



UNITED NATIONS POPULATION FUND

ITB No. UNFPA/DNK/ITB/21/001 FOR THE SUPPLY OF MENSTRUAL HEALTH MANAGEMENT PRODUCTS

CLARIFICATION NOTICE (No. 1)

Date Issued: 17 March 2021

The following clarifications are offered in response to requests received by potential bidders in the framework of the above mentioned tender document.

CLARIFICATIONS

1. Question: Can you please confirm if we are to email our tender documents?

Answer: Please refer to tender Section 3. Data Sheet, paragraph Instructions for bid submission, as per which the allowable manner of submitting your proposal is by email ONLY.

2. Question: We have designed our cup without holes around the rim as these had been proving to be very difficult to clean for many users. Many were using dental tools and toothpicks and still reported these holes remained dirty. We thought this would be detrimental for girls and women living in LMICs with no access to such devices for cleaning. The physicists and mechanical engineers we worked with recommended that instead of holes, internal arches added inside of the cup would replace the need for holes, would make cleaning easier and as all menstrual cups need to be pinched at the base to break the seal, it is more about educating the user, especially those wearing an IUD, on proper removal instructions.

Answer: The purpose of the small holes is to allow air passage through the cup while placing and removing it. When the cup is pinched while removal, the compressed air passes through the holes releasing the seal thereby aiding removal. Likewise, when the cup is placed, the “popping open” of the folded cup creates a suction pressure between the cup and the cervix.

The air holes allow air to pass through to the cup and negates the suction. This simple feature adds to the comfort of using the cups.

The alternate mechanism for holes (internal arches, in this case) is acceptable provided there is enough evidence to show that the cups are similar in performance with the one having holes. This can be presented either as clinical trial data or as lab evaluation data or post market surveillance data along with the submissions.

3. Question: Our cup was developed specifically for girls and women living in LMICs, especially so in slums and refugee settlements, who would struggle to access clean water to wash and boil their menstrual cup. The cup is physically antibacterial as a biofilm cannot form on its surface. The cup needs only to be wiped to clean. No boiling is necessary, but no harm is done to the cup if it is boiled. My question is if we will have to comply with the boiling requirement. Additionally, ageing testing was conducted on the cup. The engineer stopped at 140 years thinking there was no need to continue beyond this.

Answer: Yes, the product must comply with the boiling requirement along with the shelf-life data. You may also provide proof/data to show that the product is below the specified bioburden and safe to use after wiping upon repeated use during one menstrual cycle. Test data from accredited labs are recommended.

4. Question: UN requirement is for green compostable pads or normal plastic pads with harmful chemicals. We found contradictory information in the technical specs (like 3 years expiry which is almost impossible for a real compostable pads- max can be 15 months only, use of polyethylene as pad layer, chemical SAP as absorbent). I think pads which meets basic specs you will choose the L1, in that case compostable pads will be anyway out of any selection as materials cost of real compostable pads are at-least 3 times higher. There is mention of ISO-17088 compostable standard but it's looked optional and ethically the pad should be certified as per ISO-17088 not just the plastic back layer if we are really looking for green pads else the efforts will be futile for green pads. I believe UN organisation should not promote or distribute plastic pads with harmful chemicals which are not good for human health and cause lots of harmful effects in the environment & contribute towards climate change. If required I can share enough evidence of adverse effects of normal plastic pads. I hope you take this as a request from an organisation which is fighting for this for last 10 years on ethical, human health & environmental ground.

Answer: UN agencies strongly advocate sustainability wherever possible. We believe that women and girls achieving menstrual health and hygiene is a powerful way towards achieving sustainability goals. Materials are just one of the many ways to achieve the same. Adoption of MHM products into the daily life of women and girls matter a lot.

The specification is made generic to let all the suppliers participate in the tender. We would like to convey that we will consider all types of materials provided adequate level of performance, safety and efficacy is met. The claim on sustainability will always be an added advantage. The other point is with respect to supply chain considerations. We procure and ship items to countries who are in need. Hence, the shelf life is very important with respect to the shipping considerations. The final selection will be made where a balance between materials, performance, safety, supply chain considerations, cost and sustainability are met.

