



United Nations Population Fund
 304 Kim Ma Street, Ba Dinh District
 Ha Noi - Viet Nam

Tel: 84-24-38500100; Fax: 84-24-37265520

Email: vietnam.office@unfpa.org

Website: <http://vietnam.unfpa.org>

www.facebook.com/unfpa.vietnam

Date: 15 December 2020

Request for Quotation No. UNFPA/VNM/RFQ/20/07

(for suppliers who have a valid business license in Vietnam)

Dear Sir/Madam,

We hereby solicit your quotation for the supply and delivery of the following medical equipment:

No	Product Name	Unit of Measure	Quantity
1	Fetal Doppler <i>Technical Specifications: see details in Annex 1 of this RFQ.</i>	Each	300

If you are interested in submitting a quotation for the requested item, kindly fill in the attached Quotation Form – *Annex 2*, and send by email to: vbidtender@unfpa.org together with other required documents not later than **10h00 on 29 December 2020 (Ha Noi time, GMT+7)**

Delivery Time: 4 weeks after issuance of Purchase Order. The shortest delivery time is an advantage.

Delivery Terms: DAP (Delivered At Place)

Delivery Locations: As specified in *Annex 3*

Quality Requirements: Compliance with the Governmental standards for medical equipment and supplies, as well as technical specifications presented in *Annex 1*

Quotations submitted by email must be free from any form of virus or corrupted contents, or the quotations shall be rejected.

It shall remain your responsibility to ensure that your quotation will reach the address above on or before the deadline. Quotations that are received by UNFPA after the deadline indicated above, for whatever reason, shall not be considered for evaluation. If you are submitting your quotation by email, kindly ensure that it is signed and in the .pdf format, and free from any virus or corrupted files.

Full acceptance of the UNFPA General Terms and Conditions is mandatory. They can be located on this webpage at: <http://www.unfpa.org/suppliers>. Non-acceptance of the terms of the General Terms and Conditions (GTC) shall be grounds for disqualification from this procurement process.

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

Please take note of the following requirements and conditions pertaining to the supply of the above-mentioned goods:

Cost of Bid	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 solicitation.	
Language of the Bid	The bid prepared by the bidder and all correspondence and documents relating to the bid shall be written in English .	
Warranty	The warranty period shall be minimum 12 months .	
Goods	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.	
Delivery Terms [INCOTERMS 2010]	<input type="checkbox"/> FCA <input type="checkbox"/> CPT <input type="checkbox"/> CIP <input checked="" type="checkbox"/> DAP	
Customs clearance, if needed, shall be done by:	<input checked="" type="checkbox"/> Supplier(s) are required to obtain a valid import license from the Ministry of Health and complete all necessary customs clearance requirements for the offered product(s).	
Insurance	Cargo Insurance is to be arranged by the Supplier (if required)	
Delivery Locations	As specified in <u>Annex 3</u>	
Delivery Schedule	<input checked="" type="checkbox"/> Required <input type="checkbox"/> Not Required	
Mode of Transport	<input type="checkbox"/> AIR	<input type="checkbox"/> LAND
	<input type="checkbox"/> SEA	<input checked="" type="checkbox"/> as offered by Supplier
Currency of Quotation	<input checked="" type="checkbox"/> Local Currency (Viet Nam Dong) Conversion of currency into the UNFPA preferred currency, if the offer is quoted differently from what is required, shall be based only on UN Operational Exchange Rate prevailing at the time of competition deadline.	

