



United Nations Population Fund  
UN City  
Marmorvej 51, Copenhagen 2100  
Denmark  
Telephone: +45 4533 5000  
Website: <http://www.unfpa.org>

10 April 2015

## INVITATION TO BID

**ITB No. UNFPA/DNK/ITB/15/009**

### **FOR SUPPLY OF FISTULA KITS**

#### **INTRODUCTORY LETTER**

Dear Sir/Madam,

1. The United Nations Population Fund (UNFPA) invites sealed bids for the supply of fistula kits for its programmes and third party clients worldwide.
2. Result of the bidding will be used to establish 3 year long term agreements between the successful suppliers and UNFPA with the possibility of 1 year extension subject to satisfactory performance and price competitiveness.
3. To enable you to submit a bid, please read the following attached documents carefully:
  - Section I: Instructions to Bidders
  - Section II: Special Notes
  - Section III: Schedule of Requirements and Spend Analysis
  - Section IV: Technical Requirements for Medical Devices
  - Section V: Technical Requirements for Pharmaceutical Products
  - Section VI: UNFPA General Terms and Conditions
  - Section VII: Bidding Forms
  - Section VIII: Contract Forms
4. Bidders shall acknowledge receipt of this Invitation to Bid according to the Bid Confirmation Form (Section VII, 1) of this solicitation document by email [khvedchenya@unfpa.org](mailto:khvedchenya@unfpa.org) **no later than 22 April 2015** and to indicate whether or not a bid shall be submitted. If you are declining to bid please state the reasons for UNFPA to improve its effectiveness in future invitations.
5. Your sealed bid shall be received at the UNFPA's reception no later than **28 May 2015, 16:00 Copenhagen time**<sup>1</sup>. See Clauses 17-18 of the Instructions to Bidders (Section I) for more details on bid submission requirements.

---

<sup>1</sup> Reference: [www.timeanddate.com/worldclock](http://www.timeanddate.com/worldclock)

6. Bids received after the stipulated date and time shall not be accepted under any circumstances.
7. The bid shall be opened **on 29 May 2015, at 10:00 a.m.** Copenhagen time at UN City, Marmorvej 51, 2100 Copenhagen, Denmark. Bidders or their authorized representatives may attend the bid opening. Kindly confirm by email [khvedchenya@unfpa.org](mailto:khvedchenya@unfpa.org) **by 21 May 2015** whether your company shall be represented at the bid opening. See Clause 22 of the Instructions to Bidders (Section I) for more details on bid opening procedure.
8. Questions relating to the attached documents, if any, shall be sent latest **by 19 May 2015** in writing to the following UNFPA personnel:  
Mr. Sergey Khvedchenya, Contracts Associate, email: [khvedchenya@unfpa.org](mailto:khvedchenya@unfpa.org)
9. Samples are required under this bid and need to be received by UNFPA by **June 15, 2015 16:00**, Copenhagen time. Requirements for samples can be found under Clause 63 (Section II, Special Notes).
10. This letter is not to be construed in any way as an offer to contract with your firm.
11. UNFPA strongly encourages all Bidders to register on the United Nations Global Marketplace (<http://www.ungm.org>). The UNGM is the procurement portal of the United Nations system. By registering on UNGM, vendors become part of the database that UN buyers use when searching for suppliers. Vendors can also access all UN tenders online and, by subscribing to the Bid Tender Service, vendors can be automatically notified via email of all UN business opportunities that match the products and services for which they have registered. Instructions on how to subscribe to the Tender Alert Service can be found in the UNGM Interactive Guide for Suppliers [http://www.ungm.org/Publications/UserManuals/Suppliers/UserManual\\_Supplier.pdf](http://www.ungm.org/Publications/UserManuals/Suppliers/UserManual_Supplier.pdf).

Yours sincerely,

Sergey Khvedchenya (Mr.)  
UNFPA  
Procurement Services Branch  
Copenhagen, Denmark



**UNITED NATIONS POPULATION FUND**

**INVITATION TO BID**

**ITB NO.: UNFPA/DNK/ITB/15/009  
FOR SUPPLY OF FISTULA KITS**

**10 April 2015**

## Table of Contents

<b>SECTION I: Instructions to Bidders.....</b>	<b>6</b>
Introduction .....	6
1. Scope .....	6
2. Eligible Bidders .....	7
3. Eligible Goods and Related Services .....	7
4. Eligible Recipients of Products .....	8
5. Cost of Bid.....	8
Solicitation Documents.....	8
6. UNFPA Solicitation document .....	8
7. Clarifications of solicitation document .....	9
8. Amendments to UNFPA bid solicitation document .....	9
Preparation of Bids .....	9
9. Language of the bid .....	9
10. Documents to be submitted with the bid .....	9
11. Bid Currency and Prices .....	11
12. Most Favoured Customer Price Certification .....	12
13. INCOTERMS .....	12
14. Validity of Bid.....	12
Submission of Bids and Bid Opening .....	13
15. Partial Bids.....	13
16. Alternative Bids .....	13
17. Bids .....	13
18. Sealing and Marking of Bids .....	14
19. Bid Submission Deadline/Late Bids .....	14
20. Withdrawal, Substitution and Modification of Bids .....	14
21. Storage of Bids.....	15
22. Bid Opening .....	15
Evaluation and Comparison of Bids .....	15
23. Confidentiality .....	15
24. Clarification of Bids.....	16
25. Responsiveness of bids .....	16
26. Nonconformities, Errors, and Omissions.....	17
27. Preliminary examination of Bids.....	17
28. Bidder's qualifications evaluation .....	18
29. Technical and Quality Evaluation of Bids.....	20
30. Comparison of Price Bids.....	20
31. Review of Supplier's QMS.....	21
32. UNFPA's Right to Accept Any Bid and to Reject Any or All Bids .....	21
33. UNFPA's Right to Annul a Bidding Process .....	21
Award of Contract .....	21
34. Award Criteria.....	21
35. Signing of the contract .....	22
36. Test Purchase Orders.....	22
37. Publication of Contract Award .....	22
38. Bid Protest .....	22
39. General Terms and Conditions (GTC) .....	22
40. Supply Coverage .....	23
41. Sharing of Agreement Among UN Agencies .....	23
42. Liquidated Damages .....	23
43. Unethical Behaviour .....	23
44. Corrupt and Fraudulent Practices.....	23
45. Transparency .....	24
46. Zero Tolerance Policy on Gifts and Hospitality .....	24

47. Insurance .....	24
48. Embargo, Economic and Trade Prohibited Transactions.....	24
49. Performance Security (PS) .....	25
50. Commencement of the LTA .....	25
51. Delivery .....	25
52. Packing List .....	27
53. Marking/Labeling.....	27
54. Pre-shipment and post-shipment inspections.....	27
55. Supplier's Responsibility for Rejected or Returned Products.....	28
<b>SECTION II: Special Notes .....</b>	<b>29</b>
56. Technical specifications reviewed .....	29
57. Technical specification of the products offered .....	29
58. Assembly of the kits.....	29
59. Packing and marking of the kits.....	29
60. Warehousing/storage and inventory. ....	30
61. Printed materials .....	31
62. Questionnaire for pharma products.....	31
63. Generic pictures .....	31
64. Bid Structure and Naming convention .....	31
65. Pictures of products offered.....	33
66. Samples .....	33
67. Request for Change of Product(s) After Award .....	33
<b>SECTION III: Schedule of Requirements and Spend Analysis .....</b>	<b>35</b>
<b>SECTION IV: Technical Requirements for Medical Devices.....</b>	<b>36</b>
1. INTRODUCTION .....	36
2. GENERAL REFERENCES .....	36
3. CONFORMITY OF PRODUCTS WITH SPECIFIC SAFETY / PERFORMANCE STANDARDS.....	37
<b>SECTION V: Technical Requirements for Pharmaceutical Products .....</b>	<b>40</b>
1. Eligibility requirements .....	40
2. Technical specifications .....	40
3. Quality assurance system .....	40
4. Product information .....	40
5. Packing Information .....	43
6. Storage and transportation of temperature sensitive pharmaceuticals .....	44
<b>SECTION VI: UNFPA General Terms and Conditions.....</b>	<b>45</b>
<b>SECTION VII: Bidding Forms.....</b>	<b>46</b>
1. Bid Confirmation Form .....	46
2. Bid Submission Form .....	47
3. Checklist on UNFPA Terms and Conditions .....	48
4. Bidders Identification Form .....	49
5. Performance Statement Form .....	51
6. Technical Information Sheet.....	52
7. Product and Price Form .....	53
8. Joint Venture Partner Information Form .....	54
<b>SECTION VIII: UNFPA Contract Forms .....</b>	<b>55</b>

## SECTION I: Instructions to Bidders

### Introduction

#### 1. Scope

- 1.1. The goods to be procured are fistula kits for UNFPA's programmes and third party clients worldwide.
- 1.2. As a result of this bidding process, UNFPA shall sign one or several non-exclusive Long Term Agreements (LTAs) with multiple vendors to cover the full range of products required.
- 1.3. In the event of UNFPA signing long term agreements, the following shall apply:
  - a. The successful Bidder(s) shall accord the same terms and conditions to any other organization within the United Nations System that wishes to avail of such terms, after written consent from the UNFPA Procurement Services Branch;
  - b. The agreements shall be valid for 3 (three) years with a possibility of further extension for 1 (one) year.
  - c. The successful Bidder agrees to supply the Goods and Services to all the developing countries, least developed countries and transition countries listed in the following link: <http://unstats.un.org/unsd/methods/m49/m49regin.htm#developed>
  - d. The long term agreement template as specified in Contract Forms (Section VIII) shall be used for the establishment of the final agreement.
  - e. UNFPA will not be committed to purchase any minimum quantity of the goods and related Services, and purchases will be made only if and when there is an actual requirement. UNFPA shall not be liable for any cost in the event that no purchases are made under any resulting LTA. All reductions in market prices mandated by the provider will be passed on in full to UNFPA.
  - f. UNFPA reserves the right to accept all or part of the bid.
- 1.4. The supplies will be ordered by the following parties:
  - a. UNFPA Procurement Services Branch (PSB) in Copenhagen:  
UNFPA will procure Fistula kits for its programmes worldwide from the selected supplier(s) based on the resulting LTA. Payment will be made through UNFPA PSB in Copenhagen.
  - b. UNFPA Country Offices:  
UNFPA Country Offices will place purchase orders against the LTA, and payment will be made through UNFPA Country Offices.
- 1.5. Due to the nature of UNFPA's mandate and business, the demand for supplies is largely unplanned. Figures on UNFPA off-take in 2012-2014 is provided in Section III. The figures are given as a guide to possible future off-take, but shall not in any way be deemed to be a commitment on the part of UNFPA regarding any quantity for future purchases.
- 1.6. The LTA supplier(s) shall provide a status report of goods supplied to UNFPA and other agencies benefitting from such LTA every six months, in a format to be agreed between the parties.

## **2. Eligible Bidders**

- 2.1. This bid is open to primary manufacturers, authorized agents and authorized resellers.
- 2.2. A Bidder and all parties constituting the Bidder may hold any nationality.
- 2.3. A Bidder shall not have a conflict of interest. All Bidders found to have a conflict of interest shall be disqualified. Bidders may be considered to have a conflict of interest with one or more parties in this bidding process, if they:
  - 2.3.1. Are or have been associated in the past, with a firm or any of its affiliates that have been engaged by UNFPA to provide consulting services for the preparation of the design, specifications, and other documents to be used for the procurement of the goods to be purchased under these bidding documents; or
  - 2.3.2. A Bidder that is under a declaration of ineligibility by UNFPA in accordance with Instructions to Bidders Clause 2 at the date of contract award shall be disqualified.
- 2.4. Bidders shall not be eligible to submit a bid if at the time of bid submission:
  - a. The Bidder is listed as suspended on United Nations Global Marketplace (<http://www.ungm.org>) as a result of having committed fraudulent activities,
  - b. The Bidder's name is mentioned in the UN 1267 list issued by the Security Council resolution 1267 that establishes a sanctions regime to cover individuals and entities associated with Al-Qaida and/or the Taliban;
  - c. The bidder is suspended from United Nations Procurement Division (UNDP);
  - d. The Bidder is debarred by the World Bank Group.
- 2.5. Bids may be submitted by a Joint Venture (JV). In the case of a JV:
  - 2.5.1. The duly filled Joint Venture Partner Information Form (Section VII, 8) must be included with the bid; and
  - 2.5.2. All parties to the JV shall be jointly and severally liable; and
  - 2.5.3. The JV shall nominate a Representative who shall have the authority to conduct all businesses:
    - a. for and on behalf of any and all the parties of the JV during the bidding process; and
    - b. in the event the JV is awarded the contract, during contract execution.

