

ITB No. UNFPA/DNK/ITB/19/002

QUESTIONS AND CLARIFICATIONS

1. Whether this tender result in new LTA, will replace the existed LTA awarded according to previous tender UNFPA_PSB_ITB_15_041. Or, this is a re-tender based on previous tender \UNFPA_PSB_ITB_15_041, our offer for UNFPA/DNK/ITB/19/002 shall not exceed the existed LTA price?

Bid process UNFPA/DNK/ITB/19/002 is a new tender to cover the cycle of 3 years (2020-2023) with possibility of 1 year (2024) extension. UNFPA will do its best to minimize the overlapping time in case the new LTAs resulting of this process overlap with the existing LTAs; in such case UNFPA will decide on the best interest of the Organization.

2. Because our LTA with UNFPA has been extended for 1 year, we would like to know how to handle this extended LTA if we win the bid No. ITB UNFPA/DNK/ITB19/002 for the new LTA.

UNFPA will do its best to minimize the overlapping time in case the new LTAs resulting of this process overlap with the existing LTAs; in such case UNFPA will decide on the best interest of the Organization.

3. Could you please advise whether we can receive the bid forms in word format?

Bid forms can be found in Word format in UNGM under the tab "Documents": Annexes A – Bid Confirmation Form, B – Bid Submission Form, C - Bidders Identification Form, D – Eligibility and Qualification Form and I – Lubricant Questionnaire

4. Regarding the bid confirmation form, may we know if it's OK to send it to you by email or should I upload this form to the official UNGM website?

Bid Confirmation Form shall be sent to the email maruiz@unfpa.org no later than Monday, 16 September, 2019 as established in the Introductory Letter of the solicitation document, paragraph 4.

5. Whether the replies come by 16 September 2019 being the deadline for Annexure A? Incase replies to my clarifications come after deadline of Annex. A, whether I should wait or send the Annex A with my choice to bid.

Bid Confirmation Form shall be sent to the email maruiz@unfpa.org no later than Monday, 16 September, 2019 as established in the Introductory Letter of the solicitation document, paragraph 4.

6. Can we send a link of we transfer for sharing the Technical Data Documents instead of multiple emails.

Submission of offers must follow instructions of clause 20. Please submit all required documents as attachments by email.

7. We are a trading exporter firm. We do NOT undertake manufacturing activity for any products that we deal with. Your ITB is perennially designed for the manufacturer bidder. My query is many Annexures as designed for manufacturer, have NO responsiveness toward trader exporter. Does this make us ineligible to bid the tender? What is the scoring deficiency in case we cannot fill-in certain manufacturer oriented annexures, and which are termed extremely important to the bid? Please resolve.

8. Annexure J: This Annexure is for Manufacturer as per my understanding. Do I need to fill-in this Annexure, being a Trader-Exporter? 13. Annexure K: Being a trader-exporter, we list under category FIRM, and NOT a Corporate entity. Therefore, CSR is NOT APPLICABLE to our business. Do we need to fill-in the Annexure? Please convey.

According to Section I: Instructions to Bidder, A. Introduction, 2. Eligible Bidders, the bid is open only to primary manufacturers of male latex condoms, female condoms and water based lubricants.

9. About Eligible Bidders, is it possible for manufacturer of male condoms who is currently not on the list of WHO/UNFPA prequalified manufacturers to submit a bid?

Only male and female condom products prequalified by the WHO/UNFPA prequalification programme and lubricants manufactured and compliant with the Section II Technical Specifications at the moment of the submission of the bid are eligible for procurement.

10. Section VI – Annex D Eligibility Question 2 Litigation History – Is this in relation to contract performance only, or any litigation that the company may have undertaken irrespective of the nature of the dispute

Yes, Annex D - Eligibility and Qualification Form must include information regarding any litigation case that the company may have undertaken irrespective of the nature of the dispute.

11. Talking about Annexure E: Do I need to fill-in all 8 sheets given in the Annexure, as many of the sheets don't require any data of my product.

Bidders are encouraged to fill in as much information as possible for the Lots relevant to your bid taking into account the delivery terms requested. However, for LOT "A" only the prices per gross will be considered during the Financial Evaluation.

12. Annexure E: the last sheet of cost breakdown as required (mandatory), the manufacturer will never inform the trader of cost breakdown. How can I just give any figures of product cost breakdown? Please convey.

Please refer to section 14 – Bid Currency and Prices, paragraph 3 (page 20) where indicated that bidders are requested to indicate their price structure and the reasoning behind this request.