5. Question: I was hoping you could clarify for this particular tender what is the definition of the manufacturer. For example, it differs between the US and Canada concerning FDA and Health Canada. Whereas in the US, the manufacturer is the company that physically produces the cup, in Canada, the manufacturer is the business that developed it.

Answer: Under this tender, we define the term 'manufacturer' as the one who produces the product and keeps all design and development documentation as per national/international regulations.

6. Question: I just wondered if we are able to apply only for "Reusable Menstrual Pads" due the other 2 products are not able in our product assortment.

Answer: Please refer to tender Section 3. Data Sheet, Partial bids (lots), as per which partial bids are permitted. Bidders shall be allowed to quote prices for one or more lots identified in Section. Lot A is for reusable menstrual cups, Lot B is for reusable menstrual pads and disposable sanitary pads.

Additionally, bidders are allowed to quote for 1, 2 or all 3 sizes of each product under the current bid. Bidders are encouraged to quote for as many products and sizes as possible

7. Question: Is there a Template that you would like us to use for the Statement of Satisfactory Performance?

Answer: There is no template to use for the Statement of Satisfactory Performance, please a format of your choice.

8. Question: Regarding the samples to be provided, are we expected to provide the samples as per requirement specified for the future orders?

Answer: Samples may be provided if the supplier/manufacturer is shortlisted after the first round of screening. Please also note that as per tender Section 3. Data Sheet, Samples paragraph, samples must correspond 100% to the product(s) being offered. The bidder should indicate whether the samples provided were produced as prototypes or as normal production.

9. Question: All our material is currently in English, are we expected to provide all the material in the other languages (including the video on how to use the product) now or can it be provided if we are awarded?

Answer: In the bidding stage and for the first round of screening, English is enough. However, you shall be able to produce all information as mentioned in the technical specification in other languages, if short listed in the first round. Please make sure that you are capable of providing multilingual 'instructions for use' as it will save time for both parties.

10. Question: For the reusable pads, is there a preferred material? Or should we offer 2 options made out of different material for you to have a better idea?

Answer: The materials listed in the technical specification is for information purpose and is not limited to the ones mentioned in the specifications. As long as the offered product meets the performance, safety and efficacy criteria mentioned in the specifications and enough supporting documents and evidence are provided, we will consider the offer.

11. Question: I could not find the quantity mentioned. As this influences our lead time, could you please confirm if several orders will be placed or only 1 for the period and for all the countries?

Answer: Due to the nature of UNFPA's/UNICEF's mandate and business, the demand for supplies is highly unplanned. Figures for estimated volume are not available, given this is the first time both UN Agencies are adding these products as standalone items under their portfolios. However, it is envisaged that once the products are available for sourcing and our requestors/clients become familiar with them, the demand will increase year by year.

Specific to UNFPA only: In relation to past procurement spend, UNFPA has procured reusable menstrual pads and disposable sanitary pads in the past as a component of UNFPA Dignity Kits. The annual average quantity of purchased UNFPA Dignity Kits between 2017 and 2020 is approximately 430,000 kits; out of which an annual average quantity of 180,000 kits are of a standard configuration which includes reusable menstrual pads and disposable sanitary pads, the rest kits vary in configuration and may or may not include menstrual health/hygiene management products. Future orders under the Long Term Agreements resulting from this

tender are for standalone items but may also be considered for inclusion in UNFPA Dignity Kits; however requested volume may or may not be similar to prior experience.

12. Question: We are operating for less than 3 years, will this be an issue when we send our proposal?

Answer: Please refer to tender Section 4. Evaluation Criteria, as per which minimum 3 years of relevant experience is required for a bidder to be considered eligible.

13. Question: I have only one question, on Form C we need to fill in “the total price of our bid”, is this point where we fill in product cost in “pcs” or total bid for 3 years? I have even couldn’t find the volume (pcs-amount) for products in any document. Would you advise in which document this information is available?

Answer: In Form C, Bid Submission, total price of bid paragraph, please include your unit price for the products offered. In relation to your question for requested volume under this bid, please refer to Question 11 above.