## **3. Eligible Goods and Related Services**

- 3.1. All the goods and related services to be supplied under the contract may have their origin in any country.
- 3.2. For purposes of this Clause, the term "origin" means the country where the goods have been produced, manufactured or processed; or, through manufacture, processing, or assembly, another commercially recognized article results, that differs substantially in its basic characteristics from its components.

#### **4. Eligible Recipients of Products**

- 4.1. Items purchased under the resulting LTAs are for developing countries for use in:
- 4.1.1. Public sector family planning programs; private sector family planning programs (i.e., NGOs). The product(s) will be donated to or procured for public health systems and to private non-profit family planning institutions in developing countries. Community-based, non-profit distribution systems, social security systems, public or private are included as possible recipients of products supplied by this program. These products may not be used by recipient institutions for resale to commercial institutions or in response to Bids on local or international tenders.
  - 4.1.2. Social marketing family planning programs. The product(s) will be for programs which use standard commercial marketing techniques to promote the use of contraceptives and other family planning and HIV/AIDS prevention methods in developing countries. The products are sold to consumers and are distributed through a wide variety of outlets that may include private and public clinics, mobile sales personnel, pharmacies and other retail outlets depending on the commercial infrastructure available within the country. Selection of the distribution channel or channels within the country is at the discretion of UNFPA. The prices charged to consumers for the products range from small percentage of normal retail prices to prices that are typical of commercial products within the market. The prices charged depend on the target market, the economic situation in the subject country and the program's marketing strategy. Normally, the products are not distributed free of charge.

#### **5. Cost of Bid**

- 5.1. 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 bid.

### **Solicitation Documents**

#### **6. UNFPA Solicitation document**

- 6.1. Bidders are expected to examine all instructions, forms, specifications, terms and conditions contained within this UNFPA solicitation document. Failure to comply with these documents shall be at the Bidder's risk and may affect the evaluation of the bids, or may result in the rejection of the bid.
- 6.2. Bidding documents consist of the following:
- Section I: Instructions to Bidders
  - Section II: Special Notes
  - Section III: Schedule of Requirements and Spend Analysis
  - Section IV: Technical Requirements for Medical Devices
  - Section V: Technical Requirements for Pharmaceutical Products
  - Section VI: UNFPA General Terms and Conditions
  - Section VII: Bidding Forms
    - 1. Bid Confirmation Form
    - 2. Bid Submission Form
    - 3. Checklist on UNFPA Terms and Conditions



4. Bidders Identification Form
5. Performance Statement Form
6. Technical Information Sheet
7. Product and Price Form
8. Joint Venture Partner Information Form

#### Section VIII: Contract Forms

- 6.3. Bidders are cautioned to read the specifications carefully (see Schedule of Requirements and Technical Specifications, Section III), as there may be special requirements. The technical specifications presented herein are not to be construed as defining a particular manufacturer's product. Bidders are encouraged to advise UNFPA if they disagree.
- 6.4. The specifications are the minimum requirements for the products and related services. Products and services offered must meet or exceed all requirements herein. The products shall conform in strength, quality and workmanship to the accepted standards of the relevant industry. Modifications of or additions to basic standard products of less size or capability to meet these requirements will not be acceptable.

### **7. Clarifications of solicitation document**

- 7.1. A prospective Bidder requiring any clarification on the bid solicitation documents may notify UNFPA in writing (see deadline under point 9 of the Introductory Letter). UNFPA shall respond in writing to any request for clarification received and circulate its response (including an explanation of the query but without identifying the source of enquiry) to all prospective Bidders who have received the bid solicitation documents. A copy of UNFPA's answer shall also be posted on the UN Global Marketplace, <http://www.ungm.org/>.

### **8. Amendments to UNFPA bid solicitation document**

- 8.1. At any time prior to the deadline for submission of bids, UNFPA may for any reason, whether at its own initiative or in response to a clarification requested by a prospective Bidder, modify the bidding documents by amendment.
- 8.2. All prospective Bidders that have received the bidding documents shall be notified in writing of all the amendments to the bidding documents. In order to give prospective Bidders reasonable time to take the amendments into account in preparing their bids UNFPA may, at its discretion, extend the deadline for the submission of bids.

## **Preparation of Bids**

### **9. Language of the bid**

- 9.1. The bid prepared by the Bidder and all correspondence and documents relating to the bid shall be written in English.

### **10. Documents to be submitted with the bid**

#### **10.1. Documents Establishing Eligibility of the Bidder**

To establish their eligibility, Bidders shall:

- a. Complete the Bid Submission Form (Section VII, 2).
- b. Complete the Checklist on UNFPA Terms and Conditions (Section VII, 3)
- c. Complete Bidders Identification Form (Section VII, 4).
- d. Complete Joint Venture Partner Information Form (Section VII, 8) and provide all documents as required in the Form in the event that the bid is submitted by a Joint Venture.

#### 10.2. Documents Establishing Qualifications of the Bidder

To establish its qualifications, the Bidder shall submit to UNFPA's satisfaction the following documents:

- a. Evidence that the Bidder is established as a company and legally incorporated in the country where it resides; e.g. through provision of certification of incorporation or other documentary evidence (this is not required for companies already registered in national, regional or international Stock Exchanges);
- b. Copy of valid manufacturing license from the country of manufacturing and/or a copy of company registration in the country of operation demonstrating that it is duly authorized to supply these goods to the country of destination;
- c. Copy of the company audited Balance Sheet and Financial Statements for the last 3 (three) years;
- d. Written confirmation from the Bidder that the Bidder is neither suspended by the United Nations system nor debarred by the World Bank group;
- e. Post qualification documentation outlined in Instructions to Bidders, Clause 30;
- f. Completed Performance Statement Form (Section VII, 5) along with the Performance Evaluation Report from past clients and contacts information of clients for reference check purposes.

Failure to furnish all the information required for submission shall be at the Bidder's risk as it may then be determined that the bid does not substantially respond to the UNFPA bid document in every respect. This may result in a rejection of the bid.

#### 10.3. Documents Establishing the Eligibility and Conformity of the Goods and Related Services

Bidders shall submit:

- a. Documentary evidence that the goods conform to the technical specifications and standards (Technical Requirements, Sections IV and V) .
- b. Completed Technical Information Sheet (Section VII, 6).
- c. Manufacturer's technical product specifications or datasheets;
- d. Product catalogues (or links to on-line catalogues) containing pictures of the product(s);
- e. Copies of current certificates such as manufacturer's ISO certificate, CE certificate, etc., if stated under Technical Information Sheet (Section VII, 6).

#### 10.4. Documents Establishing Sustainability Efforts of the Bidder

UNFPA requests Bidders to submit information/documentation in their bid on their environmental and social policies:

- Your company's environmental or sustainability statement or policy;
- Does your company participate in the Global Compact?
- Does your company have an established environmentally preferable purchasing and supply chain program? If so, please describe.
- Has your company published a sustainability report? If yes, for how many years?
- Do you participate in any public reporting, such as through the Global Reporting Initiative (GRI, [www.globalreporting.org](http://www.globalreporting.org)), Ceres, or similar programs? If yes, please list.
- Is your company ISO 14001 certified?
- In the previous years has the company incurred any significant fines or sanctions for non-compliance with local, national, or international environmental laws and regulations?
- In the previous FY, what percent of total waste generated by your company and its subsidiaries was recycled or reused?

In the long term it is UNFPA's intention to incorporate environmental and social criteria considerations into the evaluation process, such as adherence to Global Compact requirements. More information can be accessed on the Global Compact web site, <http://www.unglobalcompact.org/>, or by contacting Procurement Services Branch at [procurement@unfpa.org](mailto:procurement@unfpa.org). UNFPA encourages suppliers now to consider joining the UN Global Compact and to look into other ways to help reduce their environmental impact.

## **11. Bid Currency and Prices**

- 11.1. All prices shall be quoted in US Dollars (USD). Failure to quote in US Dollars (USD) will invalidate the submission
- 11.2. In the event of an LTA being signed with the successful Bidder(s) the item prices quoted by the Bidder(s) will be entered into an e-procurement system maintained by UNFPA that can only accommodate prices in US dollars (USD). Therefore, prices shall be quoted in US dollars (USD) by the Bidder(s). Bidders shall indicate in their Bid the currency they would normally have used (i.e. the Bidder's preferred currency) if no such currency constraint existed. In order to mitigate financial risks, the successful Bidder(s) will be requested during the course of the LTA to adjust their USD price downward and to use for that purpose the UN exchange rate at time of bidding in the event of the USD appreciating by more than 10% against the Bidder's preferred currency. Similarly, should the USD depreciate by more than 10% against the Bidder's preferred currency, the successful Bidder(s) will be allowed to adjust their USD price upward by applying the UN exchange rate at time of bidding. For the purpose of calculating the percentage of appreciation or depreciation of the USD against the Bidder's preferred currency, the UN monthly exchange rates shall be used. To obtain the monthly UN exchange rate, use the following link: <http://treasury.un.org/operationalrates/Default.aspx>
- 11.3. The resulted LTA awarded to the winning bidder(s) resulting from this tender shall be valid for a period of three (3) years and fixed under the same prices, terms and conditions. The resulted LTA may be extended for one (1) additional year subject to the supplier's satisfactory performance and competitiveness of prices. For the extension of the resulted LTA, a new price may be proposed by the supplier using solely an indexation of the LTA price. If the supplier wishes to increase price for the extension of the LTA, such a proposal shall be made at least 6 (six) months prior to the expiry of the resulted LTA with supporting documents for cost increase and a report of the Cost Structure Analysis submitted to UNFPA. This indexation shall

be based on the Consumer Price Index (CPI) of the country which the product is manufactured. Only one index per LTA will be applicable. The price index of the country where the main components of product is produced is applicable.

11.4. All price information shall be indicated on the Product and Price Form (Section VII, 7).

11.5. Proposers are requested to advise as to:

- a. Quantity/volume discounts, in form of large quantity/volume discounts and staircase pricing (i.e. varying prices according to different quantities procured);
- b. Cumulative quantity/volume discount levels, i.e. discounts that increase as the cumulative order value/volume increases throughout the validity of the LTA;
- c. Early payment discounts, i.e. payment within a specified period of time faster than UNFPA's standard payment term of 30 days net;
- d. Other (trade) discounts.

## **12. Most Favoured Customer Price Certification**

12.1. By submitting an offer, the proposer certifies that, for Long Term Arrangements / Purchase Orders / Contracts resulting from this ITB, UNFPA is not being charged more than other clients for similar equipment and similar quantities and within similar circumstances.

## **13. INCOTERMS**

13.1. Bidders are requested to quote the following based on INCOTERMS 2010:

- Price of goods FCA bidders premises (Full Address shall be stated in the Product and Price Form)

13.2. The term FCA used under the present ITB shall be governed by the INCOTERMS 2010 rules, published by the International Chamber of Commerce.

## **14. Validity of Bid**

14.1. The prices of the bid shall be valid for 6 months after the closing date of bid submission as specified by UNFPA. A bid valid for a shorter period shall be rejected by UNFPA on the grounds that it is non-responsive.

14.2. In exceptional circumstances, UNFPA may solicit the Bidder's consent for an extension of the period of validity under exceptional circumstances. The request and the responses shall be made in writing.

14.3. In addition, the prices of the bid shall be valid for three (3) years under the duration of the long term agreement (LTA) with regard to the successful bidder(s).

## Submission of Bids and Bid Opening

### 15. Partial Bids

- 15.1. Partial bids are not allowed under this tender, all complete kits should be offered.

### 16. Alternative Bids

- 16.1. Up to one alternative offer per each of the items is allowed. All information/documentation required for the main item should be also applicable/provided with the alternative offers.

