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F.02(64)/RMSCL/Proc./S&S(MD)/NIB-3/2019/58 Dated 15/2/19

Corrigendum-I

Subject: - Date extension and Amendment in conditions and specification of SHORT TERM E-BID FOR RATE CONTRACT CUM SUPPLY AND EMPANELMENT OF SURGICALS & SUTURES (DRUG ITEMS)

Ref: - F.02(64)/RMSCL/Proc./S&S(MD)/NIB-3/2019/42 Dated:06.02.2019

The following amendments are made:

1	<p>Date of submission for E-bids reference no F.02(64)/RMSCL/Proc./S&S(MD)/NIB-3/2019/42 Dated:06.02.2019</p> <table border="1"> <tr> <td>Last date and time of submission of online bids</td> <td>21.02.2019 up to 6:00 PM</td> </tr> <tr> <td>Date and time of opening of Online technical bids</td> <td>22.02.2019 up to 11:00 AM</td> </tr> <tr> <td>Bid Security, Tender fees, RISL fees through challan</td> <td>21.02.2019</td> </tr> <tr> <td>Bid Security, Tender fees, RISL fees Physically</td> <td>21.02.2019 up to 6:00 PM</td> </tr> </table>	Last date and time of submission of online bids	21.02.2019 up to 6:00 PM	Date and time of opening of Online technical bids	22.02.2019 up to 11:00 AM	Bid Security, Tender fees, RISL fees through challan	21.02.2019	Bid Security, Tender fees, RISL fees Physically	21.02.2019 up to 6:00 PM	<p>Date of submission for E-bids reference no F.02(64)/RMSCL/Proc./S&S(MD)/NIB-3/2019/42 Dated:06.02.2019</p> <table border="1"> <tr> <td>Last date and time of submission of online bids</td> <td>25.02.2019 up to 6:00 PM</td> </tr> <tr> <td>Date and time of opening of Online technical bids</td> <td>26.02.2019 up to 11:00 AM</td> </tr> <tr> <td>Bid Security, Tender fees, RISL fees through challan</td> <td>25.02.2019</td> </tr> <tr> <td>Bid Security, Tender fees, RISL fees Physically</td> <td>25.02.2019 up to 6:00 PM</td> </tr> </table>	Last date and time of submission of online bids	25.02.2019 up to 6:00 PM	Date and time of opening of Online technical bids	26.02.2019 up to 11:00 AM	Bid Security, Tender fees, RISL fees through challan	25.02.2019	Bid Security, Tender fees, RISL fees Physically	25.02.2019 up to 6:00 PM
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2	<p>Annexure-XIV and BOQ</p> <table border="1"> <tr> <td>S-80</td> <td>Bone Wax Sterilised</td> <td>2gm/ Packet</td> <td>Class C</td> </tr> </table>	S-80	Bone Wax Sterilised	2gm/ Packet	Class C	<p>Annexure-XIV and BOQ are to be read as follows:-</p> <table border="1"> <tr> <td>S-80</td> <td>Bone Wax Sterilised</td> <td>2.5 gm/ Packet</td> <td>Class C</td> </tr> </table>	S-80	Bone Wax Sterilised	2.5 gm/ Packet	Class C								
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3	<p><u>Clause 2 . ELIGIBILITY CRITERIA</u> (b) For SSI Units of Rajasthan, the average annual turnover in the last three financial years (2014-15, 2015-16, 2016-17 or 2015-16, 2016-17 and 2017-18) shall not be less than Rs. 2 crores. (c) Bidder should have at least 3 years market standing as a manufacturer for the items quoted in the tender, on the date of bid opening. The period of three year shall be counted from the date of issue of Product Permission. <u>The bidder should also have manufactured at least 3 commercial batches of the quoted items every year in the last 3 consecutive years (Annexure XIV Performance statement).</u> In the case of imported products, the product should have minimum 3 years standing in the market. The importer should have at least 3 years market</p>	<p><u>Clause 2 . ELIGIBILITY CRITERIA</u> For Item code M-1 Black Disinfectant Fluid (Phenyl) (As per Schedule "O" Grade – III) (reserve for MSME units of Rajasthan) (b) For MSME Units of Rajasthan, the average annual turnover in the last three financial years (2014-15, 2015-16, 2016-17 or 2015-16, 2016-17 and 2017-18) shall not be less than Rs. 50 lacs . (c) Bidder should have at least 1 years market standing as a manufacturer for the item code M-1 in the tender, on the date of bid opening. The period of one year shall be counted from the date of issue of Product Permission. <u>The bidder should also have manufactured at least 3 commercial batches of the</u></p>																



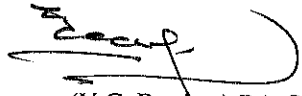
	<p>standing as manufacturer/ importer of surgical & Sutures in general. Imported items shall be accepted in brand name also.</p>	<p><u>quoted item in any one of the last three financial years (Annexure XIV Performance statement).</u></p>
<p>4</p>	<p>Clause 5(l) . TECHNICAL BID For Importer, WHO-GMP/COPP/FDA certificate of the exporting country should be submitted. For manufacturer, Quality Management System (QMS) Certificate as per Schedule V of Medical device Rules 2017 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 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). 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 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. NOTE:- In case of manufacturer/loan license if firm is not having QMS certificate, GMP certificate issued before 1 Jan 2018 will be acceptable, if valid</p>	<p>Clause 5(l) . TECHNICAL BID For Importer, WHO-GMP/COPP/FDA certificate of the exporting country should be submitted. For manufacturer, Quality Management System (QMS) Certificate as per Schedule V of Medical device Rules 2017 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 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). The Importer should produce WHO- GMP /COPP/FDA/GMP of the manufacturing firm or a certificate which is at par with WHO-GMP/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/GMP Certificate for the product during entire rate contract period of the product. If WHO-GMP/COPP/QMS/GMP 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/GMP certificate. During the period of non validity of WHO-GMP/COPP/QMS/GMP certificate of the firm the rate contract will deemed to be suspended. If the firm fails to inform RMSCL about the expiry of WHO-GMP/COPP/QMS/GMP 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. NOTE:- The WHO-GMP/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>

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	<p>on bid opening date. The WHO-GMP/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>	
5	<p>Annexure VII (Point 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* by Concerned Competent Authority vide letter No.....dated.....valid up to..... * In case if firm is not having QMS certificate, GMP certificate issued before 1 Jan 2018 will be acceptable, if valid on bid opening date. The WHO-GMP/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>Annexure VII (Point 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/GMP* by Concerned Competent Authority vide letter No.....dated.....valid up to..... * The WHO-GMP/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>

Rest terms and conditions will remain the same.


 (V.C. Bunkar) ~~RMSC~~
 Executive Director (Proc.)
 RMSC

