United Nations Population Fund
70A Nahda St., Saryat El- Maadi,
Cairo. P.O. 11435 Egypt
E mail: egypt.tenders@unfpa.org
Website: http://www.unfpa.org

Date: 5th September, 2021

REQUEST FOR QUOTATION
RFQ Nº UNFPA/EGY/RFQ/21/014
RFQ is open for local and International Companies

Dear Sir/Madam,

UNFPA hereby solicits a quotation for the following items:

Description and purpose: A colposcope is a low magnification, light-illuminated visualization device for examining the cervix, across an area measuring approximately 20 to 30 mm in diameter, with enough distance between the colposcope lens and the cervix to accommodate the surgical instruments needed for theexamination and/or treatment. It allows the examiner to view the epithelial tissues of the cervix and other anogenital areas.

Parameters and Key Characteristics			
Component	**Item**	**Characteristic(s)**	
1) Optics System	a. Binocular eyepiece focus	160mm, built-in accurate measurement ruler	
	b. Eyepiece	12.5x, wide-range vision adjustment (refraction adjustment) 0±5D	
	c. Working distance	295mm	
	d. Eye-distance adjustment range	50-75mm	
	e. Diameter of field-of-view	80mm-12.5mm	
	f. Micro focusing range	40mm	
	g. Image collection razer	F4.5-432	
	h. Light source	i) Green filter, LED and halogen light sourcealterative (White light) ii) Fan to cool the bulbs if Halogen bulbs are used. iii) Ingress protection rating: IPX2 Minimum.	
	i. Light illumination	≥30000lux Halogen light 15V/150W	
	j. Optics magnification times	2.8-17times	
2) Camera system	a. Type	1/3” color CCD camera	1/2” color CCD, successive scans
	b. Level resolution	540 lines	Level: 1360, vertical: 1024
	c. Minimum illumination	0.05 Lux	0.15 Lux
	d. Effective pixels	480,000 pixels	1280/960 resolution
	e. Signal noise ratio of lens	50dB	9 bit @25℃, gain 0dB

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Essential Features	
3) High resolution and high-definition observation system 4) LED light source, luminance adjustable changing the intensity of the light 5) Fast manual focus control, white-balance auto-adjustment. 6) User adjustable settings: Illumination and course and fine magnification 7) Green light filter 8) Beam splitter design and CCD imaging trimming 9) Built-in scale, for size measurement 10) Five-step magnification and focus, strong stereoscopic effect, distinct gradation, large viewing. 11) Flexible, convenient, lockable swing arm, barrier-free design. 12) Multi-function management software with the ability of image observation, capture, video recording, freezing, editing, report printing and storage. 13) Special Software package, with the function of acetic acid reaction countdown, applicable to dynamic observation of examination and operative treatment. 14) Support Win7/8/10	
Essential Requirements	
15) Accessories	Stand or mount to allow for hands free operation. LED TV or medical grade monitor if not integrated.Single use sheath (if using invasive portable model)
16) Spare part	Lamps, bulbs, fuses
17) Electrical Source requirements	a. Amperage: b. Voltage: 220 – 240 V c. Plug type G
18) Operational requirements	a. Temperature: 15°C to 35 °C b. Relative humidity ≥ 85% c. Storage temperature 15°C to 40 °C: 85% (non-condensing) d. Dust cover or storage container/box e. Storage area should be clean and dust-free, dry, cool, well-lit, ventilated and vermin-proof. f. Store device in original packaging on a shelf or on in a storage cabinet. g. Ingress protection rating IPX2
19) Training of users	a) Training of users in the operation and basic maintenance shall be provided. b) Clinical Staff training in cervical pre-cancer lesion treatment guidelines and device use shall be provided.
20) Warranty	a. Minimum of 2 years b. Specific inclusions and exclusions must be listed. c. Contact detail of manufacturer, supplier and local service agent to be provided.
21) Spare parts availability post warranty	8 years minimum starting from installation /commissioning.
22) Estimated life span	Minimum of 2 years