### 17. Bids

- 17.1. Bids shall be submitted in sealed envelopes in person or via mail/courier. Materials shall be submitted in two (2) soft copies on either USBs or CDs/DVDs. No hardcopies of documentation shall be sent.
- 17.2. Bidding is conducted through ONE (1) envelope. The technical bid containing the technical specifications and the financial bid containing price information shall be submitted together.
- 17.3. **The technical portion of the bid** shall be prepared in accordance with Schedule of Requirements (Section III), Technical Information Sheet (Section VII, 6) and shall include the requested documentation as per Clause 10 of the Instructions to Bidders. Technical Information Sheet (Section VII, 6) shall be submitted in electronic version.
- 17.4. **The financial portion of the bid** shall be prepared in accordance with the Product and Price Form (Section VII, 7).

The Price Form (Section VIII.7) consists of two spread-sheets:

- a) ProductList – a list of all items comprising the two Fistula Kits. All information about the products need to be provided here (except detailed technical specifications, provided in the Technical Information Sheet);
- b) KitsOverviewForm – summarised information about the kits is presented here. Bidders shall enter delivery time. Please note:
  - If prices of all items comprising a kit are entered in the ProductList correctly, then the note “Kit Incomplete” in Column D will be replaced by the sum of prices of individual items.
  - If delivery time, kitting costs and warehousing costs are entered in addition to all item prices (see point above), then note “Incomplete” in column I will be replaced by “Complete”. Only offers with “Complete” status in column I will be considered for technical evaluation.

**To make financial offer complete bidders have to provide:**

- Completed Price Form (Section VIII.7) in electronic Excel format;
  - Printed out, signed and scanned “KitsOverviewForm” spread sheet - as PDF file.
- 17.5. Technical Information Sheet (Section VII, 6) and Product and Price Form (Section VIII.7) have to be returned to UNFPA in exactly same format (locked and unmodified) as provided originally

by UNFPA. The forms are locked mainly to enable UNFPA to process data received from a high number of bidders consistently and efficiently.

- 17.6. Bidding forms shall be signed by the Bidder or a person or persons duly authorized to bind the Bidder to the contract. Scans of the signed forms need to be provided electronically (as PDF files or similar) together with other documentation. A bid shall contain no interlineations, erasures, or overwriting except as necessary to correct errors made by the Bidder. In that case such corrections shall be initialled by the person or persons signing the bid.

## **18. Sealing and Marking of Bids**

- 18.1. Bid envelope shall indicate the name and address of the bidder to enable the bid to be returned unopened in case it is declared “late” and must be clearly marked with the following:

*UNITED NATIONS POPULATION FUND (UNFPA)  
UN City  
Marmorvej 51  
2100, Copenhagen  
DENMARK  
Attention: Sergey Khvedchenya*

**DO NOT OPEN**  
**Bid Materials – ITB UNFPA/DNK/ITB/15/009**  
**Only To Be Opened By Authorised UNFPA Personnel**

## **19. Bid Submission Deadline/Late Bids**

- 19.1. Bids must be received at UNFPA on or before the date and time specified in the introductory letter of this solicitation document. If any doubt exists as to the time zone in which the bid should be submitted please refer to <http://www.timeanddate.com/worldclock> or contact the bid focal point.
- 19.2. UNFPA may, under special and exceptional circumstances, extend the bid submission deadline and such changes shall be notified in UNGM before the expiration of the original period.
- 19.3. Any bid received by UNFPA after the bid submission deadline shall be rejected. UNFPA shall not be legally responsible for bids that arrived late due to issues with mail/courier services.

## **20. Withdrawal, Substitution and Modification of Bids**

- 20.1. A Bidder may withdraw, substitute, or modify its bid after it has been submitted by sending a written notice prior to the bid submission deadline. Modification shall be submitted in a sealed envelope.
- 20.2. The Bidder may withdraw its bid after submission, provided that written notice of the withdrawal is received by UNFPA prior to the bid submission deadline requested to be withdrawn shall be shredded or shall be returned unopened to the Bidder.

- 20.3. No bid may be withdrawn, substituted, or modified in the interval between the deadline for submission of bids and the expiration of the period of bid validity specified by the Bidder on the Bid Submission Form or any extension thereof.

## **21. Storage of Bids**

- 21.1. Bids received prior to the deadline of submission and the time of opening shall be securely kept unopened until the specified bid opening date stated in the UNFPA's solicitation document. No responsibility shall be attached to UNFPA for prematurely opening an improperly addressed and/or identified bid.

## **22. Bid Opening**

- 22.1. UNFPA shall conduct the bid opening in public at the following address, date and time.

Street Address: UNFPA, UN City, Marmorvej 51  
 City: Copenhagen  
 Country: Denmark  
 Date: 29 May 2015  
 Time: 10:00 a.m. Copenhagen time (reference:  
<http://www.timeanddate.com/worldclock>).

- 22.2. UNFPA shall open all bids in the presence of at least two witnesses from UNFPA or another UN agency. The bids shall be opened publicly at the time and place specified in the ITB and an immediate record made thereof.
- 22.3. Only those who have submitted bids may attend the bid opening. However, the Bidders may authorize a local agent, embassy or trade commission (also referred to as observers) to represent them. In order to be able to attend bid opening, agents representing Bidders must provide reasonable evidence (business cards, letter of authorization, etc.) confirming the name of the Bidder they represent.
- 22.4. The report shall be available, upon request, for viewing by Bidders for a period of thirty days from the date of the opening. No information that is not included in the bid opening report can be given to Bidders.
- 22.5. No bid shall be rejected at bid opening, except for late bids. Bids that are not opened and read out at the bid opening shall not be considered further for evaluation, irrespective of the circumstances. Withdrawn bids will be shredded except for any bank securities, which will be returned to the Bidder.

## **Evaluation and Comparison of Bids**

## **23. Confidentiality**

- 23.1. Information relating to the examination, evaluation, comparison, and post-qualification of bids, and recommendation of contract award shall not be disclosed to Bidders or any other persons not officially concerned with such process until the contract award is published.

- 23.2. Any effort by a Bidder to influence UNFPA in the examination, evaluation, comparison, and post-qualification of the bids or contract award decisions may result in the rejection of its bid.
- 23.3. Notwithstanding from the time of bid opening to the time of contract award, if any Bidder wishes to contact UNFPA on any matter related to the bidding process, it should do so in writing.

## **24. Clarification of Bids**

- 24.1. To assist in the examination, evaluation and comparison of bids, UNFPA may ask Bidders for clarification of their bids. The request for clarification and the response shall be in writing by UNFPA and no change in price or substance of the bid shall be sought, offered or permitted.
- 24.2. Bidders shall submit clarifications or missing information and documentation by the deadline giving in the request. Bids shall be rejected once the deadline for submission of clarification is past without satisfactory response from the suppliers.

## **25. Responsiveness of bids**

- 25.1. UNFPA's determination of a bid's responsiveness is to be based on the contents of the bid itself.
- 25.2. 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.
- 25.3. 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.
- 25.4. UNFPA considers material deviation to include, but to not to be limited to the following situations:
  - 25.4.1. During preliminary examination of bids (verification of formal criteria)
    - a. Absence of bid form(s), change in the wording or lack of signature on key portions of the bid form when this is clearly specified in the tender document as a requirement. Any change in wording that is consistent with the standard format of the bid form(s) is not a material deviation;
    - b. The Bidder indicates in the bid that they do not accept important contract conditions, i.e. related to Warranty, Force Majeure Applicable Law, Delivery Schedule, Payment Terms, General Conditions and Limitation of Liability;
    - c. Non historical documents required in the solicitation document have not been provided, such as documents specifically related to the bidding process and that the Bidder could not be expected to possess before the solicitation document was issued;
    - d. Non eligibility of the Bidder;



- e. Financial information is included in the technical bid when using the two-envelope method.

25.4.2. During technical evaluation of bids and qualification of Bidders:

- a. Specifications of the item quoted vary in one or more significant respect(s) from the minimum required technical specifications.
- b. The Bidder does not meet the minimum conditions for qualification.

25.4.3. During financial evaluation of bids:

- a. The Bidder does not accept the required price correction as per Clause 26.1.3, c of the Instructions to Bidders.
- b. Required price components are missing;
- c. The Bidder offers less quantity than what is required.

- 25.5. If a bid is not substantially responsive to the bidding documents, it shall be rejected by UNFPA and may not subsequently be made responsive by the Bidder by correction of the material deviation, reservation, or omission.

## **26. Nonconformities, Errors, and Omissions**

26.1. Provided that a bid is substantially responsive:

- 26.1.1. UNFPA may waive any non-conformities or omissions in the bid that do not constitute a material deviation.

- 26.1.2. UNFPA may request that the Bidder submit the necessary information or documentation within a reasonable period of time to rectify nonmaterial nonconformities or omissions in the bid related to documentation requirements. Such omission shall not be related to any aspect of the price of the bid. Failure of the Bidder to comply with the request may result in the rejection of its bid.

26.1.3. UNFPA shall correct arithmetical errors on the following basis:

- a. If there is a discrepancy between the unit price and the line item total that is obtained by multiplying the unit price by the quantity, the unit price shall prevail and the line item total shall be corrected, unless in the opinion of UNFPA there is an obvious misplacement of the decimal point in the unit price. In that case the line item total as quoted shall govern and the unit price shall be corrected;
- b. if there is a discrepancy between words and figures, the amount in words shall prevail;
- c. if there is an error in a total corresponding to the addition or subtraction of subtotals, the subtotals shall prevail and the total shall be corrected.

- 26.2. If the Bidder that submitted the lowest evaluated bid does not accept the correction of errors, its bid shall be rejected.

## **27. Preliminary examination of Bids**

- 27.1. UNFPA shall examine the bids to determine whether they are complete, that all documents and technical documentation requested as per Clause 10 of the Instructions to Bidders have

been provided and to determine the completeness of each document submitted. UNFPA will also examine whether any computational errors have been made, whether the documents are properly signed, and whether the bids are generally in order.

- 27.2. UNFPA shall examine the bid to confirm that it does not contain any material deviations, reservation, or omissions related to the conditions and requirements specified in the Schedule of Requirements (Section III), General Terms and Conditions (Section VI).
- 27.3. If after the examination of the terms and conditions UNFPA determines that the bid is not substantially responsive in accordance with Clause 25 of the Instructions to Bidders, the bid shall be rejected.
- 27.4. UNFPA shall evaluate each bid that has been determined, up to this stage of the evaluation, to be substantially responsive.
- 27.5. UNFPA's evaluation of a bid will exclude and not take into account:
  - a. Customs duties and other import taxes, sales and other similar taxes, which will be payable on the goods if the contract is awarded to the Bidder;
  - b. Any allowance for price adjustment during the period of execution of the contract, if provided in the bid.

## **28. Bidder's qualifications evaluation**

- 28.1. UNFPA shall determine to its satisfaction whether the Bidder is qualified to perform the contract satisfactorily.
- 28.2. The determination shall be based upon an examination of the documentary evidence of the Bidder's qualifications submitted in the bid. An affirmative determination shall be a pre-requisite for further evaluation of a bid. A negative determination shall result in disqualification of the bid, in which event UNFPA shall proceed to the bid that was evaluated as the next lowest priced, substantially responsive bid in order to make a similar determination of that Bidder's capabilities to perform satisfactorily.
- 28.3. To determine the Bidder's capacity to execute the contract, UNFPA shall consider the following elements:
  - i. Performance Statement Form (Section VII, 5) with documentary evidence
  - ii. Copy of last 3 (three) years audited company Balance and Financial Statements
  - iii. Financial Capability:
    - a. Annual sales turnover during any one of the last three years to be at least equal to the contract value (from Financial Statements)
    - b. Liquidity ratio: Current ratio (Current Assets/ Current liabilities) > 1.
    - c. Documentary evidence that the Bidder has successfully completed at least one similar contract within the last five years for supply of goods.
    - d. Provide contact details of commercial banks and names of contact persons from whom UNFPA could seek feedback.
  - iv. Experience and Technical Capacity:
    - a. Registration details of the company;
    - b. Experience to undertake the contract:

- List of similar contracts executed for other clients, including contract details;
  - Evidence that the Bidder possesses experience in the geographical area required by the bid;
  - At least three years of experience in performing similar contracts.
- c. Company's managerial capability:
- Details of company's managerial structure;
  - Quality assurance systems in place.
- d. Bidder must have manufactured and supplied satisfactorily similar goods to a similar extent of the quantity, as mentioned against each schedule during any one of the last three years and the goods should have been in use satisfactorily with no adverse report;
- e. Client's certificates in support of the satisfactory operation of the goods as specified above;
- f. Data to support that the Bidder has the production capacity to perform the contract and complete the supplies within the stipulated delivery period or data to support that it has an installed annual production capacity for the specific item to match the quantities required. To qualify for multiple schedules, the installation capacity requirement shall be the sum of requirements against the individual schedules.
- g. Evidence that the Bidder is in the continuous business of manufacturing/supplying and providing after sale services for goods similar to those offered during the last three years prior to bid opening date;
- h. Brief write-up, backed up with adequate data, explaining available capacity and experience in the manufacture and supply of the required products within the specified time of completion after meeting all their current commitments;
- i. Confirmation that all the facilities exist at the factory for inspection and testing and these will be made available to the purchaser or his representative for inspection;
- j. The Bidder shall disclose instances of previous past performance that may have resulted in adverse actions taken against the Bidder and the manufacturers whose products are being offered by the Bidder, in the last five years. Such adverse actions may be treated as unsatisfactory performance history while deciding the award of contract. If no instance of previous past performance has resulted into adverse actions, this must be clearly indicated in the Bidder's bid;
- k. A list giving full particulars, including available sources and current prices of spare parts, special tools, etc., necessary for the proper and continuing functioning of the equipment for a reasonable period of time following installation.