<p>All documentations, including catalogs, instructions and operating manuals, shall be in this language</p>	<ul style="list-style-type: none"> <input checked="" type="checkbox"/> English <input checked="" type="checkbox"/> Vietnamese
<p>Documents to be submitted</p>	<ul style="list-style-type: none"> <input checked="" type="checkbox"/> Duly completed Quotation Form as provided in <i>Annex 2</i>, and in accordance with the list of requirements in <i>Annex 1</i>; <input checked="" type="checkbox"/> Duly completed Bid Submission Form as provided in <i>Annex 5</i> <input checked="" type="checkbox"/> Duly completed Bidders Identification Form as provided in <i>Annex 6</i> <input checked="" type="checkbox"/> Duly completed Bidder’s Previous Experience as provided in <i>Annex 7</i> <input checked="" type="checkbox"/> Proof of compliance of the quality of equipment and supplies with the Governmental standards <ul style="list-style-type: none"> ▪ A certified copy of a valid import license issued by Vietnam Ministry of Health for the offered Doppler. ▪ A certified copy of valid export license for the offered Doppler is required including any restrictions on the country of origin, use/dual use nature of goods or services and disposition to end users; <input checked="" type="checkbox"/> Quality Certificates (ISO, etc.):see a detailed list in Annex 1 <input checked="" type="checkbox"/> FTP Questionnaire for medical device completed by bidder (Annex 8) <input checked="" type="checkbox"/> Appropriate business related certificates, including <ul style="list-style-type: none"> ▪ Valid Business Registration Certificate issued by the appropriate government authorities of Vietnam ▪ Latest Internal Revenue Certificate / Tax Clearance; ▪ Valid Manufacturer’s Authorization of the Company as a Sales Agent (if Supplier is not the manufacturer); ▪ Valid Certificate of Exclusive Distributorship in the country (if applicable, and if Supplier is not the manufacturer); ▪ Complete documentation, information and declaration of any goods classified or may be classified as “Dangerous Goods” (if applicable). ▪ Patent Registration Certificates (if any of technologies submitted in the quotation is patented by the Supplier); ▪ Written Self-Declaration of not being included in the UN Security Council 1267/1989 list, UN Procurement Division List or other UN Ineligibility List;

Period of Validity of Quotes starting the Submission Date	<input type="checkbox"/> 60 days <input checked="" type="checkbox"/> 90 days <input type="checkbox"/> 120 days
Partial Quotes	<input type="checkbox"/> Permitted <input checked="" type="checkbox"/> Not Permitted
Partial Delivery	<input type="checkbox"/> Permitted <input checked="" type="checkbox"/> Not Permitted
Payment Terms	<input checked="" type="checkbox"/> 100% upon complete delivery of goods
Evaluation Criteria	<input checked="" type="checkbox"/> Technical responsiveness/Full compliance to requirements and lowest price <input checked="" type="checkbox"/> Full acceptance of the UNFPA General Terms and Conditions <input checked="" type="checkbox"/> Earliest Dispatch date / Shortest Lead Time
UNFPA will award to:	<input checked="" type="checkbox"/> One and only one supplier
Type of Contract to be Signed	<input checked="" type="checkbox"/> Purchase Order
Right to Vary Requirements at Time of Award	UNFPA reserves the right at the time of award of contract to increase or decrease by up to 25% the quantity of goods specified in this bid without any change in price or other terms and conditions.
Taxes	All quoted prices must be inclusive of all taxes (if any).
Conditions for Release of Payment	<input type="checkbox"/> Complete Installation <input type="checkbox"/> Completion of Training on Operation and Maintenance on the ground <input checked="" type="checkbox"/> Written Acceptance of Goods of beneficiaries based on full compliance with RFQ requirements
Annexes to this RFQ	<ul style="list-style-type: none"> ✓ Specifications of the Goods Required (<i>Annex 1</i>) ✓ Quotation Form (<i>Annex 2</i>) ✓ Delivery Quantity by Locations (<i>Annex 3</i>) ✓ UNFPA General Terms and Conditions (<i>Annex 4</i>) ✓ Bid Submission Form (<i>Annex 5</i>) ✓ Bidders Identification Form (<i>Annex 6</i>) ✓ Bidder's Previous Experience (<i>Annex 7</i>) ✓ FTP Questionnaire for Medical Device (<i>Annex 8</i>)

Contact Persons for Inquiries (Written inquiries only)	Name: Ms. Nguyen Minh Ha Title: Admin/Finance Associate Email: mnguyen@unfpa.org Any delay in UNFPA's response shall be not used as a reason for extending the deadline for submission, unless UNFPA determines that such an extension is necessary and communicates a new deadline to the Proposers.
--	---

Your earliest response to this RFQ would be highly appreciated.