13. In Annex E, Price Schedule Form

1) what's the difference of sheet Lot A price of condom and EXW Lot A price of condom? We can't see any difference in these 2 sheet thus we don't know how to fill in it.

Tab LOT A PriceFormCondom_GROSS must include prices under Incoterms 2010 FCA and tab EXW LOT A PriceFormCondom_GROSS must include prices under Incoterm EX WORKS. This change has been reflected through a modification of the Annex E. Price Schedule Form LOT A MALE CONDOMS – Amendment 1.

2) In Lot A price of condom, Line 95, what does the "Three condoms in a trifold" mean? Is that mean one strip of 3 condoms?

Yes, it means one strip of 3 condoms in a trifold as the example in column N, line 92-95.

3) In Lot A CAR_CAM_720 BOX, line 14, C column, what does the case look like and its mean? and does "Box of 720 pieces (3 condoms per case, 12 cases of 3 condoms, 20 cases of 36 condoms)" means 3 condoms/case---12 cases packed individually---12 cases as 1 big case and 20 big cases forms a box? Is there case sample picture for us to reference? It would be much better if we know the case material and size.

Packaging for this project will include cases containing 3 pieces. 12 cases will be included in an inner box that will contain 36 pieces (12 cases containing 3 pieces each). 20 of this inner boxes will be included in an outer box that will include 720 pieces (20 inner boxes of 36 pieces each). Unfortunately, we don't have pictures of this packaging that we can use as a reference.

14. Under section VI Annex – E: Price schedule form all the forms are refereeing under the Item number” 23 to 29 the column and would “Others Optional)” what does it mean? Can you please explain?

Lines 23 to 29 have been added in case the bidders are interested in offering other items included in the prequalification dossier that are not listed in the previous lines (item 1 to 29). In case a bidder wants to quote more than 7 items (from 23 to 29), please add new lines.

15. SECTION VI - ANNEX E: Price Schedule Form for each lot

Item No. 25 & 27, Male condom 53mm Condomize! 2 DANCERS artwork and LOGO artwork, are these 53mm condom natural color with non-flavor/scent?

Item 25 (53mm Condomize! 2 DANCERS) and Item 27 (53mm Condomize! LOGO) are 53 mm standard (no flavor/scent).

16. SECTION VI - ANNEX E: Price Schedule Form for each lot

Our UNFPA pre-qualified products i.e. (a) 52mm ribbed, (b) 52mm dotted and (c) 53mm dotted-ribbed-contoured (3 in 1) are not listed in condom item.

By considering WHO specification of width ± 2 mm, can we offer as follow?

- | | |
|--|-----------------------------------|
| - (a) 52mm dotted, (b) 52mm ribbed for | - Condom item 53mm dotted, ribbed |
| - (c) 53mm (3 in 1) for | - Condom item 52mm (3 in 1) |

Lines 23 to 29 have been added in case the bidders are interested in offering other items included in the prequalification dossier that are not listed in the previous lines (item 1 to 29). In case a bidder wants to quote more than 7 items (from 23 to 29), please add new lines.

17. Palletization: Annex E – Provides separate table to indicate the cost of palletization. However, in the case of Ecuador, Car, Cameroon, Congo and Chad, this requirement is missing. Do we understand that no palletization is required for Ecuador, Car, Cameroon, Congo and Chad?

Bidders are requested to warrant that the cost per item must include the cost of packing and palletization. For the specific projects included in the file it is not expected special palletization that will add surcharge and hence it was not included in the tabs.

18. Supplier can provide euro or american pallets, this items means the goods pack on the euro or american pallets, right? please kindly provide more details about these pallets.

Please refer to Section II: Technical Specifications, LOT A - MALE LATEX CONDOMS, 53. Item: Male Latex Condoms, Packaging Requirements

19. With reference to the Sheet name "Price form male latex Condom GHSCPSM presentation incoterms 2010 saying EXW (port/Airport origin) Do you mean to quote in the price EXW factory (or) EXW port/Airport origin. Please confirm.

Please quote EXW factory.

20. Annexure F: Since we can supply to any part of the world, basis our export registration in India, do I still need to fill-in and register for all countries. Is there any common field to show our acceptance of Global Registrations? Can I just mention N.A. and submit the Annexure?

Bidder are requested to provide the list of countries in which are registered, demonstrating that is duly authorized to supply the goods to the country of destination. Please note, the number of country registration will be scored during the Technical Evaluation.