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23) Documentation requirements	a. Instruction for use and service manual to be provided including procedures for decontamination. b. User language preference prioritized. English is mandatory. c. Contact details of manufacturer, supplier, local agent. d. Certificate of calibration and inspection to be provided (if applicable) e. List to be provided of equipment and procedures required for local calibration and routine maintenance. f. List to be provided of common spares with part numbers.
24) Packaging and Labelling	a. Primary packaging shall be by unit of use and secondary packaging shall provide protection of the packaged individual units in a box and if feasible madefrom recyclable materials. b. All paper and cardboard secondary packing is FSC marked. c. Labelling on the primary package should include the name and/or trademark of the manufacture, additional reference number or product code. d. Type of product and main characteristics, i.e. details to identify the device and its use. and should adhere to the most current version of: ISO 15223-1: Medical Devices- Symbols to be used with medical device labels, labelling information to be supplied- Part 1 General Requirements.
a) Declarationof Conformity	a. The submitter shall provide a declaration of conformity to applicable regulation(s) and/or standard(s). b. This declaration of conformity shall be established according to the model given in ISO/IEC 17050. c. Declaration of conformity shall be dated and signed by the manufacturer, it contains a reference to the medical device (name and product code) and a list of relevant ISO standards and directives for which the compliance is declared to. d. Declaration of conformity is a legally binding document.
25) Free Sale Certificate	Provide valid certification for export from country of origin.
26) Risk classification	a. USA FDA: Device Class 2 b. EU: Class IIa
27) Regulatory	a. **Compliance to (where applicable but not limited to):** i. National Regulatory Agency/Authority (NRA) requirements compliance ii. Approval by Regulatory Body of country of manufacturer (If applicable). b. **And at least one of:** i. FDA510 clearance (US FDA) ii. CE Mark (EU) with indication of Notifying Body (When applicable) iii. Other regulatory body in founding member country such as: Australia, Canada, Japan, UK

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28) Standards	**Compliant with the active version of the following standards:** **a) General manufacturing**: **i.** ISO 13485: Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes **ii.**ISO 23640: Invitro Diagnostics Medical Devices - Evaluation of stability of in vitro diagnostic reagents. **iii.** ISO 181131 – 1 In-vitro Diagnostic Medical Devices - Information supplied by the manufacturer (labelling) – part 1: Terms, definitions andgeneral requirements. **iv**. ISO 14971: Medical Devices - Application of Risk Management to Medical Devices **v**. ISO 15223-1: Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements **b) Safety & product standards**: **i.** IEC 60601-1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance. **ii.** IEC 60601-1-2: Medical electrical equipment - Part 1-2 General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests **iii.** For vaginally-inserted colposcopes: **c) Biocompatibility:** **i)** ISO 10993-1: Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process **ii)** ISO 10993-5: Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity **iii)** ISO 10993-10: Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization **d) Endoscopy (pertaining to inserted scope):** **i)** ISO 8600-1: Endoscopes – Medical endoscopes and endotherapy devices – Part 1: General requirements **ii)** ISO 8600-3: Optics and optical instruments – Medical endoscopes and endoscopic accessories – Part 3: Determination of field of view and direction of view of endoscopes with optics **iii)** ISO 8600-4: Endoscopes – Medical endoscopes and endotherapy devices – Part 4: Determination of maximum width of insertion portion **iv)** ISO 8600-5: Optics and photonics – Medical endoscopes and endotherapy devices – Part 5: Determination of optical resolution of rigid endoscopes with optics **v)** ISO 8600-6: Optics and photonics – Medical endoscopes and endotherapy devices – Part 6: vocabulary
29) Regional / Local Standards	Country-specific and regional standards may apply
30) National Registration	Essential to provide valid certification
31) Post Market Surveillance	Essential to respond to customer complaints in timely manner and notify NRA forserious and moderate adverse events according to their timelines.
32) Replacement of defective product	Desirable depending on root cause of the issue.

