Technical Information Form Instructions

Please provide clear and complete information and documents for each proposed product your company is bidding for.

1. Bidders should fill out the tabs in this file and submit this form in Excel with unlocked cells.

2. Tab "Product List" shall be used by the Bidder to provide technical information of products. Only blank cells shall be filled with product relevant information.

3. To enable product identification for medical devices, it is essential to indicate and accurate Manufacturer`s Product Code in column "BO" of tab "Product List".

4. The "Medical Devices" and "Pharmaceuticals" sheets shall be used by the Bidder to provide their own detailed specifications for specific products they are offering.

5. Bidders are not allowed to copy and paste UNFPA generic specifications or to use general statements like: "offer as per specifications", "comply", "offered as requested", "as per requirement", "yes, but different pack size instead - pack of 1000" or similar general statements/information. Similar statements might invalidate the bid. Deviations between this sheet and product literature (e.g, manufacturer brochures/webpage) may invalidate the bid. Bidders should include their corresponding specification to each item they have quoted in each line in the column named " Bidders Technical Specification of the Offered Product" in the "Medical Devices" and "Pharmaceutical" sheets.

6. In instances where a Bidder submits products whose attributes differ slightly from the specifications, Bidders should highlight these deviations in bold/red in the text. Products that meet all UNFPA's specifications will be given priority.

7. This technical sheet will be used for technical evaluation purposes and the specifications will be used in UNFPA's catalog and for Pre-shipment inspections, when required. It is the bidding party's responsibility to ensure all information is truthful and accurate. Misrepresentations might invalidate the bid.

8. For sale and distribution of regulated products such as drugs and medical devices, the bidder is required to have a license to sell, stock, exhibit or offer for sale or distribute in the respective country. The bidder shall provide all these information in the questionnaire. Please fill the "supplier details" tab.

9. All documents such as registration, license, quality certifications submitted by bidders shall be current and valid.

Important guidance to Bidders:

Esta Tabla es para Equipos Medicos. Se Requiere de los Oferentes que: / The sheet is for "MEDICAL DEVICES". Bidders are requested to:
- Completen la Columna de "COMUNES" (columnas F - K) / - complete "COMMON" (column F - K) for all the solicited products.
- Complenten as Columnas "EQUIPOS/MATERIAL MEDICO" (Columnas L-BJ) - complete "MEDICAL DEVICES" (column L- BJ) for all the medical devices.

PRODUCT LIST					COMMON					
Bid Item No.	Product Category	UNFPA Item Description	UNFPA Sales Pack Size	UNFPA Primary UOM	Shelf life in months	Manufacturer's name	Manufacturing Country (Country of origin)	Complete address(es) of the manufacturing site(s) of the finished product(s), including address of site of final product release if different from the manufacturing site address. If multiple, describe all	Manufacturer's Website	Free comment field for bidder If any thoughts or comments that do not go to any other field in this template
1	Medical Device	Gown, Isolation disposable, non sterile medium/ Batas para Paciente o examen no estériles talla M	EA	Each						
2	Disposable Medical Device	Disposable Sheet / Sabanas desechables.	EA	Each						
3	Disposable Medical Device	Disposable Speculums Medium (Tipo Graves) / Espéculos desechable talla M (Tipo Graves)	EA	Each						
4	Disposable Medical Device	Gown, surgical, non-woven, non-sterile, medium, disposable / Bata medica manga larga No Estéril talla M	EA	Each						
5	Disposable Medical Device	Shoe cover, waterproof, disposable, non sterile / Cubrebotas o protector de calzado desechable no estéril	EA	Each						
6	Disposable Medical Device	Cap, head cover, clip, non-woven, non-sterile. / Gorro para cirujano no estéril	EA	Each						
7	Disposable Medical Device	Gloves, surgical, size 7, powder free, sterile, single use / Guantes Quirúrgicos Estériles talla 7	EA	Each						
8	Disposable Medical Device	Gloves, surgical, size 7.5, powder free, sterile, single use / Guantes Quirúrgicos Estériles talla 7.5	EA	Each						