21. SECTION VI – ANNEX F: Countries of Registration

If the registration belongs to a third party client of supplier, what kind of responsibilities that will be undertaking by certificate holder?

Supplier is responsible for any and all obligations it may have under the LTA, since it is the one with a contractual relationship with UNFPA. The responsibility between the supplier and their third parties are completely under the agreements between those parties.

22. Annexure G: The Gross of 144, I understand as one master carton holding 144 packs/units. We have no such packing. Our nearest packing per carton for 3-fold condoms pack is gross of 162 packs per carton OR 486 unit condoms per carton. Can I make the change in column mentioning gross of 144 to Gross of 162?

Inner boxes must contain 144 condoms (one gross). Gross is used by UNFPA as the unit of purchase and therefore this quantity cannot be modified.

23. In Annex G, G column of Multiple order quantity (Gross), may we know what does Multiple order mean? Is that mean there are different kinds condoms in one box or just several different kinds condoms in one order and packed individually per kind to distinguish from each other?

Multiple Order Quantity limits the order to quantities multiples of this quantity. I.e. if the Multiple Order Quantity is 50, that means that the order can only be in multiple of 50 gross, such as 100, 150, 200, etc.

24. Annexure H (Financial Evaluation: LOT A): What is GROUP CATEGORY COLUMN mean? What is WEIGHTING % stand for?

Please refer to Section I: Instructions to Bidders, E. Evaluation and Comparison of Bids, 29. Evaluation of Bids, LOT A. Male Latex Condoms (page 27)

25. For ANNEX H "Bidder Scoring Form Technical Evaluation" there is a column for Bidders to select the appropriate answers. I want to understand what are we to input into the boxes in column to be filled by the bidders? Can we input "YES" for the rows selected? Or are we to input 2.1 or 3.1 or 2.2 whichever relevant to the bidder?

No information must be included in Annex H. Bid Scoring Form. The document has been only provided for information purposes regarding evaluation of bids.

26. Annexure H (Bid Scoring): This is my first year with UNFPA through UNGM TAS. Also, I am a trader, NOT manufacturer. What Data should I fill-in in the Annexure?

No information must be included in Annex H. Bid Scoring Form. The document has been only provided for information purposes regarding evaluation of bids.

27. SECTION VI – ANNEX H: Bid Scoring Form Financial Evaluation

Group C – If we are not offering any item in this Group C, will that affect our overall Bid Scoring?

Not offering Group C items will not affect overall bid scoring. Financial evaluation of Lot A will be done according to Annex H. Bid Financial Evaluation LOT A MALE LATEX CONDOM.

28. In the bidding document, Page 16, clause 5, it requires us the FSC Certification for cardboard cartons. But we are male latex condom manufactures not cardboard cartons manufacturer, how can we provide the FSC of cardboard carton?

Bidders can request the certification to the manufacturer of cardboard cartons.

29. Shippers: Do we need to have the Shippers also FSC Certified?

Shipper cartons shall be FSC or equivalent marked/certified, as indicated in page 55 of the solicitation document.

30. What is the meaning of Incoterms D as its mentioned Capacity to Deliver under Incoterms D

Incoterms Group D includes DAT - Delivery at Terminal, DAP - Delivery at Place and DDP - Delivery Duty Paid.

31. If size of attachment exceeds 25 MB can we send Technical Bid in 2 parts (2 e-mails)?

Yes. Please specify in the subject of the email, Part 1 and Part 2.

32. Please help clarify questions 11 & 65 for "Annex K" Questionnaire for bidder's Corporate Social Responsibility

Question 65: Does your company engage in the sale or manufacture of anti-personnel mines or components utilized in the manufacture of anti-personnel mines?

The UN expects its suppliers not to engage in the sale or manufacture of anti-personnel mines or components utilized in the manufacture of anti-personnel mines.

Question 11: Does your company have a policy related to conflict minerals?

Conflict minerals are tantalum, tin, gold and tungsten sourced from the Democratic Republic of Congo and its neighbouring states. Companies that are at risk of using conflict minerals are required to undertake due diligence on the sourcing and file a conflict minerals report.

33. Page No. 15 – Heading (page 14): LOT A. MALE LATEX CONDOMS APPLICABLE BIDDERS ONLY

Clause 7. Declaration whether the bidder can adapt to multiple packaging requirements - adjust based on the options selected under Criterion 10 in Section VI - Annex H. Bid Scoring Form - LOT A Male Condoms. If declaration is undertaken confirming adaptability to the changed requirements, will there be scope for price revision from the submitted bid.