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This Request for Quotation is open to all legally-constituted companies that can provide the requested products and have legal capacity to deliver in the country of Egypt, or through an authorized representative.

I. About UNFPA

UNFPA, the United Nations Population Fund (UNFPA), is an international development agency that works to deliver a world where every pregnancy is wanted, every child birth is safe and every young person's potential is fulfilled.

UNFPA is the lead UN agency that expands the possibilities for women and young people to lead healthy sexual and reproductive lives. To read more about UNFPA, please go to: UNFPA about us

Objective:

The objective of the RFQ is to identify a supplier who can provide UNFPA with the HD Video Colposcope as per above required specifications. The selected vendor is expected to provide such products, based on specific Purchase Orders submitted to the vendor.

II. Questions

Questions or requests for further clarifications should be submitted in writing to the contact person below:

Name of contact person at UNFPA:	*Noha El-Maraghy*
Email address of contact person:	*elmaraghy@unfpa.org ;* egypt.tenders@unfpa.org

The deadline for submission of questions is Tuesday, 14th September, 2021*, 02:00pm Cairo time*. Questions will be answered in writing and shared with all parties as soon as possible after this deadline.

III. Content of quotations

Quotations should be submitted in a single email whenever possible, depending on file size. Quotations must contain:

a) Technical proposal, in response to the requirements outlined in the specifications should comply with:
   - The bidder shall be required to quote for the HD Video Colposcope including catalog and full specifications, insuring the availability of maintenance, spare parts and ability to provide training to multiple users.

b) Price quotation, to be submitted strictly in accordance with Price Quotation Form "including the cost of aftersales annual maintenance contract" hereinunder attached

Both parts of the quotation must be signed by the company's relevant authority and submitted in PDF format.

IV. Instructions for submission

Proposals should be prepared based on the guidelines set forth in Section III above, along with a properly filled out and signed price quotation form, and are to be sent by email to the address indicated below no later than : Tuesday 21st September, 2021 *at 02:00 PM Cairo Time*][1].

[1] http://www.timeanddate.com/worldclock/city.html?n=69

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Name of contact person at UNFPA:	Operations unit
Official Email address :	egypt.tenders@unfpa.org

Please note the following guidelines for electronic submissions to UNFPAs PSBs dedicated email address:

- The following reference must be included in the email subject line: **RFQ Nº UNFPA/EGY/RFQ/21/014 – [Procurement of HD Video Colposcope].** Proposals, including both technical and financial proposals, that do not contain the correct email subject line may be overlooked by the procurement officer and therefore not considered.
- The total email size may not exceed **10 MB (including email body, encoded attachments and headers)**. Where the technical details are in large electronic files, it is recommended that these be sent separately before the deadline.
- When submitting electronic offers, Bidders will receive an auto-reply acknowledging receipt of the **first** email. Should you offer require to submit more than one email, in the body of this first email, bidders are requested to list the number of messages, which make up their technical offer and the number of messages, which make up their financial offer. If you do not receive any auto-reply for the first email from UNFPA's email system, please inform Ms. Noha El-Maraghy at : elmaraghy@unfpa.org. Any quotation submitted will be regarded as an offer by the bidder and does not constitute or imply the acceptance of any quotation by UNFPA. UNFPA is under no obligation to award a contract to any bidder as a result of this RFQ.

V. Overview of Evaluation Process

Quotations will be evaluated based on the compliance with the technical specifications and the total cost of the goods (price quote).

The evaluation will be carried out in a two-step process by an ad-hoc evaluation panel. Technical proposals will be evaluated for technical compliance prior to the comparison of price quotes.

VI. Award

In case of a satisfactory result from the evaluation process, UNFPA shall award a Purchase Order to the lowest priced bidder whose bid has been determined to be substantially compliant with the bidding documents.