For non-manufacturer Bidders:

- l. Legally enforceable authorization from the manufacturer assuring full guarantee and warranty obligations as per the tender conditions for the goods offered; and
- m. The Bidder, as authorized by the manufacturers, has supplied and provided after sales service for similar goods to the extent of at least 20 percent of the quantities indicated in the tender requirements in any one of the last three years, and the goods must be in satisfactory operation.
- n. Financial Experience and Technical Capacity requirements of the manufacturer similar to those mentioned above.

- 28.4. Notwithstanding anything stated above, UNFPA reserves the right to assess the Bidder's capabilities and capacity to execute the contract satisfactorily before deciding on award.
- 28.5. Even though the Bidders may meet the above qualifying criteria, they can be subject to disqualification if they have made misleading or false representations in the forms, statements and attachments submitted in proof of the qualification requirements, and/or record of poor performance such as, not properly completing contracts, inordinate delays in completion, litigation history, financial failures, etc.

## **29. Technical and Quality Evaluation of Bids**

- 29.1. Bids passing preliminary examination and bidder's evaluation shall undergo technical evaluation.
- 29.2. To reduce the evaluation time and transactional costs, UNFPA shall identify a batch of maximum 5 (five) lowest bids passing preliminary evaluation, which will be subject to technical evaluation. Technical evaluation will start from the least expensive bid and continue with second, third, and so on until at least 2 (preferably 3) bids are found technically compliant for all items. If technical evaluation does not yield at least 2 (preferably 3) substantially compliant bids, next (following) lowest bids shall be admitted to technical evaluation.
- 29.3. Bids with technical compliance of less than 60% of all items will not be considered for further evaluations.
- 29.4. Technical evaluation will be performed against the following criteria (pass/fail basis):
- a. Compliance with Specifications and other requirements as outlined under Schedule of Requirements (Section III), Technical Information Sheet (Section VII, 6) and Special Notes (Section II);
  - b. Compliance with Certification Requirements;
  - c. Other requirements, as outlines in this ITB.
- 29.5. In order to achieve coverage of all the required products comprising the kits, UNFPA reserves the right to conduct a second round of bidding among max 3 bidders with highest technical acceptance rate for the quoted products; in such instance bidders will be requested to resubmit offers for only those products which were recognised as technically unacceptable.
- Alternatively, UNFPA reserves the right to source products, which were recognised as technically unacceptable, directly from bidders who are found technically acceptable for a minimum of 70% of all products.
- 29.6. UNFPA will perform QA evaluation (pass/fail basis) of samples provided by bidders. This evaluation may be conducted by either a UNFPA QA Specialist or by a qualified and authorized third party at UNFPA's discretion.

## **30. Comparison of Price Bids**

- 30.1. UNFPA shall evaluate all substantially responsive bids which have passed technical/QA evaluation to determine the lowest priced technically compliant bid (second lowest, etc.) per each product on the ITB.
- 30.2. Bid evaluation will be made on the unit prices quoted according to the delivery conditions required under the present ITB.

**31. Review of Supplier's QMS**

- 31.1. Suppliers Quality Management Systems (QMS) may also be reviewed on site if deemed necessary by the technical function or where no third party certified ISO 9001:2008 (or equivalent) QMS is in place.
- 31.2. The QMS will, if considered necessary, be verified through the visit/inspection of the manufacturing/supply sites. Sample evaluation of products may also be undertaken at this time.

**32. UNFPA's Right to Accept Any Bid and to Reject Any or All Bids**

- 32.1. A bid that is rejected by UNFPA may not be made responsive by the Bidder by correction of the non-conformity. A responsive bid is defined as one which conforms to all the terms and conditions of the UNFPA's bid solicitation documents without material deviations. UNFPA shall determine the responsiveness of each bid against the UNFPA solicitation documents.
- 32.2. UNFPA reserves the right to reject any bid if a Bidder has previously failed to perform properly or complete on time in accordance with contracts or the Bidder who in UNFPA's perspective is not in a position to perform the contract.
- 32.3. The Bidders waive all rights to appeal against the decision made by UNFPA.

**33. UNFPA's Right to Annul a Bidding Process**

- 33.1. UNFPA reserves the right to annul the bidding process and reject all bids at any time prior to award of purchase order, without thereby incurring any liability to the affected Bidder(s) or any obligation to provide information on the grounds for UNFPA's action.

**Award of Contract****34. Award Criteria**

- 34.1. In the event of a contract award, UNFPA shall award Long Term Agreement(s) to the lowest priced Bidder(s) whose bid(s) has been determined to be substantially responsive to the bidding documents.
- 34.2. Any arrangement under this condition shall be made on the basis of the lowest priced substantially responsive, the second lowest priced substantially responsive, the third lowest priced substantially responsive , etc.
- 34.3. UNFPA reserves the right to make multiple arrangements (main and backup) for any item(s) to cover the full range of products required.
- 34.4. If required, the Bidder shall permit UNFPA representatives access to their facilities at any reasonable time to inspect the premises that shall be used for the production, testing and packaging of the products. The Bidder shall also provide reasonable assistance to the representatives for such inspection, including copies of any test results or quality control reports as may be necessary. UNFPA may inspect the manufacturing facilities of the lowest evaluated responsive Bidder to assess his capability to successfully perform the contract as per the terms and conditions specified in the ITB.

- 34.5. The proposed LTA shall be valid for a period of (3) three years, with a possibility for extension for (1) one year subject to satisfactory performance of the successful bidder.
- 34.6. The proposed LTA(s) is non-exclusive.

### **35. Signing of the contract**

- 35.1. Prior to the expiration of the period of bid validity, UNFPA shall send the successful Bidder a Long Term Agreement, which constitutes notification of the award. The successful Bidder shall sign, date the contract and return it to UNFPA within 10 days of receipt of the contract. After receipt of the contract, the successful Bidder shall deliver the commodities in accordance with the quantity, quality and delivery schedule outlined in its bid in conjunction with UNFPA terms and conditions. Actual quantities procured will vary from Purchase Order to Purchase Order.

### **36. Test Purchase Orders**

- 36.1. In case of an award, proposers who have not previously received Purchase Orders from UNFPA may receive an order for a limited quantity until satisfactory performance is established.
- 36.2. In this case initial deliveries will be subject to a pre-delivery inspection at the supplier's premises prior to delivery. The pre-delivery inspection will determine if the products meet the LTA/PO specifications in full. This may result in direct inspection of finished products to verify measurements, materials etc. The pre-delivery inspection is normally conducted by a third party inspection agency contracted by UNFPA as relevant.

### **37. Publication of Contract Award**

- 37.1. UNFPA shall publish the contract award on United Nations Global Marketplace <http://www.ungm.org>, with the following information: 1) LTA Reference Number 2) Description of the Goods or Services procured 3) Supplier Name and Country 4) Issue Date of the LTA and 5) LTA validity period.

### **38. Bid Protest**

- 38.1. Suppliers perceiving that they have been unjustly treated in connection with the solicitation or award of a contract may lodge a complaint directly to the Chief, Procurement Services Branch at [procurement@unfpa.org](mailto:procurement@unfpa.org), who will then make an assessment of the complaint and provide a reply to the Supplier within a week and, if required, advise the Supplier on further recourse.

### **39. General Terms and Conditions (GTC)**

- 39.1. Once contracted, General Terms and Conditions (Section VI) (GTC) shall apply to any resulting long term agreement (LTA) and related Purchase Orders.

**40. Supply Coverage**

- 40.1. By participating in this Bid, the supplier agrees to supply the Goods/Services to all the developing countries, least developed countries and transition countries listed in the following link: <http://unstats.un.org/unsd/methods/m49/m49regin.htm#developed>

**41. Sharing of Agreement Among UN Agencies**

- 41.1. Once contracted, the supplier agrees that UNFPA is free to share this agreement with other UN Agencies for their use in direct ordering under the same prices and conditions as stated in the agreement.

**42. Liquidated Damages**

- 42.1. In case the Vendor fails to perform under the terms and conditions of the Purchase Order or Long Term Agreement, including but not limited to failure of obtaining necessary export licenses or delivering all the goods by the date or dates of delivery, UNFPA shall without prejudice to any other rights or remedies, exercise one or more of the following rights:
- a. Procure all or part of the goods from other sources, and in that event UNFPA may hold the Vendor responsible for any excess cost occasioned thereby. In exercising such rights UNFPA shall mitigate its damages in good faith;
  - b. Refuse to accept delivery of all or parts of the services;
  - c. Terminate the Purchase Order or Long Term Agreement;
  - d. For late delivery of goods, UNFPA shall claim liquidated damages from the Supplier and deduct 0.5% of the value of the goods pursuant to the Purchase Order per additional day of delay, up to a maximum of 10% of the value of the Purchase Order. The payment or deduction of such liquidated damages shall not relieve the Supplier from any of its other obligations or liabilities pursuant to any current Long Term Agreement or Purchase Order.

**43. Unethical Behaviour**

- 43.1. UNFPA strictly enforces a policy of zero tolerance concerning unethical, unprofessional or fraudulent acts of UNFPA suppliers. Accordingly, any registered company that is found to have undertaken unethical, unprofessional or fraudulent activities will be suspended or forbidden to continue business relations with UNFPA.

**44. Corrupt and Fraudulent Practices**

- 44.1. UNFPA requires that all suppliers observe the highest standard of ethics during procurement and execution of work. Pursuant to this policy, UNFPA defines the terms set forth as follows:
- 44.2. Corrupt practice means the offering, giving, receiving or soliciting of anything of value to influence the action of a public official in the procurement process or in the execution of a contract;

- 44.3. Fraudulent practice means a misrepresentation of facts in order to influence a procurement process or the execution of a contract to the detriment of the client, and includes collusive practice among suppliers (prior to or after bid submission) designed to establish bid prices at artificial non-competitive levels and to deprive the client of the benefits of free and open competition.
- 44.4. UNFPA will declare a supplier ineligible, either indefinitely or for a stated period of time, to be awarded a UNFPA-financed contract/agreement if at any time it determines that the supplier has engaged in any corrupt or fraudulent practices in competing for, or in executing a UNFPA-financed contract/agreement.
- 44.5. UNFPA's policy regarding fraud and corruption is available at <http://www.unfpa.org/public/home/procurement/pid/8864> and applies fully to this Invitation to Bid. The submission of any offer implies that the Bidder is aware of this policy.

#### **45. Transparency**

- 45.1. Suppliers, their subsidiaries, agents, intermediaries and principals must cooperate with the UNFPA Division for Oversight Services as well as with any other oversight entity authorized by the Executive 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.

#### **46. Zero Tolerance Policy on Gifts and Hospitality**

- 46.1. UNFPA has adopted a zero tolerance policy on gifts and hospitality. In view of this UNFPA personnel is prohibited from accepting any gift, even of a nominal value, including drinks, meals, food products, hospitality, calendars, stationery, transportation, recreational trips to sporting or cultural events, theme parks or offers of holidays, or and any other forms of benefits. The supplier shall not offer any forms of gifts, hospitality or benefits to UNFPA personnel.