According with Section I: Instruction to Bidders C. Preparation of Bids, 14. Bid Currency and Prices, fixed prices are required for this bid. 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. Such evidence will have to be submitted for the various price components (price structure) before any price revision can be approved, e.g. raw material measured against internally recognized benchmarks, official changes of minimum staff salaries issued by governments, evidence of electricity price increase, etc.

34. Page No: 15 – Technical Bid – Lot C: Female condom – applicable bidders only

Clause no 3: “Declaration whether the bidder can adapt to multiple packaging requirements – adjust based on the options selected under Criterion 5 in Section VI – Annex H. Bid Scoring Form - LOT C Female Condoms.” If declaration is undertaken confirming adaptability to the changed requirements, will there be scope for price revision from the submitted bid.

Please refer to question 33.

35. Page No. 15 – Heading: LOT B. WATERBASED LUBRICANTS IN SACHETS APPLICABLE BIDDERS ONLY

Clause 1. Declaration whether the bidder can supply special packaging presentations, if selected any option under Criterion 3 in Section VI - Annex H. Bid Scoring Form - LOT B Lubricant Sachets. If declaration is undertaken confirming adaptability to the changed requirements, will there be scope for price revision from the submitted bid.

Please refer to question 33.

36. To provide the copies of the audited financial statements, we would like to know the audited financial statements just need to provide the balance sheets and income statement, or it also needs the Cash flow statement.

Cash flow statement are also needed.

37. Capacity to hold UNFPA stock without additional cost, would you please kindly provide the maximum stock time and quantity?

Maximum stock time and quantity will be defined on a case by case basis as a result of the negotiation with each supplier according to their capabilities.

38. SECTION I C, CLAUSE 13, LOT A – ITEM 5

Declaration whether bidder can hold UNFPA stock without costs (i.e. warehousing) - if selected 8.1 in the Section VI - Annex H. Bid Scoring Form Technical Evaluation - LOT A Male condoms. What is the period of time to uphold this stock?

Please refer to question 37.

39. Lubricants: the formulation we sell has been in the market since 2015 and sold through pharmacies, beauty, and fashion stores across the world. The retail sales are in 30ml bottles which have the CE mark, 510k etc. For this bid, we are performing compatibility tests to provide 5ml sachets. Based on previous experience, the CE mark is transferable as long as the new packaging is supported by compatibility tests. So while the sachets have not been sold, the product/formulation has been for several years in very reputed retailers (Boots, Watsons, etc.). Can we still bid using the sachets?

Yes, manufacture/supplier can bid for the sachets and provide the relevant documentation requested in the bid document for review.

40. In Bid documents under the head “Lot A Male Latex Condoms applicable bidder only” Page 16 Under Point 3 It is said that the summary data on the last 30 lots of product manufactured at the sight. The data should be for 2018.” Do you want is to provide the date in both produced in 2018. Please clarify if the data should be produced for the “Last” 30 lots of 2018 or random lots from 2017 and 2018.

Last 30 lots of 2018, if less than 30 batches were produced during this time, then the batches should include both 2018 and 2017 production.

41. How many quantities of samples we should provide? Do you want samples for all the varieties we are about to quote? What is the last date to submit samples and where should we send the samples?

The quantities of samples for the different lots has been stipulated in page 18 under the samples section. Yes, supplier need to submit samples of all varieties. For date and place where you should send the samples please refer to “Samples” in the Section I: Instruction to Bidders, Preparation of Bids, 13. Documents to be submitted with the bid.

42. Secondary packing for LUBRICANTS: The individual sachets are to be packed in trays of 250 sachets with 4 trays per shipper carton. This means 1000 sachets per shipping carton. We need clarification of how the tray dimension is expected as we are currently supplying to UNFPA PSB in 100 sachets per secondary box printed on boxboard 400gsm substance.

Please kindly follow UNFPA specifications. Technical evaluation committee will evaluate all offers based on the submissions, and make a decision based on the found compliance to the technical and quality requirements.

43. For Samples required for Lot A, B & D which we are interested to bid for, the samples required must be accompanied with CoA and external testing result for the sample batches. Are the samples for submission to UNFPA must be made for UNFPA only OR they can be also samples made for our own brand but relevant to the male condom (Lot A) type for sample reference?