14. Question: Could you please provide anticipated quantities for each item (disposable pads, reusable pads, reusable cups), or, if not possible, historical procurement volumes from the past 2-3 years? This information will assist us in providing you with the optimal price offer.

Answer: Please refer to tender Section 2. Instructions to bidders, paragraph UN standard payment terms. Additionally please refer to Question 11 above.

15. Question: Noted you will arrange payment within 30 days after receiving the shipping documents, please advise which payment term will be used in this bidding, L/C, T/T or D/P?

Answer: The means of payment is T/T.

16. Question: I have looked through the tender document package & would like to ask for clarification on the number of reusable sanitary pads and menstrual cups /cases.

Answer: Please refer to Question 11 above.

17. Question: I want to enquire if the delivery of the product is to Denmark only or to multiple countries as listed.

Answer: Please refer to tender Section 3. Data Sheet, paragraph Eligible recipients of goods and associated services, where among others is stated that goods will need to be supplied to developing countries, least developed countries and transition countries.

Additionally, please refer to tender Section 2, Instructions to bidders, paragraph Delivery arrangements and documentation, as per which UNFPA/UNICEF reserve the right to either purchase CPT or FCA to the nearest airport/port and to contract the freight component separately, whichever combination is in the best interest of UNFPA/UNICEF.

18. Question: It is important for us to know, what would be the order, in case we participate. I know that you are not able to say exactly the amount, but we need to know if we speak about 1000 pcs / 10 000 pcs/ 20 000 pcs..... at the same time. It is impossible for us to tell you, without knowing this information, what would be the delivery time and the price. As well, what stock we should keep for you to be able to cover possible orders. If we receive the order from you, is it still possible to decline that order from our site, if we know that we would not be able to fulfil your request?

Answer: In relation to your question for requested volume under this bid, please refer to Question 11 above. In relation to your question on the possibility to decline the order after the award, please consider that in the case a Long Term Agreement (LTA) is awarded to your company, the LTA is binding to the supplier in terms of price and all other contract conditions, including lead time, with no limitations apart from the supplier's production capacity.

19. Question: About shipping - is it always in a different place?

Answer: Please refer to question 17 above.

20. Question: Our Menstrual Cups come with an instruction manual in English and French, do we need to make arrangements to include Arabic and Spanish?

Answer: Yes, the instructions to use are needed in Arabic and Spanish as well. This is clearly stated in the specification requirements.

21. Question: Should we adhere to the format on the instruction for use in document 5:3:1? Ours addresses every instruction indicated but in a different format.

Answer: It is important that the details in the “instruction for use” in the specification shall be covered so that the users understand and follow the instruction to ensure proper and correct usage. Any extra information that suppliers think is important, during use and disposal, is also welcome.

22. Question: Our Product franchise is for sale in Africa, can our bid be accepted for only African Countries?

Answer: Please refer to question 17 above. Additionally, if your product can only be made available to specific countries/regions please clearly state it in your proposal including the countries where your product can be made available for product distribution.

23. Question: We are only bidding for menstrual cups, do we need to sign the Trilateral agreement and submit with the bidding documents or is it just for our information if we are successful?

Answer: UNFPA Trilateral Agreement provided in this bid is a template. There is no requirement to sign and submit the Trilateral agreement with your bid. Only successful suppliers being awarded with a Long Term Agreement will need to sign Trilateral Agreements.

24. Question: We also couldn't find any payment terms for the Supply of Sanitary Pads. Let me know if we have to give our own expected payment terms or you will share the payment terms.

Answer: Please refer to Question 15 above.

25. Question: In the safety and products standards section we found ISO 10993, ISO 6887-1:2017, ISO 6888-1:1999, are these compulsory testing we need to have for pads or these are desirable.

Answer: These are testing requirements as per internationally accepted standards to prove the safety and efficacy of the products unless manufacturers use other accepted testing standards to show proof for the safety requirements mentioned in the specification. It is compulsory to demonstrate the safety of the products under offer.

26. Question: Where will the goods be sent to from our warehouse?

Answer: Please refer to question 17 above.