#### **47. Insurance**

- 47.1. UNFPA will insure the Goods during shipment from the supplier warehouse to the final destination.
- 47.2. For Goods which UNFPA keeps in stock, the Goods are covered by UNFPA insurance. In the event that the supplier's additional insurance is required, UNFPA will request the supplier to insure the Goods and UNFPA will pay for the additional insurance costs as soon as the Goods transit into UNFPA's inventory and ownership. The supplier will be given two (2) months' notice in the event that UNFPA wishes to extend insurance coverage of the goods in inventory.

#### **48. Embargo, Economic and Trade Prohibited Transactions**



- 48.1. UNFPA has its programs in developing and transitional countries, including the countries which might be sanctioned or embargoed by the United States Office of Foreign Assets Control (OFAC). The supplier shall inform UNFPA at the time of bidding, as well as during validity of the LTA (in the case of an award) its export controls and restrictions pertaining to the OFAC embargo and/or economic and trade prohibited transactions. The supplier shall provide assistance to UNFPA Procurement Services Branch in delivering the goods and/or services to the OFAC's embargoed countries through a third-party.

#### **49. Performance Security (PS)**

- 49.1. The successful bidder(s) may be required to submit a Performance Security (PS) within seven (7) working days from the receipt of the Purchase Order amounting to 10% of the value of the Purchase Order and shall be valid for forty-five (45) days after the date of delivery of the PO.

#### **50. Commencement of the LTA**

- 50.1. Upon the establishment of LTA with successful Bidder(s), a Request for Quotation (RFQ) will be sent to those suppliers with whom an LTA has been signed for the required goods/services for the availability of the products and freight quotation.
- 50.2. Suppliers will normally be given three (3) business days to provide a quotation. Depending on the complexity of the order and the destination, more or less time may be given.
- 50.3. In order for UNFPA to request separate freight quotes from shipping companies, suppliers will be required to include accurate shipping weights, volumes, dimensions and numbers of containers and of pallets in their quotations. Should there be any major discrepancies between the shipping dimensions quoted in the offer in response to the RFQ and the actual shipping dimensions, those quoted in the suppliers' offer in response to the RFQ will prevail.
- 50.4. Depending on the quantities being requested at the RFQ stage or the complexity of the case, Bidders may be requested to provide a performance security.
- 50.5. The successful supplier(s) may be requested to quote for goods and related services not listed in the LTA.

#### **51. Delivery**

- 51.1. Bidders shall indicate the guaranteed maximum lead time for delivery of each item offered. Bidders are advised to state realistic lead times since UNFPA shall monitor and measure delivery performance in comparison with guaranteed minimum lead time indicated in this Bid.
- 51.2. Deliveries shall be made as per instructions in UNFPA's Purchase Orders, as issued in accordance with the provisions of the LTA. Proposers shall indicate the guaranteed minimum lead time for delivery for each item offered (subject to quantities), defined as time from receipt of order and:
- a. Although prices under this LTA will be fixed on a FCA basis, the Purchase Orders will be placed under CPT delivery terms;
  - b. The maximum LTA Delivery Lead Time FCA in weeks refers to the maximum number of weeks from the date of receipt of Purchase Order by the Supplier to the date and time of departure of the main carrier;

- c. The supplier will be asked to submit binding freight quotations to UNFPA for each Purchase Order. For freight quotations below USD 50,000, UNFPA will go with supplier freight. For freight quotations above USD 50,000, UNFPA will compare suppliers offer for freight with freight LTA offers and choose the lowest freight option. The supplier shall submit actual freight invoice together with other shipping documents to UNFPA and this information will be part of payment documents. UNFPA will pay the actual invoice cost to the supplier, but never more than the binding freight amount the supplier quoted. This means that if the actual freight invoice is higher than the quoted freight, the supplier will have to cover the cost difference. If the actual invoice is lower than the quoted freight, UNFPA will only pay the actual freight invoice;
  - d. The agreed Purchase Order Due Date is provided inclusive of 1 week of pre-shipment inspection;
  - e. For sea freight, main carrier refers to the ship. The Actual Time of Departure (ATD) is taken from the original Ocean Bill of Lading (OBL) or Seaway Bill (SWB) provided the Seaway Bill is accepted by the country of destination for custom clearance. ATD is defined as the actual date and time the vessel departs for shipment after pre-shipment inspection has taken place;
  - f. For air freight, main carrier refers to the flight. The Actual Time of Departure (ATD) is taken from the Airway Bill (AWB). ATD refers to the actual date and time that the flight departs for shipment after pre-shipment has taken place.
- 51.3. No partial deliveries shall take place unless written approval has been obtained from the UNFPA Buyer. Individual delivery instructions shall be contained in the Purchase Orders.
- 51.4. The supplier shall regularly update specific shipment tracking information related to any issued Purchase Order in the UNFPA on-line Order Tracking System (OTS). The Estimated Time of Departure (ETD), Actual Time of Departure (ATD), Estimated Time of Arrival (ETA) and Actual Time of Arrival (ATA) shall be entered into the OTS. The website of the OTS is:  
<http://shipping.unfpa.dk/supots>
- 51.5. If awarded with a Purchase Order, a shipping advice note shall be scanned and sent by e-mail to UNFPA at the time for dispatching the cargo; the note shall contain the following information:
- a. PO reference;
  - b. Quantity and type of Goods;
  - c. Invoiced value of the Goods;
  - d. Name of freight forwarder;
  - e. Date of departure from port of shipment;
  - f. Name of vessel or carrier;
  - g. Bills of Lading number(s);
  - h. Expected time of arrival at port of discharge;
- 51.6. If awarded with a Purchase Order, immediately upon shipment of the contracted goods, the supplier must send by email the following shipping documents to the respective UNFPA Buyer.

Furthermore, immediately upon the shipment of the contracted goods, the supplier shall:

- i. send by email the following shipping documents to the respective UNFPA Buyer;
- ii. dispatch two sets of original of the following documents by courier (DHL or Federal Express, etc) to UNFPA and the Consignee:
  - a. One negotiable copy of the Bill of Lading/CMR/AWB (marked "freight prepaid")
  - b. Original commercial invoice


- c. Original packing list
- d. One copy of the certificate of origin
- e. One copy of certificate of analysis for each of the batches, according to appropriate standards
- f. One copy of registration in the country of origin / WHO free sales certificate
- g. Copy of shipping advice
- h. Copy of the actual freight invoice
- i. Any other specific document (if applicable)

## 52. Packing List

- 52.1. All packing lists shall clearly indicate the Purchase Order number, the items(s) contained in each package with a brief description, goods value, quantity, gross weight, dimensions, manufacturing batch number (where applicable) and cross-reference to the carton numbers and markings including the full consignee address. The markings on the boxes shall be as per Purchase Order instructions.

## 53. Marking/Labeling

- 53.1. The marking and labelling on export cartons shall strictly adhere to the following UNFPA requirements:

<p>{UNFPA logo}</p>  <p>UNFPA/Project No.: Contents: Country of destination: UNFPA PO No.:</p>	<ul style="list-style-type: none"> <li>• Supplier name</li> <li>• Case / Carton number</li> <li>• Manufacturing date</li> <li>• Weight</li> <li>• Volume</li> <li>• Max. temperature, if applicable</li> <li>• Specific instructions (if any)</li> </ul>
---	--

## 54. Pre-shipment and post-shipment inspections.

- 54.1. UNFPA reserves the right to conduct pre-shipment and/or post-shipment inspection of any and all goods relating to all Purchase Orders. UNFPA or its contracted inspection agent shall be given reasonable and sufficient time before delivery of the goods to inspect them and to reject or refuse acceptance of any item not conforming to this technical specifications or the specifications stated in the UNFPA's Purchase Order. Payment for the goods pursuant to the Purchase Order shall not be deemed an acceptance of the goods. Inspection prior to shipment or post-shipment shall not relieve the supplier from any contractual obligations. Until quality of the goods is established, all orders will be inspected.
- 54.2. The UNFPA inspection agency will share the final inspection/analytical testing report to the Supplier. The Supplier shall send the inspection/testing report along with the other shipping documents to the consignee via email.
- 54.3. Should there be any pre-shipment discrepancy(ies), the Supplier shall correct the discrepancy(ies), replace the goods, pay for the freight cost and the re-inspection fee at cost.

- 54.4. UNFPA shall conduct random post-shipment inspection and testing at selected ports of destinations. The objective of these inspections will be to determine whether:
- a. Goods have deteriorated during transportation.
  - b. There has been any tampering with the Goods during the period between inspection and delivery at final destination.
  - c. Goods submitted for pre-shipment inspection are identical to those delivered to the final destination.

**55. Supplier's Responsibility for Rejected or Returned Products**

- 55.1. Once contracted, should any product fail the pre- or post-shipment inspection, the supplier shall be responsible for disposal of and or the return of the rejected goods to the country of origin. The supplier shall bear the cost of all related activities, including product replacement, freight and re-inspection costs.
- 55.2. Should any part of the Goods fail to meet the workmanship and requirements of the specifications, the supplier shall replace the items within the time specified for delivery, or extension granted.
- 55.3. Inspection does not relieve the supplier from its contractual obligations and the Goods are subject to final acceptance after delivery.

## SECTION II: Special Notes

### 56. Technical specifications reviewed

- 56.1. Detailed technical specifications of UNFPA standard items have been reviewed and updated under the present ITB and may be different from specifications of the corresponding items in the UNFPA's web catalogue (<http://www.myaccessrh.org/catalog>). New detailed technical specifications will be reflected in the catalogue as a result of completion of the bidding exercise.

### 57. Technical specification of the products offered

- 57.1. When completing Technical Information Sheet (Section VII, 6) 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 size instead - 30 cm" or similar general statements/information. Bidders shall provide their own detailed specifications for specific products they are offering.
- 57.2. Bidders are requested to keep to the structure of products detailed specifications in the Technical Information Sheet (Section VII, 6) when entering specifications, i.e.: "Product Description", "General Design Requirements", "Supplied With", etc. when entering information about their products.

### 58. Assembly of the kits

- 58.1. Kits shall be assembled/packed according to contents of each kit.
- 58.2. On the Product and Price Form (Section VII.7) Bidders are asked to quote:
- a. delivery lead time for fresh production kits (both for placement into stock and for direct shipments); delivery lead time is defined as from the time the supplier receives the UNFPA Purchase Order until goods are delivered under the terms of this bid. Suppliers are advised to state realistic lead times, since UNFPA shall monitor and measure delivery performance
  - b. kitting costs separately for each of the kits (considering varying complexity and size/volume of all kits).
- 58.3. For the kits kept in stock (see below), UNFPA will review remaining shelf life, if applicable, on an on-going basis and occasionally (2-4 times a year) re-order expiring item(s). In such cases, winning bidders will be asked by UNFPA to replace expiring item(s) with new ones within the preassembled kits and destroy the old items; this will be negotiated and priced on case-by-case basis.

### 59. Packing and marking of the kits

- 59.1. All items are to be over-packed in outer export carton (triple wall) boxes with plastic strapping. Items inside the shipping cartons must be packed to withstand transport to and within the country of destination. In some cases, individual packing would be logical. The supplier will need to manage internal packaging effectively given the items and nature of them within the kits and the shipping cartons. (i.e. scissors and gloves should not be together in the same box).

- 59.2. To facilitate logistics in the country, the boxes containing the supplies shall be:
- Marked with the weight and volume of each kit;
  - Are clearly marked with the kit number, description, consignee and other relevant information;
  - Clearly labelled with the storage conditions of the products.