Samples are to meet the requirement of WHO/UNFPA specifications. As indicated in Sample Section, samples shall be in their final status and packaging as intended to be supplied on Purchase Orders. If this is not possible then provide explanation and commitment when the appropriate samples will be submitted.

44. Samples submission – The Bid indicates that 5 samples need to be submitted each proposed type/ design / variation of the male condom. Will it be in order for us to submit one representative sample in each of the variant – For e.g., in color, can we submit sample in one color and indicate the colors we can supply. Similarly, in the case of flavors, can we submit sample for one flavor and indicate the flavors that we are capable of supplying – Or - Do we need to submit samples in all the variant that we will be quoting? Can we draw samples from our production run for our other customers and submit samples?

Yes, 5 pieces of samples for each variant need to be submitted by the supplier. Samples are to meet the requirement of WHO/UNFPA specifications. As indicated in Sample Section, samples shall be in their final status and packaging as intended to be supplied on Purchase Orders. If this is not possible then provide explanation and commitment when the appropriate samples will be submitted.

45. Regarding the sample status, as in the bid documents Page 18, it requires the samples should together with the Certificate of Analysis and independent laboratory test results. As you know the cost is really high if we provide the third party test results (like from TUV) of each kind of condom. May we know if it's ok for us to provide the internal laboratory test results? If so, should we provide the test result for each flavor, each size(width) and each lot? Or we could provide just one flavor of each size for your reference?

If the manufacturer/supplier's laboratory is ISO 17025 accredited, then test reports can be shared from the manufacturer/supplier's laboratory. The report can be a combined one for the variant samples submitted. If the laboratory is not accredited, then the test results for the main supply can be obtained from an accredited laboratory while that for other variant types are submitted from manufacturer's laboratory.

46. Kindly advise whether bid sample to be sent in plain aluminum foil packs in gross pouch. Also clarify the qty of samples required against each type of product. Kindly advise address to which sample to be sent.

The exact quantities for each type of product is mentioned in the page 18 of the bid document. Inner packaging does not need to be gross size as the requested samples for each type of product is less than 144. The individual packaging should however be foiled in accordance with UNFPA's specifications which is the plain aluminum foil packs.

47. If we need to send hard copies of all documents together with samples?

Samples must be accompanied with the hard copy of Certificate of Analysis and independent laboratory test results. These documents can be also sent by email together with the rest of the required documents.

48. We manufacture many types of condoms, such as different colors and flavors which are in UNFPA Prequalification Dossier. We can give 5 samples for each type but all types may not have independent laboratory test results (Page No. 18) as this would be very expensive to do for 20/30 different types. Is it Ok that independent laboratory test results are provided only for the main type of condoms?

It is acceptable to provide test result from independent laboratory for the main types of condoms. The other types can be submitted as a release test report from the manufacturer's laboratory.

49. Page No. 16 – Heading: LOT A. MALE LATEX CONDOMS APPLICABLE BIDDERS ONLY

Clause 3. Summary data on the last 30 lots of products manufactured at that site. Kindly clarify as to whether the analysis data comprising of 30 lots, in the prescribed bid reporting template (Section VI – Annex J), is required for each variant of condom offered in the bid or whether the data of the base variants (49 N/53 N plain non scented, non-flavored) would suffice the requirement.

It is not obligatory for the data of the 30 lots be submitted for each variant of condom. The data for the base variants is acceptable.

50. Page 16- Point 4 – Heading: Documents Establishing the Qualification and Conformity of Goods for ANY LOT

In Page 16, copy of ISO 4074 certification is sought along with other Quality Management System certifications. This is product related standard and hence, certifying body will not provide a certification of compliance to the product standard, even though compliance is verified as part of the audit. Kindly confirm if Manufacturer certificate of compliance is acceptable.

The certifying body provides certification of compliance to the product standard. Similarly, if there is no body for ISO 4074 accreditation, then a certificate of conformity issued by a competent certification body might be acceptable.

51. Page No: 17 – LOT C: female condom applicable bidders only

“Summary data on the last 20 lots of products manufactured including results for burst properties, freedom from holes, visible defects and package integrity.” We are planning to bid for the following variants:

1. Velvet (Type A) Female Latex Condom – Plain Natural Unscented Variant.
2. Velvet (Type A) Female Latex Condom – Pink Colour Unscented Variant.
3. Velvet (Type A) Female Latex Condom – Strawberry Scented Pink Colour Variant.
4. Velvet (Type A) Female Latex Condom – Plain Natural Vanilla Scented Variant.

