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Ref. No.:- F.02(76)/RMSCL/Proc./S&S(MD)/NIB-8/2020/342

Dated:- 7/10/2020

Corrigendum – III

Subject:- Amendment in Date and bid condition

Ref.:- NIB No. F.02(76)/RMSCL/Proc./S&S(MD)/NIB-8/2020/285 Dated:03.09.2020

(Technical bid opening due on dated –13.10.2020)

S. No	Existing date / condition	Amended date / condition												
1.	<p>F.02(76)/RMSCL/Proc./S&S(MD)/NIB-8/2020/285 Dated:03.09.2020</p> <table border="1"> <tr> <td>Last date and time of submission of online bids</td> <td>12.10.2020 at 6.00 PM</td> </tr> <tr> <td>EMD, Tender fees, RISL fees through challan and Physically</td> <td>12.10.2020 at 6.00 PM</td> </tr> <tr> <td>Date and time of opening of Online technical bids</td> <td>13.10.2020 at 11.00 AM</td> </tr> </table>	Last date and time of submission of online bids	12.10.2020 at 6.00 PM	EMD, Tender fees, RISL fees through challan and Physically	12.10.2020 at 6.00 PM	Date and time of opening of Online technical bids	13.10.2020 at 11.00 AM	<p>F.02(76)/RMSCL/Proc./S&S(MD)/NIB-8/2020/285 Dated:03.09.2020</p> <table border="1"> <tr> <td>Last date and time of submission of online bids</td> <td>19.10.2020 at 6.00 PM</td> </tr> <tr> <td>EMD, Tender fees, RISL fees through challan and Physically</td> <td>19.10.2020 at 6.00 PM</td> </tr> <tr> <td>Date and time of opening of Online technical bids</td> <td>20.10.2020 at 11.00 AM</td> </tr> </table>	Last date and time of submission of online bids	19.10.2020 at 6.00 PM	EMD, Tender fees, RISL fees through challan and Physically	19.10.2020 at 6.00 PM	Date and time of opening of Online technical bids	20.10.2020 at 11.00 AM
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2	<p>Clause 5(L) For Importer, WHO-GMP/COPP/FDA certificate etc. of the exporting country should be submitted. For manufacturer, Quality Management System (QMS) Certificate as per Schedule V of Medical device Rules 2017/ ISO 13485 issued by CDSCO Registered Notified body should be submitted. The QMS certificate must not be older than one year from the due date of Bid submission in the case where validity is not mentioned in the certificate. <u>The QMS certificate/ ISO 13485 of all the manufacturing plants, of which products have been quoted, should be submitted.</u> The Bidder shall also furnish an undertaking in the format given in Annexure-VII point no.9 declaring that the Bidder complies with the requirements of QMS (as per Medical Device rules 2017)/ ISO 13485. The Importer should produce WHO-GMP/COPP/FDA of the manufacturing firm or a certificate which is at par with WHO-GMP issued by exporting countries like US- FDA approval, etc. In the case of imported surgical and sutures drugs items, labels and product literature of all quoted products must be submitted. The Firm will continue to hold WHO-GMP/COPP/QMS Certificate for the product during entire rate contract period of the product. If WHO-GMP/COPP/QMS certificate expires, it is firm's responsibility to inform RMSCL about the same and not to accept any further purchase order till re-issue /renewal of WHO-GMP/COPP/QMS certificate. During the period of non validity of WHO-GMP/COPP/QMS certificate of the firm the rate</p>	<p>For manufacturer with valid medical device License no QMS/GMP Certificate required, in case of valid drug license WHO-GMP/ GMP certificate issue by competent drug authority is mandatory.</p>												

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	<p>contract will deemed to be suspended. If the firm fails to inform RMSCL about the expiry of WHO-GMP/COPP/QMS certificate and accept purchase order of RMSCL and later on it comes to the knowledge of RMSCL. In this situation firm shall be liable for a panel action. Product of the firm shall be liable to be debarred for a period of two years from the date of order.</p> <p>NOTE:- The WHO-GMP/COPP/QMS certificate must not be older than one year from the last date of Bid submission in case validity is not mentioned in the certificate.</p> <p style="text-align: center;"><u>Annexure VII Declaration & Undertaking</u></p> <p>9. That we have approved qualified staff, machines & equipments along with capacity to manufacture above category of Surgical & Sutures and our unit have been issued WHO-GMP/COPP/ QMS/ISO 13485* by Concerned Competent Authority vide letter No.....dated.....valid up to.....</p>	<p>9. That we have approved qualified staff, machines & equipments along with capacity to manufacture above category of Surgical & Sutures.</p>
3.	<p>Clause 7(b) (b) Technical Evaluation of the Bid will be done on the basis of documents submitted by the bidder</p>	<p>Clause 7(b) OPENING OF TECHNICAL BID AND TECHNICAL EVALUATION b) Technical Evaluation of the Bid will be done in two stages. (i) Technical Evaluation of the Bid will be done on the basis of documents submitted by the bidder. (ii) Evaluation / Examination / Testing of samples of Items (sutures only). Bids of the item, samples not found technically fit in such evaluation will be declared as rejected / non-responsive.</p>
4.	<p>Clause 8 BID SECURITY The Bid Security Deposit shall be @ Rs. 20,000/- for each item of surgical quoted subject to minimum of Rs. 2.00 lacs and maximum of Rs. 5.00 Lacs. In case Bid Security submitted by the bidder is at the minimum or more but number of quoted items is more than the Bid Security submitted, the quoted items by the bidder will be counted in sequence up to the Bid Security deposited. However, without minimum earnest money the offer will not be considered at all. Bid Security will not be taken from undertakings, corporation of GoI & GoR. Further, Bid Security will be taken @ Rs. 5,000/- per item of surgical quoted subject to minimum of Rs. 50,000/- and maximum of Rs. 1.25 Lacs, from MSME Units of Rajasthan. They will furnish copy duly attested by gazetted officer of the registration of MSME units issued by the Director of Industries in respect of the stores for which they are registered. Duly attested copy of Acknowledgement of EM-II issued by DIC with an affidavit worth Rs.10 as per Annexure-II(B) under preference to Industries of Rajasthan rules</p>	<p>Clause 8.1 PRODUCTION OF SAMPLES (A) Bidder shall submit 12 sample units of each quoted item (sutures only), free of cost. The items submitted as samples (sutures only) should be of the same specifications as asked for in the bid. Any deviation from specifications will result in the rejection of the sample. The samples (normal/ regular sales packs of sutures only) will be used for quality evaluation by the technical evaluation committee and/ or laboratory analysis, as the case may be, as decided by the Tender inviting authority. Samples of the items (sutures only) which are supposed to be sterile should be sterile. The decision based on quality evaluation of the sample will be final for the purpose of this tender. (B) The samples (sutures only) for evaluation shall be submitted in a separate sealed cover superscripted by "Tender No. _____". The sample (sutures only) as above shall be submitted on or before the time of depositing Bid Security, or within 3 days of technical bid opening. The bidder should submit, along with the samples, the list of sample of sample items in the given</p>