Bid Item No.	MEDICAL DEVICES													
	1.1 Manufacturer's Product Name or Brand name or description If multiple, describe all	1.2 Manufacturer's Product code, Reference number, Model number, Serial number If multiple, describe all	1.3 Date of last inspection of the manufacturer Describe	1.4 Identification of Subcontractor (name and address) (IF e.g. final assembly, final sterilization, sub part manufacturing is done by other party than 1.1)	2.0 EC Class Describe	2.1 Purpose, Dimensions, Size, Diameter, Volume, Type, Shape, Model meet the UNFPA requirements. (YES/NO)	2.1.1 Clarification if Failed Compliance in 2.1 Describe	2.1.2 Weight of the item (grams) Describe	2.2 Material, Raw Material, Material Features meet the UNFPA requirements. (YES/NO)	2.2.1 Clarification if Failed Compliance in 2.2 Describe	2.2.2 Item is/has stainless steel? Describe the AISI type of stainless steel	2.3 Identify Documents in the Dossier: Product Brochure, Leaflet, Technical Data Sheet and Instruction Manual is provided (YES/NO)	2.4 Are the Technical Specifications from the Supplier 'exact replicate or identical' to UNFPA Technical Specificatons (YES/NO)	2.5 Photos of product are provided (YES/NO)
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Bid Item No.	3.1 Is Item prequalified by WHO or approved by other UN procurement agencies for long term contract (e.g. WHO Procurement, UNICEF) Describe agency and provide details	3.2.1 Valid EC certificate (= CE mark)? YES/NO	3.2.2 Describe expiry date of the EC certificate MM/YYYY	3.2.3 The name and country of EC certifying authority (e.g. notifying body) Describe	3.2.4 EC Representative's name and country. Describe	3.3 Valid FDA approval and 510k (or PMA) clearance? YES/NO	3.4 ISO 17050 Declaration of Conformity Signed and dated and with correct scope? YES/NO	3.5.1 ISO 13485 - QMS converting MDD 93/42/EEC, MDR 2017/745 for Medical Devices in correct device class Valid? YES/NO	3.5.2 Describe expiry date of the QMS 13485 certificate MM/YYYY	3.5.3 The name and country of QMS 13485 certifying authority (e.g. notifying body) Describe	3.6.1 ISO 9001 - QMS Valid? YES/NO	3.6.2 Describe expiry date of the QMS 9001 certificate MM/YYYY	3.6.3 The name and country of QMS 9001 certifying authority (e.g. notifying body) Describe	3.7 Free Sale Certificate, Certificate for Export or similar YES/NO	3.8 Compliance to Other Item-specific Safety Standards Describe Standard	3.9 ISO 14001 - Environment Valid YES/NO	3.10 ISO 50001 - Energy Management Valid YES/NO	3.11 List of all other documentation provided by the Supplier or Manufacturer Describe Name the document	3.12 Manufacturing Licence (1.1) Valid YES/NO	3.13 If applicaple - Safety documents of Subcontractor (1.5) (e.g. ISO 13485) Describe
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Bid Item No.	4.1 Reusable, re-sterilized Item? YES/NO	4.1.1 Reusable, re-sterilized Item - Instructions are provided for efficient cleaning, desinfecting and sterilization, and certificate to prove that material endures sterilization process. YES/NO/not	4.2 Sterile or single use Item? YES/NO	4.2.1 Sterile or single use Item - Method of sterilization Describe	4.2.2 Sterile or single use Item - ISO 13485 for specific sterilization process: ISO 11135 (ETO) ISO 11137 (gamma radiat) ISO 17665 (steam) ISO 20857 (dry heat) ISO 14937 (other)	4.2.3 Sterile or single use Item - Three (3) latest, individual batch sterilization certificates are submitted YES/NO/not applicable	4.3.1 Packaging requirements are efficient enough to protect the product? YES/NO	4.3.2 Is the cardboard carton FSC marked? YES/NO	4.4 Photos of primary and secondary LABELS are submitted YES/NO	4.5 Photos of primary and secondary packaging are submitted YES/NO	4.6 Storage conditions Describe	4.7 Installation manual, spares provided and service/repair information correspond to given UNFPA specifications Describe
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4.8 Training and Support Needed for device operation YES/NO/not applicable	4.9 Work instructions sufficient elsewhere and copy of it is provided YES/NO/not applicable	4.10 Electrical Equipment - large variety of voltages and frequencies and plugs guaranteed for various customers globally YES/NO/not applicable	4.11 Installation of Self-Disposal saw provided and approved YES/NO	4.12 Instructions for use are provided in all 3 languages EN, FR, SPI YES/NO/not applicable

Important guidance to Bidders:
Kindly pay attention to complete the below information as per the specifications confirmed by the manufacturer and yourself.
1. Complete every single row following the model of UNFPA technical specifications. Example is provided on row 3.
2. If possible, highlight all differences or deviations between offered product and UNFPA specifications with a different color font.
3. The technical specifications declared here shall be the true reflection of the device.
4. Evidence or proof of compliance to bidders specifications of all items must be accompanied with the bid response. (please do not attach any pictures/documents in this file). It is very important that photographs of products from various angle shall be provided by the bidder with bid response.
Notes:
- If there is a deviation between this information and the supplied device, this will create a PSI discrepancy and initiate a potential 'Change of Specification' process (part of supplier's performance evaluation).
If you have comments for UNFPA, please write them in column E. Do not type phrases such as 'confirmed' or 'as per catalog' in this column D.