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

Best regards,

Nguyen Minh Ha
Admin/Finance Associate
Tel No. +84-24-38500 328;
Cellphone: +84 (0) 989063740
Email: mnguyen@unfpa.org

SPECIFICATION OF THE DOPPLER FETAL HEARTRATE DETECTOR

1. General requirement

- The machines must be from manufacturers who are legally registered to manufacture the particular device by their national regulatory authority and have valid manufacturing licenses.
- It should have EC certificate (referencing the name/number of the notifying body), and/or 510k FDA clearance, and/or approval letter or certificate from a National Regulatory Body. Only devices that have a CE mark and/or FDA 510K clearance and that are actually marketed in Europe are eligible for bidding.
- It should have 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 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.
- It should have photo(s) of the product and packaging (at various angles if necessary, preferably in a format where the dimensions and features can be visually verified from the photos).
- Meet ISO 9001-Quality Management
- Meet ISO 13485 - Medical devices: Quality Management System
- Encouraging to satisfy ISO 14001- Environmental Standard Certification and ISO 50001- Energy Standard Certification
- Power supply: 220 V; 50 Hz.

2. Technical requirements

2.1- Product description

- Doppler, foetal heart rate (FHR) detector, with accessories
- To be used in basic health infrastructures for routine examination of foetal life, from about 10-12 weeks gestation through to delivery. It notes that this product is not “At home Dopplers” that are also available in the market and not advised for diagnostic purpose.
Transducer frequency, approximately 2MHz
- Self-test is performed each time the device is switched
- Large LCD shows, foetal heart rate in beats per minute (bpm), pulse indicator and sound volume level
- Built-in loudspeaker with volume adjustment
- System reports, with audio-visual alert: operational status, malfunctions and low battery
- Advanced noise/disturbance suppression system assures quality diagnostic sound
- Regular size, approx: 18 to 20 cm.
- Light weight, battery powered, handheld, easy to operate and carry (pocket size)

2.2- Supplied with:

- 1 x Soft carry bag easy to clean
- 1 x Instructions manual (instructions for assembly, use and maintenance in English and Vietnamese)

2.3- Instructions for use:

- To be used in basic health infrastructures for routine examination of foetal life, from about 10-12 weeks gestation through to delivery.
- Doppler foetal heart rate detector should be operated by an adequately trained person only.
- Clean and disinfect the device after each use.
- Doppler foetal heart detector must be used and maintained according manufacturer's instructions.

2.4- Accessories/ spare parts/consumables:

- Ultrasound gel
- Batteries

2.5- Packaging & Labelling

- Unit presentation: 1 (one) Doppler, FHR detector, with accessories and Instructions for use (in English and Vietnamese)
- Symbols used according ISO 15223
- CE with notified body number

2.6- Regulation & conformity requirements:

- CE mark conforming to Medical Device Directive (MDD) 93/42/EEC
- CE certificate (for Class IIa, with Notified Body Number)

2.7- Classification:

Class IIa (MDD 93/42/EEC)

2.8- Safety & product Standards:

Must comply with following standards

IEC 60601-1:1988 + A1:1991 + A2:1995 (mandatory)

ISO 13485: 2003

IEC 60601-1:2005;

IEC 60601-1-1:2000

IEC 60601-1-2:2007;

IEC 62366:2007

IEC 61266:1994

2.9- Environmental requirements:

- Restriction of hazardous substances directive (ROHS) compliance
- Led

3. Other requirements:

- Supply schedule: ≤ 4 weeks from the date this contract takes effect.
- Provide training for professional staff (in Vietnamese) in the Centers of Disease Control (CDC) of 12 target provinces (see the Annex for Distribution Plan)
- Provide installation and operation manual at the request of the local health authorities in 12 target provinces and providing maintaining services periodically during the warranty period
- Product warranty at least 12 months.
- Delivery requirement: providing the following documents for each set of purchased products:
 - o Certificate of origin, quality of goods or legal equivalent (CO, CQ).
 - o Valid business license issued by appropriate authorities in Vietnam
 - o Valid import license for the offered Doppler issued by the Vietnam Ministry of Health
 - o Certificate of goods assessment issued by an organization with legal inspection function.
 - o Authorization letter of the manufacturer or certificate of partnership.
 - o User Manual in Vietnamese and English: 01 set.
 - o Certificate of at least 12-month warranty issued by supplier or manufacturer.