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	<p>1995 in respect of stores for which they are registered.(Annexure-II(B)). In case Bid Security submitted by the bidder is at the minimum or more but number of quoted items is more than the Bid Security submitted, the quoted items by the bidder will be counted in sequence up to the number matching the Bid Security deposited. However without minimum Bid Security the offer will not be considered at all.</p> <p>The Bid Security shall be paid through separate prescribed challans (format enclosed in Annexure-I) in any branch of the Punjab National Bank Account no. 2246002100024414 & IFSC Code no. PUNB0224600 throughout country upto 28.09.2020 or through D.D. / bankers cheque in favour of M.D. RMSCL physically in the office of RMSC by 6:00 PM on 28.09.2020. Bid Security Deposit in any other form will not be accepted.</p> <p>The Bids submitted without sufficient Bid Security will be summarily rejected. The Bid Security will be forfeited, if the Bidder withdraws its Bid after last time & date fixed for receiving bids or in the case of a successful Bidder, if the Bidder fails within specified time to sign the contract agreement or fails to furnish the performance security.</p>	<p>format in Annexure -XV. (Enclosed)</p> <p>NOTE:- Samples should be submitted for sutures only. Samples of surgical items are not required.</p> <p>Clause 8.2 BID SECURITY</p> <p>The Bid Security Deposit shall be @ Rs. 20,000/- for each item of surgical quoted subject to minimum of Rs. 2.00 lacs and maximum of Rs. 5.00 Lacs. In case Bid Security submitted by the bidder is at the minimum or more but number of quoted items is more than the Bid Security submitted, the quoted items by the bidder will be counted in sequence up to the Bid Security deposited. However, without minimum earnest money the offer will not be considered at all. Bid Security will not be taken from undertakings, corporation of GoI & GoR. Further, Bid Security will be taken @ Rs. 5,000/- per item of surgical quoted subject to minimum of Rs. 50,000/- and maximum of Rs. 1.25 Lacs, from MSME Units of Rajasthan. They will furnish copy duly attested by gazetted officer of the registration of MSME units issued by the Director of Industries in respect of the stores for which they are registered. Duly attested copy of Acknowledgement of EM-II issued by DIC with an affidavit worth Rs.10 as per Annexure-II(B) under preference to Industries of Rajasthan rules 1995 in respect of stores for which they are registered.(Annexure-II(B)). In case Bid Security submitted by the bidder is at the minimum or more but number of quoted items is more than the Bid Security submitted, the quoted items by the bidder will be counted in sequence up to the number matching the Bid Security deposited. However without minimum Bid Security the offer will not be considered at all.</p> <p>The Bid Security shall be paid through separate prescribed challans (format enclosed in Annexure-I) in any branch of the Punjab National Bank Account no. 2246002100024414 & IFSC Code no. PUNB0224600 throughout country upto 19.10.2020 or through D.D. / bankers cheque in favour of M.D. RMSCL physically in the office of RMSC by 6:00 PM on 19.10.2020. Bid Security Deposit in any other form will not be accepted.</p> <p>The Bids submitted without sufficient Bid Security will be summarily rejected. The Bid Security will be forfeited, if the Bidder withdraws its Bid after last time & date fixed for receiving bids or in the case of a successful Bidder, if the Bidder fails within specified time to sign the contract agreement or fails to furnish the performance security.</p>
5		<p>New Annexure XV added PROFORMA FOR SUBMISSION OF SURGICAL / SUTURE SAMPLES (Enclosed)</p>

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ANNEXURE-XV
Ref Clause No.8.1

PROFORMA FOR SUBMISSION OF SUTURE SAMPLES

NIB No. _____

Name of Bidder _____

Address _____

S.No	Item Code	Name of the Item	Normal/ regular sales packs	
			Qty	Batch No.

Station :

Signature and Seal

Date :



Note:-

- It may be noted that if any further amendments are issued then a corrigendum will be published and informed.
- Rest of the terms and conditions will remain the same.


(Srinivas Meena)
Executive Director (Proc.)
RMSCL

