REP), FDA and equivalent. Lot/batch, MFD and expiry date. Word 'non-sterile, single use, disposable.'			

5. Price Schedule Form

Name of Bidder: _____

Date of Bid: _____

ITB/ Bid No: _____

Currency of Bid price: _____

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

(Note: Preferred number of days is: 07 days)

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

Item No. and Name	UOM	Quantity	Price / UOM	Total Price for Each item	Transportation cost to destination (specify mode of transportation) for each item	Total Cost (Destination)

Vendor's Comments:

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

_____ _____

Name and title **Date and Place**

6. Delivery Schedule Form

Name of the Bidder: _____

Date of Bid: _____

ITB/ Bid No: _____

Item No.	Quantity	Days
Specify Item no, and name		
Specify Item no, and name		
Specify Item no, and name		

Vendor's Comments:

Name and title **Date and Place**