59.3. Volume and weight (export carton) of kits as currently procured by UNFPA:

- Fistula Kit1: 39 x 28 x 24cm and 6,2 kg
- Fistula Kit2: 60 x 40 x 27cm and 7,0 kg

## **60. Warehousing/storage and inventory.**

- 60.1. Winning bidders will be required to keep some of the pre-assembled Fistula Kits in stock. Cost of storage shall be quoted in the Product and Price Form (Section VII.7) as a flat rate per kit regardless of the actual storage period. Average storage of those kits to be kept in storage is 4-6 months. Approximate quantities of kits to be kept in storage is 200 of Kit1 and 200 of Kit2.
- 60.2. Winning bidders shall have warehouse facilities, suitable for storage of the pre-assembled kits.
- 60.3. Keep cool items, if any, shall be packed/stored/transported separately and in accordance with temperature requirements for such items.
- 60.4. The warehousing premises of the supplier who is a wholesaler or distributor must be certified compliant in accordance with Article 10 of Council Directive 92/25/EEC, Article 80 (g) 2001/83/EU and adhered to Good Distribution Practice of Medicinal Products for Human Use (94/C 63/03) or equivalent. The wholesaler or distributor must be certified and licensed by the national authorities to assemble, store, transport pharmaceutical products. The wholesaler or distributor must conform to the principles and guidelines of good storage practices for pharmaceuticals as required by World Health Organization (WHO), ensuring storage conditions are observed at all times, including during transportation, that contamination from or of other products are stored in appropriately safe and secure areas, that an adequate turnover of the stored medicinal products takes place and that products are stored in appropriately safe and secure areas. A tracing system should enable any faulty product to be found and there should be an effective recall procedure in place. For more information, please see attached Section V: Guidelines on Good Distribution Practice of Medicinal Products for Human USE (94/C 63/03).
- 60.5. In the technical proposal, the supplier who is a wholesaler or distributor shall describe its good distribution practices, quality assurance, warehousing capability, shelf- life management system, processes and procedures such as stock management, etc. The supplier shall submit its quality assurance policy which should be in line with the Model Quality Assurance System for Procurers.
- 60.6. The supplier must prepare a monthly report on the stock of each kit on hand with the following information:
- the quantities of each kit;
  - the expiration dates (If applicable) of the each item within the kits.

**61. Printed materials**

- 61.1. Leaflets, which are part of the kits, need to be produced and included into the kits by the successful bidders.
- 61.2. Samples can be downloaded from the following: [LINK](#)
- 61.3. Samples of printed leaflets are required together with samples of other items.

**62. Questionnaire for pharma products**

- 62.1. Interagency Finished Pharma Product Questionnaire (IAFPP Questionnaire) is provided as a separate file in the bid documentation package.
- 62.2. Bidders are required to fill in the IAFPP Questionnaire for items 66 and 67 and provide it in the folder with other documents for these products.

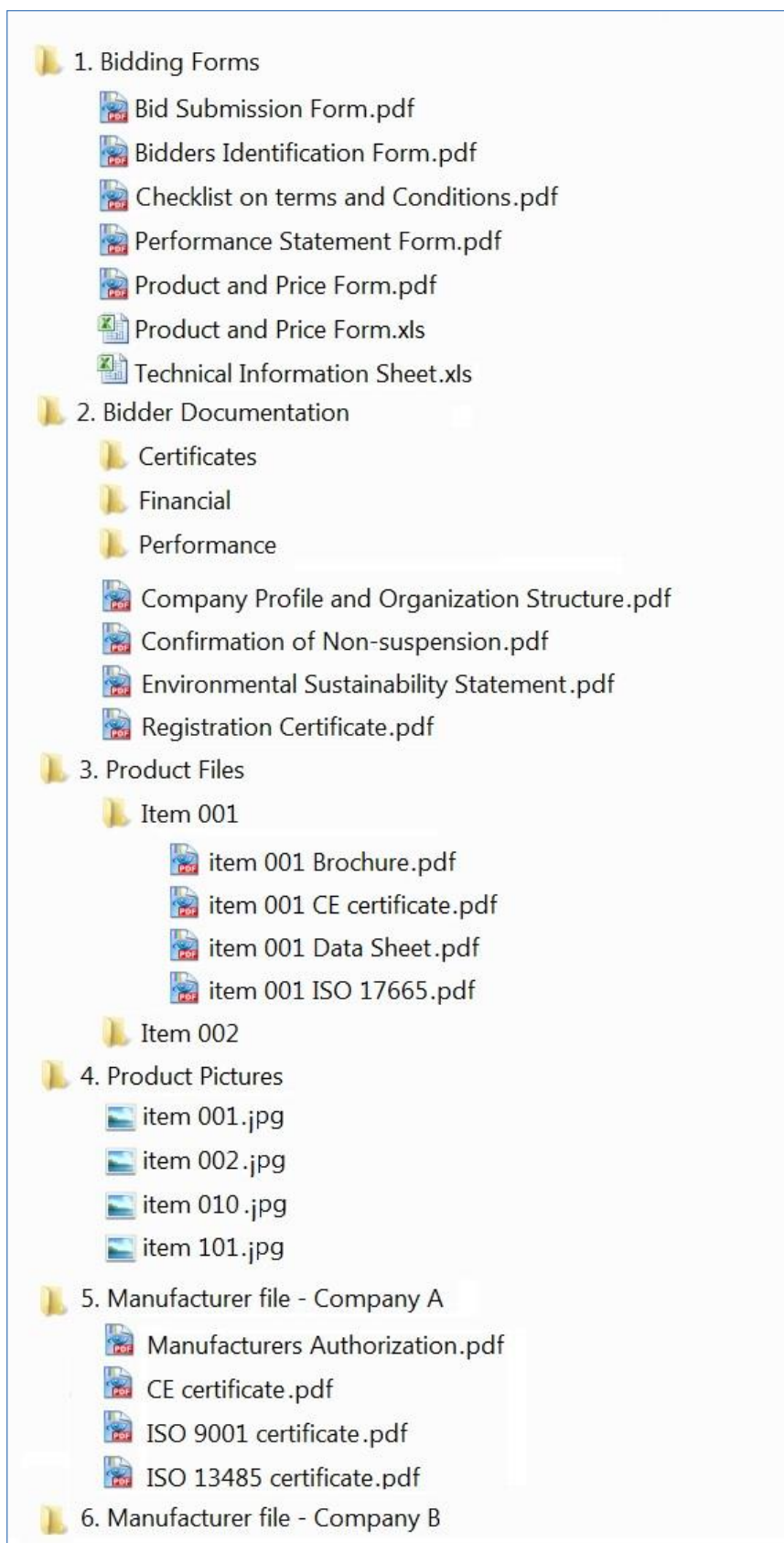
**63. Generic pictures**

- 63.1. To enable bidders to identify products easier, pictures of some products are provided in a separate archive file in the bid documentation package.

**64. Bid Structure and Naming convention**

- 64.1. UNFPA recommends bidders to keep to the following folder structure of their submissions (as a minimum):
  - Main parent folder with covering Letter and overview of the contents of the Bid submission;
  - Separate folder with all bidding forms; Technical Information Sheet and Product and Price Form shall be submitted in Excel format;
  - Separate folder with all documentation requested under Clauses 2, 10, 28 (except bidding forms, mentioned already above);
  - Separate Folder per each item with documentation requested for such item under detailed technical specifications of the Technical Information Sheet (Section VII, 6) and Technical Requirements (Sections IV and V); for convenience items of the same category (or from the same manufacturer) can be joined into one folder in order to provide shared documentation/certificates for such items in one place;
  - Separate folders for pictures (see below);
- 64.2. It is recommended to attach separate documents as separate files (instead of scanning multiple documents into one PDF file) with self-explanatory naming, for example: "Item 001 – CE certificate.pdf", "Bidder registration certificate.pdf", etc.

*Below is an example of the bid structure, contents of folders and file names. This is provided for guidance only and is not meant to limit bidders in creating more detailed (self-explanatory) structure or to override requirements of other clauses of this bid.*





**65. Pictures of products offered**

- 65.1. Bidders shall provide at least one picture for each/all main and alternative items offered.
- 65.2. All pictures shall be stored in a separate folder "Product Pictures" with the following naming of the files (according to ITB item numbers): "001.jpg", "002.jpg", ... "010.jpg", "011.jpg", etc.  
For alternative offers: "001a.jpg", "002a.jpg", ... "010a.jpg", "011a.jpg", etc.
- 65.3. Picture shall be approx. 350\*350 pixels, preferably of higher resolution.

**66. Samples**

- 66.1. Bidders are required to submit product samples for all items. Samples should be sent separately from bid documentation, in case samples are delayed in customs. Samples will be subject to technical review and laboratory analysis where appropriate. The samples submitted are non-returnable.
- 66.2. The list of items, for which samples are required and quantities, is in a separate file in the bid documentation package.
- 66.3. Samples should be received by the **deadline of June 15, 2015 16:00**, Copenhagen time at the following address:  
*UNITED NATIONS POPULATION FUND (UNFPA)*  
*UN City*  
*Marmorvej 51*  
*2100, Copenhagen*  
*DENMARK*  
*Attention: Sergey Khvedchenya*
- 66.4. Packages with samples need to be marked as following:  
*Samples– ITB UNFPA/DNK/ITB/15/009*  
*Only To Be Opened By Authorised UNFPA Personnel*
- 66.5. Failure to provide samples or documentation in a timely manner shall be sufficient ground to declare the submission invalid.
- 66.6. The bidder shall bear all costs associated with sending the samples, UNFPA shall in no case be responsible or liable for those costs, regardless of the conduct or outcome of the solicitation.
- 66.7. Sample shall be properly organized and prepared for ease of inspection by UNFPA's inspector as follows:
- 1 unit of sample packed in a box or plastic bag and clearly labelled with Item No (main or alternative) and item name as per the Bidding Document.
- 66.8. UNFPA may choose to elect an independent inspection agency to inspect the samples, which will be informed to the short-listed bidders. Samples provided to UNFPA are non-returnable.

**67. Request for Change of Product(s) After Award**

- 67.1. It should only be under very rare exceptional instances when the supplier is not able to provide a product according to the specifications as approved during bid process and hence included in the awarded Long Term Agreement (LTA). In those instances, it is important that the quality of

the product as approved in the LTA is not negatively affected. The risks of using different specifications and/or manufacturer should be carefully and thoroughly assessed by the supplier and a risk management plan should be provided.

- 67.2. In addition, the supplier shall apply for request for change in writing by filling in and submitting the "Request to Change the Specifications/Technical Requirements" Form to UNFPA QA for technical assessment.

### SECTION III: Schedule of Requirements and Spend Analysis

Below are figures of Fistula Kits off-take under UNFPA LTAs in 2012-2014.

Product Description	Q-ty procured in 2012-20014	Amount spent, 2012-20014, USD
Fistula Kit 1, Instruments (comprised of 38 items)	1,123	321,257
Fistula Kit 2, Consumables (comprised of 29 items)	1,197	633,349

#### Detailed Technical Specification of items

See “Section VII-6 - Technical Information Sheet for ITB UNFPA-DNK-ITB-15-009.xls” file for detailed list and specification of all products comprising the kits.

## SECTION IV: Technical Requirements for Medical Devices

### 1. INTRODUCTION

The following document provides UNFPA's technical requirements in the procurement of medical devices (medical equipment, renewable medical supplies and medical kits excluding pharmaceuticals that might accompany kits). It is intended to give to submitters all the necessary information for them to complete understandable and homogenous dossiers.

From a general stand point, UNFPA's technical requirements are based on the current standards and regulations, for both manufacturer's quality assurance and devices compliance.

The technical requirements also apply when the submitter is not the legal manufacturer (i.e: a distribution company).

### 2. GENERAL REFERENCES

#### 2.1. International guidance

UNFPA recognizes recommendations by the International Medical Device Regulators Forum (IMDRF). The following guidance shall be taken into consideration by the manufacturer:

- GHTF/SG1/N68:2012: Essential Principles of Safety and Performance of Medical Devices
- GHTF/SG1/N77:2012: Principles of Medical Devices Classification
- GHTF/SG1/N78:2012: Principles of Conformity Assessment for Medical Devices. For more information on IMDRF, refer to the IMDRF website: <http://www.imdrf.org/>.

#### 2.2. Declaration of conformity

The submitter shall provide a declaration of conformity to applicable regulation(s) and/or standard(s). This declaration of conformity shall be established according to the model given in *ISO/IEC 17050*.

#### 2.3. Compliance with regulatory requirements

Medical devices proposed to UNFPA for procurement and supply must be from manufacturers who are legally registered to manufacture the particular device by their national regulatory authority and have valid manufacturing licenses and or a Free Sales Certificate.

Any official clearance or legal certificates, (e.g. 510k clearance, CE certificates, or equivalent licences shall be provided, where applicable).

#### 2.4. Quality Management System standards

The manufacturer of the product shall provide evidence that their quality management systems conform to the current version, at the time of the submission to the following quality management system international standards (or local – national transcription of these standard):

- ISO 9001 – Quality Management Systems: Requirements
- ISO 13485 – Medical Devices: Quality Management Systems

In the case where a significant part of the production processes is subcontracted by the legal manufacturer to a contractor (for example: final sterilization, final assembly, sub part manufacturing), then the requirement for QMS also applies to the contract manufacturer(s).