Special Note:

- 1. All documents submitted must be in English or be accompanied with certified translation.*

Quotation Form

Name of Bidder: _____

Name of Bidder: _____

Request for Quotation No: _____

Currency of Bid price: _____

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

Delivery terms (specify mode of transportation and the route) _____

Expiration of Validity of Quotation (The quotation shall be valid for a period of at least 90 days after the Closing date). _____

You can include an Excel spreadsheet instead of this format. The table columns should be modified as appropriate for specific case.

Price Schedule:

Item	Product Name and Description	Unit Price	Quantity	Total price for units	Transportation cost to Destination	TOTAL (VND)
1						
2						
3						
GRAND TOTAL (including VAT):						

In your offer, please include:

1. Specific technical specifications of products offered
2. Quality standard of the products

Vendor's Comments:

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

Name and title

Date and Place

DELIVERY QUANTITY BY LOCATIONS
DISTRIBUTION LIST

Doppler Fetal heartrate detector

No	PROVINCE	QUANTITY	RECIPIENT
1	Thanh Hoa	25	The Center of Disease Control of Thanh Hoa province (Trung tâm Kiểm soát bệnh tật tỉnh Thanh Hóa) Address: 474 Hải Thượng Lãn Ông - P, Quảng Thắng - Thành phố Thanh Hóa, tỉnh Thanh Hóa Phone number: 0237 3954 173 Email: lesonytdpthanhhoa@gmail.com
2	Nghe An	25	The Center of Disease Control of Nghe An province (Trung tâm Kiểm soát bệnh tật tỉnh Nghệ An) Address: 140 Đường Lê Hồng Phong, Trường Thi, Thành phố Vinh, Nghệ An Phone number: 037 306 3737 Email:
3	Ha Tinh	25	The Center of Disease Control of Ha Tinh province (Trung tâm Kiểm soát bệnh tật tỉnh Hà Tĩnh) Address: 229 Nguyễn Huy Tụ - Thành phố Hà Tĩnh Phone number: 0239 3891183 Email: cdchatinh@gmail.com
4	Quang Binh	25	The Center of Disease Control of Quảng Bình province (Trung tâm Kiểm soát bệnh tật tỉnh Quảng Bình) Address: 164 Bà Triệu - Đồng Phú - TP.Đồng Hới - tỉnh Quảng Bình Phone number: 0232 3889 993 Email: thongtindientu.cdcqb@gmail.com
5	Quảng Trị	25	The Center of Disease Control of Quảng Trị province (Trung tâm Kiểm soát bệnh tật tỉnh Quảng Trị) Address: 54 Hoàng Diệu, Phường Đông Giang, TP Đông Hà, tỉnh Quảng Trị Phone number: 02333 852583 Email: quangtricdc@gmail.com
6	TT-Hue	25	The Center of Disease Control of Thua Thien-Hue province (Trung tâm Kiểm soát bệnh tật tỉnh Thừa thiên-Huế) Address: 10- 12 Nguyễn Văn Cừ - Phường Vĩnh Ninh - Thành phố Huế Phone number: 0234 3822466