27. Question: What order quantities can we approximately expect?

Answer: Please refer to Question 11 above.

28. Question: Since managing menstruation must include waste management, will you entertain the bundling of small sized, poly tie handle disposal bags packaged with sanitary pads for the bid?

Answer: In section 5.3.3, there is a requirement stated as “Each pad may be folded and shall be provided with a pull away cover, preferably environment friendly, for disposal of pads after use”. The aim of the pull away cover is disposal only. If the manufacturer has a different way of taking care of disposal, it is acceptable as long as the requirement in the specification is met.

29. Question: Would it be possible to download proper technical sheet form from web site or UNGM portal like how we received in the past bid number wise for current LTA products with all the parameters mentioned separately to match by bidder. It will definitely help us in communication with the suppliers.

Answer: Please consider that product specifications are included both under Annexes 5.3.1, 5.3.2 and 5.3.3 (pdf) and in Form G.1 Technical Bid (excel).

30. Question: We do not have three years of audited accounts, shall we not bother bidding if we are not compliant with one of the requirements.

Answer: Please refer to question 12 above.

31. Question: I have a doubt about the 19 documents that appear in the tender which are the ones I should send and which ones not, and where should I send them before the deadline.

Answer: Please refer to tender Section 3. Data Sheet, the following paragraphs:

Instructions for bid submission, as per which the allowable manner of submitting your proposal is by email.

Deadline for bid submission, as per which the deadline is 30 March 2021, at 17:00 (time zone: CET (<https://www.timeanddate.com/time/zones/cet>))

Documents establishing eligibility and qualifications of the bidder, Technical Bid and Financial Bid and Price Submission, all of them offering details on the necessary forms to be submitted.

Additionally, tender Section 7 Bidding Forms, provides all bidding forms which need to be used when submitting your proposal and shall be accompanied by the necessary supporting documents.

32. Question: We have an inquiry on the qualification criteria of section 4, "Evaluation Criteria". The criteria mentions on Minimum 3 years of relevant experience, though our company has two years of experience. We would like to know if we can still participate.

Answer: Please refer to question 12 above.

33. Question: We are not directly manufacturers (the factory does not belong to our company), but neither are we distributors (the patent and the molds belong to us). So it seems a bit tricky to fill in the documents correctly. Could our particularities meet your expectations? If so, what would be the right way to fill the documents? Couldn't be one of the solutions that we answer and indicate some of the certifications of our manufacturer?

Answer: Please refer to tender Section 2. Instructions to bidders, paragraph eligible bidders, as per which the bid is open to primary manufacturers and Marketing, Supply and Distribution Agreement Representatives of the Manufacturer who meet the quality standards outlined in this tender.

Additionally, please refer to tender Section 4. Evaluation Criteria, which outlines the Eligibility Criteria to assess if your company qualifies.

34. Question: I just wanted to know if there is any point for us to submit our application and make the bid, seeing as we are only legally registered in 1 country since a few months ago. I saw the requirement is 3 years?

Answer: Please refer to question 12 above.

35. Question: We do have a question for the Safety and product standards outlined in the requirements. As we are currently in the process of registering our product as a medical device (even though this is not a requirement at the moment in Europe and to our knowledge is only a

requirement in a few markets), some of the requirements will be met during this year but are at the moment not ready. I can see that you expect the date of the contract to be 1. September, and by then we do expect to have all documentation in place for the product requirements.

So my question is, if we are able to apply in terms of Product and Quality standards, while we will have documentation for ISO13485 and ISO10993 ready later this year?

Answer: During the time of document submissions, we would like to see the data proving safety and other requirements. We did not ask ISO 13485 as a mandatory requirement at this point of time. If you can provide the same, it is good. However, all test reports and data relevant to the safety are required for all the three types of products included in the tender.

36. Question: We are reading through the bid documents, and want to make sure that physical samples will not have to be submitted by the bid submission deadline (30th March). Letter of invitation clearly explains the procedure, but no. 48 in ITB is not that clear.

Answer: This is to confirm that samples are not to be sent by the bid submission deadline, that is 30 March 2021. UNFPA/UNICEF shall invite only bidders whose bid has been determined to be substantially responsive after the preliminary, eligibility and qualifications and technical evaluation of the technical bid.