Bid Item No.	UNFPA Item Description	UNFPA Detailed Technical Specifications	Bidders Technical Specification of the Offered Product	Bidders Comments
1	Gown, Isolation disposable, non sterile, medium / Batas para Paciente o examen no estériles talla LM	Single use, disposable, made of non-woven material, length mid-calf. **Size M**. Critical zones may be more fluid resistant than non- critical zones.		
2	Disposable Sheet / Sabanas desechables.	**Product description:** Rectangular plastic sheet, used to protect equipment from soiling. **Material:** Non-woven 2 layers fabric. 1st layer polyethylene, shiny side. 2nd layer non-woven absorbent material, viscose type. The non-woven fabric must be reinforced lengthwise with blue polyether fibers. - Absorbent and impervious protection. - Good resistance to tears. - Individually folded for swift fitting. - Non-allergic. - Hygienically clean for hospital use. **- Size:** approx. 80 x 120cm.		
3	Disposable Speculums Medium (Tipo Graves) / Espéculos desechable talla M (Tipo Graves)	**Product description:** Graves specula are bivalve and self-retaining, they are also known as the “duckbill speculum”. By retracting both the anterior and posterior vaginal walls, they are used to examine the vagina and cervix. Because of the upper blade, no anterior vaginal wall retractor is needed, and screws keep the blades in place; thus, an assistant is not required and the healthcare provider can work hands-free. The blades also serve to protect the vaginal walls while performing any procedure; however, it has a limitation in that it restricts space in the vaginal cavity, and blades might mask lesions on the vaginal walls. Lateral edges must be blunt; **Material:** must be biocompatible following ISO 10993-1, -5 and 10 biocompatible medical grade plastic (e.g. acrylic, non-PVC, non-latex). Recommended sizes: Medium – blade length: 95mm (+/- 5%), blade width: 35mm (+/- 5%)		
4	Gown, surgical, non-woven, non-sterile, medium, disposable / Bata medica manga larga No Estéril talla M	**Product description:** Single use, disposable, non-woven material, length mid-calf, long cuff, non-sterile. Critical zones may be more fluid resistant than non-critical zones. **Size M**		
5	Shoe cover, waterproof, disposable, non sterile / Cubrebotas o protector de calzado desechable no estéril	**Product description:** **Length :** 410 mm (suitable for all shoe sizes) **Height :** 15 cm / 20 cm **Fabric :** Non woven i. e. PP Spun bond (20 to 60 GSM) Waterproof, disposable		
6	Cap, head cover, clip, non-woven, non-sterile. / Gorro para cirujano no estéril	**Product description:** Non-woven surgical cap Round, bouffant surgical cap elasticated **Colors:** blue or green **Material:** nonwoven polypropylene, Adult model, standard size, Single use / Non-sterile		
7	Gloves, surgical, size 7, powder free, sterile, single use / Guantes Quirúrgicos Estériles talla 7	**Product description:** Gloves, surgical, nitrile (preferable), latex, polyisoprene or polychloroprene, sterile, powder-free, single use. Gloves should have long cuffs, reaching well above the wrist, ideally to mid-forearm. Minimum thickness 0.10 mm. **Size:** 7		
8	Gloves, surgical, size 7.5, powder free, sterile, single use / Guantes Quirúrgicos Estériles talla 7.5	**Product description:** Gloves, surgical, nitrile (preferable), latex, polyisoprene or polychloroprene, sterile, powder-free, single use. Gloves should have long cuffs, reaching well above the wrist, ideally to mid-forearm. Minimum thickness 0.10 mm. **Size:** 7.5		

Date	
Bid reference number (RFQ, RFP, ITB)	
Name and address of of Bidder company	
Name and title of person filling this form	
Name of Authorised personnel	
Registration Number	
Quality management system (ISO 9001 / ISO 13485-2016 etc)	
Documents to submit	
Copy of Licence to distribute/stock/sell medical devices	Attach separately
Good Distribution Practices inspection report	Attach separately
Copy of Registration	Attach separately
Copy of quality management system certifications, if available	Attach separately
Declaration by Bidder	I certify that the distribution/stocking/sale of medical devices is conducted according to National Laws in_____(Country), and the supply chain engaged by the company is secure to prevent proliferation of sub-standard and falsified products. I certify that the company always complies with the National Good Distribution Practices. Name Official title Signature Date
***documents shall be current and valid**	