### 3. CONFORMITY OF PRODUCTS WITH SPECIFIC SAFETY / PERFORMANCE STANDARDS

#### 3.1. List of applicable standards

The standards to which the device is claimed to be compliant to should be part of a list of local recognized standards (e.g., EC list of harmonized standard, as published on the OJCE, FDA recognized standards, etc...). Proof of conformity to product specific standards shall be provided for the product category covering the products to be supplied.

For example stainless steel surgical instruments should meet the requirements of ISO 7151; ISO 7153; ISO 7741 and ISO 13402.

#### 3.2. Sterile products:

##### 3.2.1. Certification of the sterilization process

The sterilization plant (the manufacturer itself or any contract sterilizer company) that performs this task shall be covered by a valid ISO 13485 certificate for the specific sterilization process:

- ISO 11135 (ETO sterilization)
- ISO 11137 (Gamma Irradiation)
- ISO 17665 (Steam sterilization)
- ISO 20857 (Dry heat)
- ISO 14937 (for any other sterilization method)

The relevant certificate shall also be submitted at the bid stage.

##### 3.2.2. Individual sterilization batch certificates

During bid evaluation, UNFPA requires copies of certificates of sterilization from the last 3 most recently released batches from the manufacturer.

*Note: The individual batch sterilization certificate must be issued by the legal manufacturer, who owns the entire responsibility of the compliance of the finished device.*

During the procurement phase, certificates of sterilization for each batch procured by UNFPA shall be provided to the pre-shipment inspector for each Purchase Order.

#### 3.3. Packaging and labelling

Primary packaging shall be by unit of use and secondary packaging shall provide protection of the packaged individual units in a box.

*Note: UNFPA and other UN agencies will from 2014 going forward require that all paper and cardboard secondary packing is FSC marked. Similarly, UNFPA will gradually between 2014-2020 increase its requirement for the use of recycled material in secondary packing. Plastic used in secondary packing will gradually be required to be fully biodegradable.*

Labelling shall meet, at least, the requirements described in the Global Harmonization Task Force document: GHTF/SG1/N70:2011: Label and instruction for Use for Medical Devices. The language should be in English or Spanish or French as specified.

Labelling on the medical device itself (if on medical device itself it should be in a format that will not be dislodged during cleaning, disinfecting or sterilization of the device) or on the

primary packaging of each unit or on the primary packaging of multiple devices should contain the following where applicable:

- a. Name and/or trademark of the manufacturer including the address of the manufacturer. Name and address of Authorised Representative or Distributor maybe added but this additional label should not obscure any of the manufacturer's labels;
- b. Manufacturer's product reference;
- c. Type of product and main characteristics, i.e. details to identify the device and its use;
- d. If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging;
- e. Lot number prefixed by the word "LOT" (or equivalent harmonised symbol, if applicable)/batch code or serial number;
- f. For products supplied sterile or for single use disposable devices, a date of when the device may be safely used with year and month should be clearly indicated including the sterilization method where applicable. In order to verify the stated shelf life, the date of manufacture should be provided;
- g. Information for particular storage conditions that apply (temperature, pressure, light, humidity, etc., as appropriate (or equivalent harmonised symbol.);
- h. Information for handling, if applicable (or equivalent harmonised symbol).

For devices that have CE marking approval, the CE mark should be on the item itself, or on the primary packaging as appropriate. Please note: if on device itself, this should not be removable during handling, use or cleaning of the device.

### **3.4. Shelf life**

The shelf life of the device shall be clearly indicated. Devices with less than 75% shelf life will not be accepted by UNFPA.

For sterile products, expiration date should not exceed 5 years from date of sterilization.

### **3.5. Instruction for use/product manuals**

Instructions for use or manuals must be provided in the following languages or as specified: English, Spanish or French, as per request based on recipient country of distribution. This should include any assembly instructions.

### **3.6. Other requirements**

#### **3.6.1. *Installation, spares and service***

In addition to installation details, information should be provided on service, repair and spares where applicable. Any special tools or test equipment required should also be specified at both bid stage and Purchase Order stage.

#### **3.6.2. *Training and support***

For equipment where training is required before competent technical staff can use the device, this should be clearly indicated at the bid stage and also at Purchase Order stage with information of who will provide this training.

#### **3.6.3. *Warranty***

A copy of warranty should be provided for all equipment.

**3.6.4. *Re-usable products***

Clear information/instructions should be provided on cleaning, disinfecting and sterilization methods and types for the device. The method should be adapted to the local constraints of the countries or region the device is intended to be used.

**3.6.5. *Electrical devices***

The available voltage and plug types should be specified and if contracted, the correct voltage and plug type should be supplied for the respective country of destination as per Purchase Order.

**3.6.6. *Disposal of the device***

Where appropriate, the necessary information shall be provided for the safe disposal or decommissioning of the device after its recommended time of use.

*Note: Some specific regulation may locally apply*

**3.7. Environmental management systems**

Manufacturers are encouraged to provide ISO 14001 certification.

Manufactures will – over time - be requested to provide proof of ISO 14001 (Environmental Standard) and ISO 50001 (Energy Standard) certification. It is therefore encouraged, but not required before 2015-16, to have these certifications in place.

## **SECTION V: Technical Requirements for Pharmaceutical Products**

### **1. Eligibility requirements**

Only products approved by a National Regulatory Agency are eligible for this bid (as defined below by product).

Bidders shall disclose (part of the Bidders Identification Form, Section VIII.4) whether it or the manufacturer has been involved with product recall or in litigation and arbitration, or whether any FDA 483 warning letters have been issued against the company in the past five years.

### **2. Technical specifications**

Specifications of Pharmaceutical Products are listed in the Technical Information Sheet (Section VIII.6).

Wherever items offered are not in compliance with specifications indicated by UNFPA, or wherever alternatives are offered, it is the supplier's responsibility to provide full descriptive specification and documentation of such items. In such instances the item or items must be clearly marked as not being in compliance with specifications. A field for comments is included to explain variations from the UNFPA specifications.

### **3. Quality assurance system**

Bidders are requested to submit a Quality Manual explaining the quality system of the supplier and should include the quality policy in relation the various activities undertaken by the supplier. The quality system should be in line with the current WHO's Good Distribution Practices Annex 5, Technical Report Series 957, 2010. Activities to be covered in the QM should also include the following:

- Vendor/supplier/manufacturer pre-qualification;
- Product pre-qualification;
- Storage;
- Distribution of pharmaceutical products including thermo-labile products.

Prequalification of pharmaceuticals and manufacturers/suppliers of pharmaceuticals should be consistent with WHO's current "A Model Quality Assurance System for Procurement Agencies," Annex 3, Technical Series 986, 2014.

### **4. Product information**

#### Product quality assurance

The pharmaceutical products proposed under this bid shall meet the following criteria:

- a. Products shall be:
  - i. In compliance with the ICH regulatory standards with authorization to market the products in the ICH/Stringent Regulatory Agency countries and not just for export only; or
  - ii. In compliance with National Regulatory Standards of the country of manufacture.



- b. Products specifications shall comply with or be superior to International Pharmacopeia (Ph.Int), United States Pharmacopeia (USP), British Pharmacopeia (BP), European Pharmacopeia (Ph.Eur) - using not more than one year old Pharmacopeia specifications.

#### Manufacturing sites

A manufacturing site is where any aspect of manufacture of any of the components of the final product occurs.

Once contracted, the supplier shall inform UNFPA of any change in the status of every GMP certificate identified in the list of manufacturing sites included in the respective bid.

UNFPA (WHO in the case the product is prequalified by WHO) must be informed of any changes to the manufacturing site(s) once the National Regulatory Agency has made a decision on the variation. Failure to obtain prior approval of such changes may result in termination of the LTA and any pending orders.

In case of any manufacturing facility relocation or substitution of manufacturing facilities, the supplier shall notify UNFPA of the change and request approval to supply the contracted products from the new location. If the change is approved by UNFPA after an inquiry to WHO for GMP status of the new location, approval will be provided by means of a formal contract modification.

In case any Notice of Concern (NOC) is issued by WHO Prequalification Team or any NRA in relation to a site where a product supplied is manufactured, the supplier has the responsibility of informing UNFPA on the products affected.

#### Manufacturer conformity with quality management system standards

For the purpose of quality assurance, it is mandatory for bidders which are not the manufacturer of the products to provide the manufacturer information. Bidders which are not the manufacturer of the products they intend to bid for must obtain information from the respective manufacturer prior to bid submission.

The pharmaceutical products shall be manufactured in conformance with current GMP (and other supporting guidelines) as recommended by the World Health Organization.

As part of the Inter-Agency Finished Pharmaceutical Product Questionnaire 2014, suppliers are requested to submit the documents as listed in the Annexures.

Certificates submitted for quality management systems of the manufacturer shall be in English and must indicate the following:

- a. Manufacturer's name
- a. Specific facility and location
- b. Date of issue
- c. Date of expiry
- d. Scope of inspection
- e. Certifying company's name
- f. Certifying company's country

In case of supplying a copy in a different language, certified translation into English must be submitted.

#### Shelf life

For products with shelf life, the products shall be recently manufactured and have a minimum shelf life of 75% remaining at time of delivery to consignee.

#### Storage conditions

Particular storage conditions (temperature, pressure, humidity, etc.) shall be clearly stated, if applicable. Labelling of the product shall be according to the WHO TRS 953, Annex 2, Appendix 3.

Country of origin

Bidders shall clearly state the country of origin for each product in the Product and Price Form (Section VIII.7). Country of origin is defined as the country where at least 80% of the product is manufactured.

Product HS Code

Bidders shall submit HS code of each product item in Product and Price Form (Section VIII.7). HS Code is the Harmonized Commodity Description and Coding System Code maintained by the World Customs Organization (WCO), an independent intergovernmental organization with over 170 member countries based in Brussels, Belgium.

Stability studies

UNFPA supplies many countries with pharmaceutical products and some countries require that the long-term stability studies are performed under Zone VIB conditions. In order to ensure the product quality is maintained throughout the product shelf-life we require that all pharmaceuticals should have undergone stability studies under  $30 \pm 2^{\circ}\text{C}$  /  $75 \pm 5\%$  RH. Bidders may provide sound scientific justification for not performing the studies e.g. product is unstable at these temperature. A commitment to start and complete stability studies under  $30 \pm 2^{\circ}\text{C}$  /  $75 \pm 5\%$  RH will be acceptable.

Interchangeability/bioequivalence

For medicines that are eligible for bioequivalence studies (references include to WHO TRS 937, Annex 8), a bioequivalence study protocol and report should be attached to the Inter-Agency Finished Pharmaceutical Product Questionnaire 2014. Where the finished pharmaceutical product is eligible for a biowaiver, a comparative dissolution study as per WHO TRS 970, Annex 4, Appendix 1 should be attached to Inter-Agency Finished Pharmaceutical Product Questionnaire 2014.

Registration

Bidders shall provide a list of countries registered in the Bid for the products offered.

Once contracted, if product registration is required, the supplier shall be responsible for registration of the Goods with the relevant authorities in the Consignee's country.

Patient information leaflets and package inserts

For medicines, bidders shall submit Patient Information Leaflets (PILs), instructions, etc. in three languages (English, French and Spanish) for the Goods stated in the Product and Price Form (Section VIII.7).

For medical devices, the supplier shall supply the Goods with manuals or instructions sheets (providing instructions for safe installation, set up, assembly, usage, recommended storage condition and maintenance of the product) in three languages (English, French and Spanish) along with the shipment.

Sterilization

Bidders shall submit validation of sterilization methods for all sterile goods offered under this Bid. In the case of pharmaceuticals, and as part of the Finished Pharmaceutical Product questionnaire, suppliers shall submit validation of sterilization methods for all sterile Active Pharmaceutical Ingredients and Finished Pharmaceutical Products offered under this Bid

Managing product recalls

UNFPA reserves the right to suspend procurement of products in case of identification of inferior quality and inform publicly where applicable, the NMRA and patients who may be affected.

In the event that UNFPA in co-operation with NMRA in supplied countries decides on product recall, the supplier shall organize this recall and necessary associated activities at the cost of the supplier. Any additional recall expenditure incurred by UNFPA shall be compensated by the supplier.

## 5. Packing Information

### Packing of goods for international delivery

The cost of packing and the packing material cost shall be included in the bid price offered for the items.