37. Question: What is the number of pads and cups you need per year?

Answer: Please refer to Question 11 above.

38. Question: Are we going to be several suppliers on the requested items? Or you will select one sole supplier for the total?

Answer: Please refer to the tender Section 3. Data sheet, as per which Contract Award is to be made to Multiple Bidders for lots A and B.

39. Question: Ship to address is only to DK? If not, to which other countries?

Answer: Please refer to Question 17 above.

40. Question: What is the delivery schedule? Quantity per month? Is it going to be one shot?

Answer: Please refer to Question 17 above.

Additionally, please refer to the tender Section 2. Instructions to Bidders as per which, the validity of the LTAs will be 3 (three) years with the possibility of an additional 2 (two) year extension period subject to satisfactory performance and price competitiveness. These LTAs will not be considered as contracts, nor oblige UNFPA/UNICEF to any financial commitment whatsoever. Only Purchase Orders made pursuant to such LTAs will constitute a commitment on UNFPA's / UNICEF's part. During the LTA validity period multiple Purchase Orders may be placed.

41. Question: What is the expected absorbency of one pad in grams? What's the length and weight of one single product? What's the thickness of one single pad? What's the maximum number of pads in one package?

Answer: Please refer to the specifications shared where you can find answers to all the above questions. There is no mention of thickness in the specification as weightage was given to absorbency. However, thickness shall be comparable to market samples already in the market. Please refer to the packaging and labelling for packaging options.

42. Question: Is the special layout dedicated to the packaging? If yes, how many colors? Who is making the layout? Are there any markings, signs or certificates to place on the single packaging? What about any other information to be placed on the packaging? What languages should be placed on the packaging (single and carton box)?

Answer: There is no special layout for packaging specified. The layout is upto the manufacturer to decide. However, the specifications have labelling instructions mentioned in the specification. Please refer to the packaging and labelling instructions for instructions to use and languages.

43. Question: How many packages should be in one carton box? How many layers should have a carton box (3 or 5)? How many carton boxes should be on one pallet? What's the maximum pallet height? Are the EURO pallets allowed? Are disposable pallets allowed?

Answer: The manufacturer, based on their shipping validation studies, can decide on the number of primary packages in one carton box. Bidders/manufacturers may include all these information during document submission.

Please refer to the tender Section 5.1 packing specifications, clause 2. Pallets describes the pallet specifications and clause 3. Cartons describes the flute designation.

44. Question: Noting the following eligibility requirement "The bid is open to primary manufacturers and Marketing, Supply and Distribution Agreement Representatives of the Manufacturer who meet the quality standards outlined in this tender", we will not be eligible to submit a bid because we are not a manufacturer of any of the three required products. We only sell one of the products but these are manufactured by a third party manufacturer.

Answer: The eligibility requirement stated is correct. In other words, if you are not the primary manufacturer but you are a representative of the manufacturer under Marketing, Supply and Distribution Agreement then you can participate in the bidding process, provided you can provide all documentation as per the quality requirements in this tender.

Additionally, please refer to Question 5 above.

45. Question: We have developed a disposable menstrual cup made by biodegradable materials. i.e. after usage our device biodegrade leaving a very low ecological footprint. We are assuming that since it's a new category in the hygiene market it is not included under the bid conditions. We would like to inquire whether we could still submit a proposal as we qualify to the " GREEN PROCUREMENT STRATEGY " program published by the UNFPA.

Answer: Since the disposable menstrual cup is not included in the bid and also, it may call for a different set of applicable standards, we shall not consider the offer for the current bidding process. However, it is a great initiative in terms of sustainable solutions.

46. Question: We were not sure if this was invitation only bid, if it was, is it possible to be added to the invitation list for similar bids as we are an established and respected MHM company who has been part of the UNGM since 2016?

Answer: Specific to UNFPA only: UNFPA posts all bids notices for any potential solicitation process in the United Nations Global Marketplace (UNGM). Please regularly check UNGM for bid announcements. Alternatively, you may wish to consider registering in UNGM tender alerts and signing up for the product codes relevant to your company portfolio. This way once a bid is issued you will receive an automated notification.