No	PROVINCE	QUANTITY	RECIPIENT
			Email: CDC@thuathienhue.gov.vn
7	Quang Nam	25	The Center of Disease Control of Quang Nam province (Trung tâm Kiểm soát bệnh tật tỉnh Quảng Nam) Address: 129 Đường Trưng Nữ Vương, Phường Tân Thạnh, Tam Kỳ, Quảng Nam Phone number: 02353604439 Email: skmtcdcqna.tra@gmail.com
8	Quang Ngai	25	The Center of Disease Control of Quang Ngai province (Trung tâm Kiểm soát bệnh tật tỉnh Quảng Ngãi) Address: 64 Bùi Thị Xuân, Nghĩa Lộ, Quảng Ngãi Phone number: 0255 3716 052 Email:
9	Phu Yen	25	The Center of Disease Control of Phu Yen province (Trung tâm Kiểm soát bệnh tật tỉnh Phú Yên) Address: 01 Lý Thái Tổ - P6 – Tp. Tuy Hòa – Phú Yên Phone number: (0257) 3835133 - 6256012 Email:
10	Khanh Hoa	25	The Center of Disease Control of Khanh Hoa province (Trung tâm Kiểm soát bệnh tật tỉnh Khánh Hòa) Address: 04 Quang Trung, Vạn Thạnh, Thành phố Nha Trang, Khánh Hòa Phone number: <u>0258 3822 574</u> Email:
11	Binh Dinh	25	The Center of Disease Control of Binh Dinh province (Trung tâm Kiểm soát bệnh tật tỉnh Bình Định) Address: Khu C3, đường Điện Biên Phủ, Nhơn Bình, Quy Nhơn, Bình Định Phone number: 0256 3848932 Email: tksbtbinhdinh@gmail.com
12	Gia Lai	25	The Center of Disease Control of Gia Lai province (Trung tâm Kiểm soát bệnh tật tỉnh Gia Lai) Address: 98 Phan Đình Phùng, Tây Sơn, PT. Pleiku, Gia La Phone number: 0269 3824372 Email: cdc.gialai@gmail.com
	TOTAL	300	

UNFPA General Terms and Conditions

You can find below links for General Conditions of Contract based on contract type:

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

Bid Submission Form

To: UNFPA

Dear Sir / Madam,

The Undersigned, having read the Bidding Document of Request for Quotation (RFQ) No. UNFPA/VNM/RFQ/20/07, hereby offers to supply the goods specified in the schedule at the price or prices quoted, in accordance with any specifications stated and subject to the Terms and Conditions set out or specified in the document

We agree to abide by this Bid for a period of three months from the date fixed for opening of Bids in the RFQ, and it shall remain binding upon us and may be accepted at any time before the expiration of that period.

We understand that you are not bound to accept any Bid you may receive.

Dated thisday of[*year*].

Signature:

Name:

Title:

Company:

Postal Address

Telephone No.

Fax No.

Email address

Validity of Offer

Bidders Identification Form
Bid No. UNFPA/VNM/RFQ/20/07

1. Company/Institution Name: _____

2. Address, Country: _____

3. Telephone: _____ Fax _____ Website _____

4. Date of establishment: _____

5. Name of Legal Representative: _____

6. Contact Person: _____ Email: _____

7. Type of Company: Natural Person Co.Ltd. Other _____

8. Organizational Type: Manufacturer Wholesaler Trader Other: _____

9. Number of Staff: _____

10. Years supplying to UN organizations: _____ and to UNFPA: _____

11. Subsidiaries in the region:

Indicate name of subsidiaries and address

a) _____

b) _____

c) _____

12. Commercial representative in the country (for international companies only)

Name: _____

Address: _____

Telephone: _____ Fax: _____

Bidder’s Previous Experience

Order No. & Date	Description ¹	Client	Contact person, phone number, email address	Date of service		Contract Amount (Currency)	Satisfactory completion
				From	To		

Indicate the description of products, services or works provided to their clients.

To be attached: Evidence (client’s letter or certificate) in support of satisfactory completion of above orders.

Signature and stamp of the Bidder:		Countersigned by and stamp of Chartered Accountant	
Name and title:		Name and title:	
Name of Company:		Name of Company:	
Telephone:		Telephone:	
Email:		Email:	
Date:		Date:	

¹ Please indicate relevant contracts to the one requested in the RFQ.