VII. 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 20%, the volume of goods specified in this RFQ without any change in unit prices or other terms and conditions.

VIII. Payment Terms

UNFPA payment terms are net 30 days upon receipt of shipping documents, invoice and other documentation required by the contract.

IX. Fraud and Corruption

UNFPA is committed to preventing, identifying, and addressing all acts of fraud against UNFPA, as well as against third parties involved in UNFPA activities. UNFPA's Policy regarding fraud and corruption is available here: Fraud Policy. Submission of a proposal implies that the Bidder is aware of this policy.

Suppliers, their subsidiaries, agents, intermediaries and principals must cooperate with the UNFPA Office of Audit and Investigations Services as well as with any other oversight entity authorized by the Executive

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Director and with the UNFPA Ethics Advisor as and when required. Such cooperation shall include, but not be limited to, the following: access to all employees, representatives agents and assignees of the vendor; as well as production of all documents requested, including financial records. Failure to fully cooperate with investigations will be considered sufficient grounds to allow UNFPA to repudiate and terminate the Agreement, and to debar and remove the supplier from UNFPA's list of registered suppliers.

A confidential Anti-Fraud Hotline is available to any Bidder to report suspicious fraudulent activities at UNFPA Investigation Hotline.

X. Zero Tolerance

UNFPA has adopted a zero-tolerance policy on gifts and hospitality. Suppliers are therefore requested not to send gifts or offer hospitality to UNFPA personnel. Further details on this policy are available here: Zero Tolerance Policy.

XI. RFQ Protest

Bidder(s) perceiving that they have been unjustly or unfairly treated in connection with a solicitation, evaluation, or award of a contract may submit a complaint to the UNFPA Head of the Business Unit Ms. Frederika MEIJER- Representative Egypt CO, at: meijer@unfpa.org. Should the supplier be unsatisfied with the reply provided by the UNFPA Head of the Business Unit, the supplier may contact the Chief, Procurement Services Branch at procurement@unfpa.org.

XII. Disclaimer

Should any of the links in this RFQ document be unavailable or inaccessible for any reason, bidders can contact the Procurement Officer in charge of the procurement to request for them to share a PDF version of such document(s).

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PRICE QUOTATION FORM

Name of Bidder:	
Date of the quotation:	Click here to enter a date.
Request for quotation №:	UNFPA/EGY/RFQ/21/014
Currency of quotation:	EGP/USD
Validity of quotation:	*The quotation shall be valid for a period of at least 3 months after the submission deadline*

Price quotation must exclude Taxes since UNFPA is exempted from all taxes

Price Quotation Form

Item	Product Name & Description	UOM	Unit Price	Number of Units	Total (USD)
1	HD Video Colposcope	Each		1	
2	Annual Maintenance Contract post guarantee period	Annual		1	
3	Clinical Staff training in cervical precancer lesion treatment guidelines and device use	User			
4	Delivery Charges based on the following 2010 Incoterm, to: CPT 70 A Nahda St., Intersection with St., No. 22, Sarayat Maadi, Cairo, Egypt	Each		1	
				GRAND TOTAL	

Vendor's Comments:

I hereby certify that the company mentioned above, which I am duly authorized to sign for, has reviewed RFQ UNFPA/EGY/RFQ/21/014 including all annexes, amendments to the RFQ document (if applicable) and the responses provided by UNFPA on clarification questions from the prospective service providers. Further, the company accepts the General Conditions of Contract for UNFPA and we will abide by this quotation until it expires.

	Click here to enter a date.
Name and title	Date and place

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ANNEX I:
General Conditions of Contracts:
De Minimis Contracts

This Request for Quotation is subject to UNFPA's General Conditions of Contract: De Minimis Contracts, which are available in:
https://www.unfpa.org/resources/unfpa-general-conditions-de-minimis-contracts