Specific to UNICEF only: Please visit UNICEF's tender calendars and if any items being tendered in 2021 that's of your company's interest please follow the guide to inform UNICEF of your interest to be invited to participate in a given tender.

47. Question: We understand that this is a two envelope bidding process and the financial bid should not be given with the technical bid. So are we correct to say that FORM C: BID

SUBMISSION should not be used at all in this process, as it includes the price information? It is still mentioned among the documents given in the checklist.

Answer: Please be advised that a TWO-envelope bidding system requires interested Bidders to submit their Technical Bid separately from their Financial Bid containing price information, but both are to be submitted prior to the bid submission deadline. The deadline for bid submission of all bidding forms and documents is 30 March 2021, at 17:00 CET time.

48. Question: The incoterms are down as FCA; is there a precise point of delivery? Can the named delivery / FCA location be our named warehouse in the UK?

Answer: Please refer to the tender Section 3. Data Sheet paragraph Incoterms, as per which Bidders are requested to quote unit prices in accordance with the following delivery terms (INCOTERMS 2020): FCA Port of Departure (export packing and palletizing for air/sea freight included). Please indicate in your proposal the nearest sea port and airport, name and location.

49. Question: What lead times do you usually accept, from placing the PO to the goods being at the FCA location?

Answer: There is no stated expected lead time under this solicitation. It is imperative that the Bidders state realistic guaranteed minimum lead times.

50. Question: The max pallet height is 1.1m inc the pallet but can the pallets be double stacked in the vehicle?

Answer: Please refer to the tender Section 5.1 packing specifications.

51. Question: Are these products being distributed in to the US or anywhere else where they are considered class 1 medical devices? If a supplier's products are not CE marked and not FDA approved would they still be considered for other countries where this isn't required or do all the products you purchase require multiple global standards / certification to ease procurement?

Answer: The classification of these products differ with respect to the country and regulatory bodies such as FDA or EU. If you claim your product as a consumer product, then the applicable standards apply.

In this bid, we consider products that have proven to have adequate safety and efficacy as well along with conformity to any of the internationally accepted regulatory bodies. We strongly recommend providing proof to show these aspects either in terms of clinical studies, markets

catered, test reports from accredited labs as per the applicable standards mentioned in the specifications.

52. Question: How many suppliers to the United Nations plan on awarding business to?

Answer: Please refer to Question 38 above.

53. Question: Is there any indication on volume at this stage?

Answer: Please refer to Question 11 above.

54. Question: When do you plan on placing your first order?

Answer: Please refer to the tender Section 3. Data sheet, as per which expected date for commencement of contract is 1 September 2021. Please also refer to the tender Section 2. Instructions to bidders, paragraph award criteria, as per which in the event of a contract award the LTA(s) established do not oblige UNFPA/UNICEF to make any financial commitment whatsoever. Only Purchase Orders made pursuant to such LTAs will constitute a commitment on UNFPA's / UNICEF's part.

55. Question: To confirm, you only accept USD as a form of currency?

Answer: It is confirmed that as per the tender Section 3. Data Sheet, paragraph currency, prices shall be quoted in USD (US dollars).

56. Question: In "Technical specifications for Reusable pads" in subsection "Safety" it is mentioned that the "product must comply with following standards ISO 10993 - 5&10" so on and so forth - should the product comply with the mentioned standards or the organization should have all the ISO certifications?

Answer: ISO 10993 5 &10 are the two test methods that determine the extent of biocompatibility of the products (how safe the products when comes in contact with the human body/body fluids). These were included to assess the safety of the products as they repeatedly come in contact with the mucosal area.

The ISO certifications for organizations say, ISO 13485 is a quality management standard. There will always be weightage if the manufacturer is certified with ISO 13485-2016 QMS for medical devices.

57. Question: In Section 7. Form H. Financial Bid can you please explain what do you mean by alternative offer? Is it offering alternative products or changes in the number of pads in a pack?