Fast Track Procurement Questionnaire for Medical Devices

PART I. Manufacturer information

Bidder (if not manufacturer): [Click here to enter text.](#)

Manufacturer:

Name of manufacturer: [Click here to enter text.](#)

Country: [Click here to enter text.](#)

Address (office): [Click here to enter text.](#)

Address (manufacturing site(s)): [Click here to enter text.](#)

Contact person’s name: [Click here to enter text.](#)

Email: [Click here to enter text.](#)

Phone: [Click here to enter text.](#)

PART II. Product information

Product Identification (Trade name, Type, Model, Package size, Intended use, etc.):
[Click here to enter text.](#)

Product Code, Reference number(s): [Click here to enter text.](#)

Product details (materials, dimensions, size, volume, features, etc. For electrical devices specify voltage, frequency and plug supplied.): *(E.g. If a stainless steel product, identify AISI type or composition. If a plastic product, identify type or composition.)*
[Click here to enter text.](#)

PART III. Regulatory Status

3.1 Is the product CE marked? Certification body and number: Click here to enter text.	<input type="checkbox"/> Yes	Start Date: Click here to enter text. Expiry Date: Click here to enter text.
	<input type="checkbox"/> No	
3.2 Is the product FDA approved? 510k clearance #: Click here to enter text. PMA clearance #: Click here to enter text.	<input type="checkbox"/> Yes	Start Date: Click here to enter text. Expiry Date: Click here to enter text.
	<input type="checkbox"/> No	
3.3 Is the product approved by National Regulatory Agency or Department? Name of agency and type of approval: Click here to enter text.	<input type="checkbox"/> Yes	Start Date: Click here to enter text. Expiry Date: Click here to enter text.
	<input type="checkbox"/> No	
3.4 Provide details of <u>any other</u> current regulatory approvals for this product.	<input type="checkbox"/> Yes	Start Date: Click here to enter text. Expiry Date: Click here to enter text.
	<input type="checkbox"/> No	

Name of jurisdiction and type of approval: Click here to enter text.	
--	--

3.5 **Manufacturer** QMS ISO 13485 Yes No
 QMS ISO 9001 Yes No

a. Certification body and number: [Click here to enter text.](#)

b. Expiration date: [Click here to enter text.](#)

3.6 FOR STERILE PRODUCTS - If the manufacturing process is subcontracted:

Name and address of the subcontractor	QMS certification of the subcontractor - Identify Regulatory body and/or number and expiry date
Click here to enter text.	Click here to enter text.

3.7 FOR ELECTRICAL or BATTERY-OPERATED PRODUCTS

If the device contains Lithium metal and Lithium ion batteries, does it comply with clause 38.3 of the recommendations on "Transport Of Dangerous Goods" from the United Nations?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Does it comply with the latest IATA Dangerous Goods Regulations (DGR)?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Testing laboratory, Test Report reference, specify standard	Click here to enter text.

PART IV. Checklist of required documentation

Product class (EC MEDDEV)	Minimum documentation required
	Documents to be submitted must be true and valid copies. All documents submitted must be in English or be accompanied with certified translation.
class I (non-measuring, non-sterile and/or non-reusable surgical instrument, rsi)	<input type="checkbox"/> Copy of ISO 13485* (or ISO 9001*) QMS certificate. <input type="checkbox"/> A signed and dated Declaration of Conformity (DoC) according to ISO 17050 stating compliance to the relevant ISO standards and directives (for manufacturer), and which has reference to the offered product. <input type="checkbox"/> Photo of the product and packaging (at various angles if necessary, preferably in a format where the dimensions and features can be visually verified from the photos).
class I measuring class I sterile class I rsi class IIa	<input type="checkbox"/> Copy of EC certificate (referencing the name/number of the notifying body), and/or 510k FDA clearance, and/or approval letter or certificate from a National Regulatory Body. <input type="checkbox"/> 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 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.

	<input type="checkbox"/> Photo of the product and packaging (at various angles if necessary, preferably in a format where the dimensions and features can be visually verified from the photos).
class IIb class III	<input type="checkbox"/> Copy of EC certificate (referencing the name/number of the notifying body) with an additional copy EC Design Examination certificate, and/or 510k/PMA FDA clearance, and/or approval letter or certificate from a National Regulatory Body. <input type="checkbox"/> 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 reference to the offered product. Proof of compliance to ISO standards in a form of copies of certificates shall be submitted if available. <input type="checkbox"/> Photo of the product and packaging (at various angles if necessary, preferably in a format where the dimensions and features can be visually verified from the photos).

*) UNFPA accepts the versions of currently active standards, which are recognized by the International Organization for Standardization at the time of document submission.