Is it ok to submit the summary data of last 20 lots for the 1st type i.e. Plain Natural Unscented Variant (since all the UNFPA orders are executed in this variant)?

Yes.

52. Page No: 18 - Samples

“LOT C – Female Condom: 10 Pieces for each proposed type of female condoms.” It is requested to give exception of Condomize designs for female condoms also like for Lot A. MALE CONDOMS.

Yes, exception is given to Condomize designs unless available. This change has been reflected through a modification of the bid document - Amendment 1.

53. Page No: 18 - Samples Packing

“Provide samples as they would for normal procurement – plain foil. If this is not possible then provide explanation and commitment when the appropriate samples will be submitted.” Considering existing prequalified UNFPA suppliers, shall we supply the samples in coloured foil instead of plain foils?

As clearly mentioned in page 18, the samples are to be supplied in plain foil NOT colored foils. Manufacturer/supplier is to provide explanation and commitment regarding when the appropriate samples will be submitted.

54. Page No. 17 – Heading: LOT B. LUBRICANTS SACHETS APPLICABLE BIDDERS ONLY

Clause 1. Water based lubricants - Summary data from any independent external testing conducted on the same 20 lots together with the SECTION VI – ANNEX I. LUBRICANTS QUESTIONNAIRE

- a. Kindly clarify if analysis of summary data pertaining to In-house test results of 20 batches suffice the requirement.

Yes, summary data from in-house test results can suffice.

- b. Kindly clarify as to whether the analysis data comprising 20 lots, in the prescribed bid reporting template (Section VI – Annex I), is required for each variant of lubricant, since contents will not vary in 2ml, 3ml, 4ml and 5ml sachets.

The analysis data could compromise of different variants in sizes of lubricants.

55. Page No. 18 – Heading: SAMPLES

Bullet point 2: LOT B. LUBRICANT SACHETS: 10 pieces for each proposed type of lubricants sachets Together with CoA and Independent laboratory test results. Kindly clarify if Independent laboratory test results are required for all variants of samples submitted.

The independent laboratory test results are applicable to the main type in size of lubricants manufactured by supplier.

56. Page No. 53 – Sterility of Water based Lubricants

Page No. 53 indicates that ‘Lubricants may be supplied sterile’. However, page no. 54, clause 2 (bioburden levels), indicates that ‘Lubricants need not be sterile’. Please clarify.

The emphasis is that ‘Lubricants may or may not be supplied sterile. In any case they are to be subjected to control of microbial contamination. This requirement will be evaluated.

57. Page 16- Point 4 – Heading: Documents Establishing the Qualification and Conformity of Goods for ANY LOT and Page No. 57 – Heading: Quality Management System

In Page 16 & 57, copy of ISO 19671 certification is sought along with other Quality Management System certifications. This is product related standard and hence, certifying body will not provide a certification of compliance to the product standard, even though compliance is verified as part of the audit. Kindly confirm if Manufacturer certificate of compliance is acceptable.

The certifying body provides certification of compliance to the product standard. Similarly, if there is no body for ISO 19671 accreditation, then a certificate of conformity issued by a competent certification body might be acceptable.

58. Goods Manufacturing Certificate, In China, the condom does not have the Good Manufacturing Practices certification, could we use other certificates to prove this item?

Yes, other certifications from a competent certification body may be acceptable.

59. SECTION I C, CLAUSE 13, LOT A – ITEM 3

If we are compliance to Good Manufacturing Practice but we do not get certified for GMP, can ISO 13485:2016 certificate be accepted?

Yes, ISO 13485 certificate is acceptable. Nevertheless, other certifications for regulatory compliance from a competent certification body may need to be submitted as well.

60. SECTION II: Technical Specifications Lot A Male Condoms

Packaging Requirements – there is dimension of inner box or gross box for 144pcs but not for 100pcs, shall we submit this 100pcs box sample with dimension?

It is not required to submit any other pack size than 144 pcs per inner box.

61. SECTION VI – ANNEX J: Bid Reporting Template

- a. The summary data on last 30 lots of products is inclusive of all product types, or 30 lots for each individual type?

Inclusive for all types of a specific product e.g all types of male condoms.

- b. Test Summary Report Template in excel format given.
 - The worksheet has already pre-setting of “%” for column of freedom from holes, visual defects, package seal integrity, length, width and thickness.
 - How do convert all these data into %?

The excel sheet of Annex J should not be set in percentage just the number of non-conforming pieces.