Answer: Up to two alternative offers per each of the items are allowed. All information/documentation required for the primary offers should also be applicable/provided in the alternative offers.

58. Question: In Section 7. Form H. Financial Bid for reusable pads for acceptable sales pack size is mentioned as “pack of 3 to 6 pieces” can you please clarify if we should bid for 3 or 6 or any other criteria?

Answer: Please include the sales pack size for the product you quote (3, 4, 5 or 6) both in Form H. Financial Bid and in Form G.1 Technical Bid, under tab MHM products (P) and MHM products (A) - if applicable- column “Bidders technical specification of the offered product”.

59. Question: In Section 4 Evaluation Criteria subsection “Qualification Criteria” it is mentioned that “bidder should have minimum 3 years of relevant experience” - first can you elaborate meaning of “relevant” and second if bidder does not have 3 years of experience how does it impact the bid?

Answer: Please refer to Question 12 above.

Additionally, Please use tender Form E: Eligibility and Qualification Form to document previous relevant experience. Please list only previous similar assignments, and emphasize the experience and qualifications you have that match the requirements of the current tender, whether it is in the area of manufacturing or selling the exact products under the current tender or similar products.

60. Question: The tender document “UNFPA-DNK-ITB-21-001 MHM products” Page 29 said “All prices shall be inclusive of VAT and other applicable indirect taxes.” As a international bidder do we need to give our quotation including VAT and other applicable indirect taxes ?

Answer: Yes, that is correct.

61. Question: To apply for the bid we must go with all the articles or we can send just one? For example, can we just apply for “Disposable Sanitary pads”?

Answer: Yes, you can apply for only “disposable sanitary pads”. Please refer to Question 6 above for more information.

62. Question: The submission is for this email - bidtender@unfpa.org until 30 March or we must send over traditional mail in paper?

Answer: Please refer to Question 1 above. Submissions in paper format are not accepted.

63. Question: As menstrual cups are not categorized as medical devices within the EU (as per EU MDR regulation EU2017/745) the product cannot obtain CE mark. Please confirm, can the products be submitted without the 'CE mark'?

Answer: It is a consumer product as per EU directive and the product shall conform to general product safety directive by EU as mentioned in specification. By CE mark, it is the CE self certification by manufacturer for which there is no need to involve the notified body. We strongly recommend that you provide enough data and test results as per applicable standards to show the safety and efficacy of the product.

64. Question: Our cups are registered with the FDA but FDA does not have product marking and FDA's logo is for official government use only. FDA's logo should not be used to misrepresent the agency or to suggest that FDA endorses any private organization, product, or service. Misuse of FDA's logo may violate federal law and should never be used on medical devices. Please confirm, can the products be submitted without an 'FDA mark'?

Answer: You can submit. Since the Menstrual cup is class 2 as per FDA, we don't expect to be labelled as “FDA approved”, which is given only to class III devices. Please make sure that the safety and efficacy aspects of your product are met as per specifications and that you shall be providing us proof for the same.

65. Question: There is a mention of ISO-17088 as compostable standard but it seems that it is optional and ethically the pad should be certified as per ISO-17088 but not the plastic back layer. Can you please confirm?

Answer: If you claim your product as “compostable”, you are supposed to provide us with a test result from an accredited lab. It is optional and it has been included to promote the sustainability goals of the UN.

66. Question: Can the USFDA certification be accepted instead of the CE mark?

Answer: Since the Menstrual cup is class 2 as per FDA, we don't expect to be labelled as "FDA approved". FDA registration and a letter from FDA approving sale in the USA is also acceptable. You may also provide us all these details during document submissions.

67. Question: Since the Corona crisis is still ongoing, the raw material prices are increasing so it is very difficult to get prices for 4 years till 2024 considering market fluctuations, would it be acceptable if the price validity is given for 2021 & 2022 only?

Answer: Please refer to the tender Section 3. Data Sheet, paragraph Financial bid and price submission. As per which prices quoted by the bidder shall be fixed during the bidder's performance of the contract and not subject to variation on any account. However, price revisions will be considered on a yearly basis provided that the LTA holders submit proof of the changes of prices in line with the indication provided in the bid.