The packing of the product(s) shall be suitably over-packed for shipment in strong triple-wall cardboard boxes and in a manner that shall provide adequate protection of the goods with sufficient buffering of the equipment for carriage by air, sea, and road to final destination and subsequent inland distribution including remote locations under adverse climatic and storage conditions, and high humidity – i.e. not less than 17kN edge crush resistance with minimum 60% remaining with 90% at a temperature of 40°C (tropical conditions).

The handling and transport of dangerous goods is subject to rules and regulations based on international transport agreements (ADR, RID, IMDG Code, IATA DGR, ICAO) in order to prevent injury to persons, damage to cargoes and living resources. Hence, should any Goods comprised in this Agreement be classified as dangerous goods, it is the supplier's responsibility to ensure that the packing of the Goods take into account any special requirements for dangerous or hazardous goods or cold chain items and are labeled correctly, transported safely and accompanied by the necessary transport certificates during shipment. The Cost of packing, including export packing, is included in the price.

Outer cartons shall be numbered consecutively. No carton may contain items from more than one manufacturing batch. Cartons containing non-uniform contents must be specially marked with red at the top corners.

Case identification as requested on the order must be mentioned on all invoices.

Packaging of product shall comply with WHO GMP standards:

- Primary packaging – sterile or non-sterile as appropriate. E.g. for sterile items, transparent film to allow clear identification of the content – sachet, plastic box, peel-off sachet. For pharmaceutical products in tablets/capsule. For item with 30 tablets/capsules or less, it shall be in blister pack. For item with more than 30 tablets/capsules, it should be in bottle;
- Secondary packaging – to protect the primary packaging – e.g. cardboard, rigid wrapping.

### Marking and labelling

The labelling of the product shall meet the following requirement:

- a. Primary packaging shall be imprinted with the following:
  - i. Name of manufacturer
  - ii. Address of manufacturer's manufacturing site – where there is space enough
  - iii. Article reference of the manufacturer and the supplier
  - iv. Details to identify device in English, French and Spanish; description, composition as appropriate
  - v. Batch number prefixed by the word "LOT" or equivalent harmonized symbol
  - vi. Items with limited shelf life, expiry date using the words "use before (month)/(year) or prefixed by "EXP" or equivalent harmonized symbol (month)/(year)
  - vii. Items without expiry date, the date of manufacture (year) prefixed by the harmonised symbol, unless information already incorporated into the batch number or serial number

- viii. For single use items, the words “DO NOT RE-USE” or “FOR SINGLE USE” or equivalent harmonized symbol
  - ix. For sterile items, the word “STERILE” or equivalent harmonized symbol, plus a warning which advises to “check the integrity of the sterile packaging before use.”
  - x. Name of drug;
  - xi. Pharmaceutical dosage form
  - xii. Active pharmaceutical ingredient(s); type and amount;
  - xiii. Net quantity per unit
  - xiv. Instructions/direction for use
  - xv. Storage conditions including warnings and precautions
  - xvi. If reconstitution is required, state the storage conditions after reconstitution and shelf-life;
- b. Secondary packaging for pharmaceutical products shall be imprinted with the following:
- i. Name of manufacturer
  - ii. Address of manufacturing site
  - iii. Labelling same as on primary packaging, in addition –
  - iv. Any special storage conditions and or handling conditions
  - v. Instructions for use in English, French and Spanish.
- c. Summary of Product Characteristics, package inserts and Patient information leaflets. The content should be in line with WHO SPC template which may be accessed at [http://apps.who.int/prequal/WHOPAR/WHOPARGUIDE/file04a\\_Annotated\\_SPC\\_template.pdf](http://apps.who.int/prequal/WHOPAR/WHOPARGUIDE/file04a_Annotated_SPC_template.pdf)

## **6. Storage and transportation of temperature sensitive pharmaceuticals**

Medicines requiring controlled temperatures during storage and transportation shall be provided in accordance with the Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products, WHO TRS 961, Annex 9.

To maintain the desired temperature during transportation container with dry ice or thermal jackets may be used. Such containers should protect the product from mechanical damage and any anticipated ambient temperature range during transportation and transit; they shall be tamper proof and allow for the recipient to establish that the product has not been tampered with while in transportation and transit.

Temperature in the container(s) during transportation and transit shall be monitored using appropriately calibrated monitoring devices.

Compliance with the required temperature conditions shall be demonstrable to UNFPA and records shall be kept as per Good Distribution Practices.

## **SECTION VI: UNFPA General Terms and Conditions**

UNFPA General Conditions of Contract for provision of Goods can be found at:

<http://www.unfpa.org/sites/default/files/resource-pdf/UNFPA%20General%20Conditions%20-%20Goods%20EN.pdf>

## SECTION VII: Bidding Forms

### 1. Bid Confirmation Form

Date: [Date]

To: UNFPA  
Mr. Sergey Khvedchenya

Email: [khvedchenya@unfpa.org](mailto:khvedchenya@unfpa.org)

From: [Company name]  
[Contact person]  
[Telephone]  
[Email address]  
[Postal address]

Subject: ITB No.: UNFPA/DNK/ITB/15/009

YES, we intend to submit a bid.

NO, we are unable to submit a bid in response to the above mentioned Invitation to Bid due to the following reason(s):

- ☐ The requested products and services are not within our range of supply
- ☐ We are unable to submit a competitive bid for the requested products at the moment
- ☐ The requested products are not available at the moment
- ☐ We cannot meet the requested specifications
- ☐ We cannot offer the requested type of packing
- ☐ We can only offer FCA prices
- ☐ The information provided for quotation purposes is insufficient
- ☐ Your ITB is too complicated
- ☐ Insufficient time is allowed to prepare a quotation
- ☐ We cannot meet the delivery requirements
- ☐ We cannot adhere to your terms and conditions (please specify: payment terms, request for performance security, etc)
- ☐ We do not export
- ☐ Our production capacity is currently full
- ☐ We are closed during the holiday season
- ☐ We had to give priority to other clients' requests
- ☐ We do not sell directly, but through distributors
- ☐ We have no after-sales service available in the recipient country
- ☐ The person handling bid is away from the office
- ☐ Other (please specify)

**If UNFPA has questions to the Bidder concerning this NO BID, UNFPA should contact Mr./Ms. \_\_\_\_\_, phone/email \_\_\_\_\_, who will be able to assist.**

## 2. Bid Submission Form

To: UNFPA  
Marmorvej 51  
2100 Copenhagen  
Denmark

Ref: ITB No.UNFPA/DNK/ITB/15/009

Dear Sir / Madam,

We, the Undersigned, have examined and have no reservations to the Bidding Documents No. UNFPA/DNK/ITB/15/009 and amendments, if any. We hereby offer to supply Fistula kits in accordance with the specifications stated and subject to the Terms and Conditions specified in the documents.

We agree to abide by this bid for a period of 6 months from the date fixed for opening of bids in the Invitation to Bid, and it shall remain binding upon us and may be accepted at any time before the expiration of that period.

We have no conflict of interest in accordance with Instructions to Bidders Clause 2.3;

Our firm, its affiliates or subsidiaries—including any subcontractors or suppliers for any part of the contract—have not been declared ineligible by UNFPA, in accordance with Instructions to Bidders Clause 2.4;

We understand that you are not bound to accept the lowest evaluated bid or any other bid that you may receive.

Date: .....

Signature and seal of the bidder: .....

Name and Title: .....

Company: .....

### 3. Checklist on UNFPA Terms and Conditions

Kindly complete and submit this document as part of the Technical Proposal.

Criterion	Response from the bidder
Did your firm review the original UNFPA/DNK/ITB/15/009 including, all Annexes, subsequent revisions posted on United Nations Global Market Place and the answers to the questions received from prospective bidders in full before submitting the technical and financial proposals?	
Does your firm fully agree with all the Terms and Conditions given in the UNFPA/DNK/ITB/15/009 including Annexes, the subsequent revisions and the clarifications provided through the answers to the questions received from prospective bidders?  (if your answer is other than YES please fill the table below)	

The original Term/ Condition as per UNFPA/DNK/ITB/15/009 and the subsequent revisions.	Proposed deviation (Alternate clause), if any, by the bidder	Reason for proposing alternate clauses

**Special Note:** If your firm proposes any deviations from the terms and conditions stipulated on the ITB document all such should be summarized using this form. Such proposals should not be indicated within the main body or any other part of your technical proposal. Please be advised that if the proposed modifications are not acceptable to UNFPA, UNFPA reserves the right to reject the bid. Please avoid proposing semantic changes.

	On behalf of Business Authority	On behalf of Legal Authority
Signature		
Name		
Title		
Company		
Email address		



## 4. Bidders Identification Form

ITB No. UNFPA/DNK/ITB/15/009

### Organization

Company/Institution Full Name	
Address, City, Country	
Telephone/FAX	
Website	
Date of establishment	
<b>Legal Representative:</b> Name/Surname/Position	
<b>Legal structure:</b> natural person/Co.Ltd, NGO/institution/other (please specify)	
<b>Organizational Type:</b> 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)	

### 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)	

### Expertise of Staff

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

**Financial and Economic Standing**

Turnover in 2012 (USD)	
Turnover in 2013 (USD)	
Turnover in 2014 (USD)	
Liquidity ratio (Current assets less stock/current liabilities) 2012	
Liquidity ratio (Current assets less stock/current liabilities) 2013	
Liquidity ratio (Current assets less stock/current liabilities) 2014	
Current ratio (Current assets/current liabilities) in 2012	
Current ratio (Current assets/current liabilities) in 2013	
Current ratio (Current assets/current liabilities) in 2014	

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

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

**5. Performance Statement Form**

(For the last five years)

Bid No. UNFPA/DNK/ITB/15/009

Name of Bidder: \_\_\_\_\_

Order No. & Date	Client	Contact person/phone	Description & quantities of ordered items	Value of order (USD)	Date of completion		Satisfactory completion
					As per contract	Actual	

To be attached: Documentary evidence (client's letter or certificate) in support of satisfactory completion of above orders.

\_\_\_\_\_

Signature and seal of the Bidder

\_\_\_\_\_

Date

\_\_\_\_\_

Countersigned by and seal of Chartered Accountant

\_\_\_\_\_

Date

## **6. Technical Information Sheet**

Use the attached file “Section VII-6 - Technical Information Sheet for ITB UNFPA-DNK-ITB-15-009.xls” for detailed requirements.

## **7. Product and Price Form**

Use the attached file “Section VII-7 - Product and Price form for ITB UNFPA-DNK-ITB-15-009.xls”.

## 8. Joint Venture Partner Information Form

*[The Bidder shall fill in this Form in accordance with the instructions indicated below.]*

Date: *[insert date (as day, month and year) of Bid Submission]*

ITB No.: UNFPA/CC/YY/NNN

Page \_\_\_\_\_ of \_\_\_\_\_ pages

1.	Bidder's Legal Name: <i>[Insert Bidder's legal name]</i>
2.	JV's Party Legal Name: <i>[Insert JV's Party legal name]</i>
3.	JV's Party Country of Registration: <i>[Insert JV's Party country of registration]</i>
4.	JV's Party Year of Registration: <i>[Insert JV's Part year of registration]</i>
5.	JV's Party Legal Address in Country of Registration: <i>[Insert JV's Party legal address in country of registration]</i>
6.	<p>JV's Party Authorized Representative Information</p> <p>Name: <i>[Insert name of JV's Party authorized representative]</i></p> <p>Address: <i>[Insert address of JV's Party authorized representative]</i></p> <p>Telephone/Fax numbers: <i>[Insert telephone/fax numbers of JV's Party authorized representative]</i></p> <p>Email Address: <i>[Insert email address of JV's Party authorized representative]</i></p>
7.	<p>Attached are copies of original documents of: <i>[Check the box(es) of the attached original documents]</i></p> <p><input type="checkbox"/> Articles of Incorporation or Registration of firm named in 2, above, in accordance with Instructions to Bidders Sub-Clauses 3.1 and 3.2.</p> <p><input type="checkbox"/> JV Agreement, or letter of intent to enter into such an Agreement, signed by the legally authorized signatories of all the parties</p>

## **SECTION VIII: UNFPA Contract Forms**

Samples of UNFPA Contract Forms are available on the UNFPA procurement website:

- 1) [Long Term Agreement](#)
- 2) [Purchase Order](#)