68. Question: Is it possible to share the (past/forecast) consumption quantities for the requested products to get a rough idea about the procurement pattern?

Answer: Please refer to Question 11 above.

69. Question: About ISO-44001: is this requirement mandatory or any other equivalent can be considered and accepted?

Answer: There is no mention of ISO 44001 in the specifications.

EU Ecolabel, Sustainable, recycled, re-used or reusable materials for packaging and the manufacturer of the disposable pad preferably shall be in compliance with ISO 14001. This is again optional and any environmental management system equivalent to ISO 14001 is acceptable.

70. Question: We are a menstrual cup company - can we bid ONLY for the menstrual cups?

Answer: Yes you can, please refer to Question 6 above for more information.

71. Question: We only have two sizes (small and medium) - can we bid even if we cannot present an offer for a size large?

Answer: Yes you can, please refer to Question 6 above for more information.

72. Question: Where are the quantities for the tender?

Answer: Please refer to Question 11 above.

73. Question: Which countries is to export the goods to?

Answer: Please refer to Question 17 above.

74. Question: Is UNICEF the buyer?

Answer: This is a joint solicitation process, allowing both Agencies, UNFPA and UNICEF, to place individual orders under the resulting LTAs.

75. Question: For Reusable Menstrual Cups do we need to show proof of compliance with ALL following ISO standards: a) ISO 13485 or ISO 9001 CE mark (CE self-declaration), or FDA registration, or MDSAP, or equivalent, b)ISO 10993-1, c) ISO 10993-3, d) ISO 10993-5 and e) ISO 10993-10? Regarding the required manufacturer's license No. can you please elaborate which license you refer to?

Answer: We expect the manufacturer to have some quality management system, safety and conformance according to regulatory bodies. We included all the above mentioned standards in order to cater to a broad range of manufacturer's situated across the globe. Whatever is applicable to you 'as a manufacturer' can be provided. The license is a permission from national regulatory authority allowing permission for manufacturing at the specified site.

76. Question: For Reusable Menstrual Pads do we need to show proof of compliance with the following ISO standards: a) ISO 10993 – skin sensitization, b) ISO 6887-1: Microbiology of the food chain, c) ISO 6888-1: Microbiology of food and animal feeding stuffs?

Absorbency test is required. Please inform the test protocol.

Required color of the pad: Would a standard pink colour be acceptable?

Regarding the required manufacturer's license No. can you please elaborate which license you refer to?

Answer: Indicative testing for absorbency is shared in the specification. You may also refer to some of the product standards that you are familiar with. You may also refer to the footnotes in the specification and refer them for test methods and other details. Please refer to the specification for colours and you may also submit a picture of the product along with submissions.

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77. Question: For Disposable Sanitary pads do we need to show proof of compliance with ALL following ISO standards a) ISO 10993 Part-5&10: Testing to assess the safety, b) ISO 6887-1:2017 Microbiology of the food chain, c) ISO 6888-1:1999/AMD 2:2018 Microbiology of food and animal feeding stuffs and d) ISO 17088:2008- Specifications for compostable plastics or equivalent?

Absorbency test is required. Please inform the test protocol.

Regarding the required manufacturer's license No. can you please elaborate which license you refer to?

Answer: Indicative testing for absorbency is shared in the specification. You may also refer to some of the product standards that you are familiar with. You may also refer to the footnotes in the specification and refer them for test methods and other details.

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78. Question: Regarding Form B: Checklist, In the technical bid part: "Have you provided the required documents in support of form H.2 Questionnaire .. " Is there another questionnaire that we have not received? I have not seen any H.2 Questionnaire. Also, does the instruction to bidders Section 2: refer to clause 19 ? Is that correct?

Answer: There is no form H.2, this should read form G.2 Questionnaire for Menstrual Health Management (MHM) products. Also the instructions to bidders Section 2 should read clause 16. Technical Bid.

79. Question: Is there any chance for being informed of any purchased quantity during the LTA? Even an estimation?

Answer: Please refer to Question 11 above.

80. Question: Where can we find please our UNFPA client Number?

Answer: There is no requirement for providing your UNFPA vendor number.