

TENDER NO. BMSIC/MEDICAL DEVICES/CONSUMABLE/20-02

Check list - I: Evaluation sheet to be used for preliminary evaluation of technical bids

Company Name: ISCON Surgicals Limited Total Number of Pages Submitted in bid documents: 120

Sl. No	SBD clause serial No	Description of the Clause/ Technical Eligibility Criteria as per SBD as mentioned in the Check List	Document/ fees submission status (Yes/ No)	Page number	Do the provided documents meet the eligibility criteria ? (Yes/ No)	Remarks
1	3. (a)	Tender Fee (Non -Refundable) of Rs 10,000/- in form of Demand Draft drawn in Favor of "Managing Director, Bihar Medical Services and Infrastructure Corporation Limited" payable at Patna. This fee is payable only once for one tender irrespective of items contained therein.	Yes	109	Yes	
2	3.(b)	Bidder are required to submit Earnest Money Deposit in the form of Demand Draft / Bank Guarantee drawn in favor of Managing Director, Bihar Medical Services and Infrastructure Corporation Limited from any Scheduled/Nationalized bank payable at Patna as follows:- Upto 5 Medical Devices/Consumable- Rs 50,000/- (Fifty thousand only), for 6 to 10 Medical Devices/Consumable- Rs 1,00,000/- (One Lakh only), for 11 to 20 Medical Devices/Consumable- Rs 1,50,000/- (One Lakh fifty thousand only) and for More than 20 Medical Devices/Consumable Rs 2,50,0,000/- (Two Lakhs fifty thousand only)	Yes	108	Yes	
3	3.(c)	Documentary evidence of the constitution of the company/ firm/ Proprietorship such as Memorandum and Articles of Association, Partnership Deed etc. should be submitted with details of the Name, Address, Telephone Number, Fax Number, e-mail address of the firm and of the Managing Director / Partners / Proprietor should be submitted.	Yes	20-70	Yes	
4	3.(d)	The details of Bidder Name, Address, Telephone Number, Fax, Number, e-mail address of the bidder and of the Managing Director / Partners / Proprietor should be submitted in Annexure-V.	Yes	-	Yes	confirmed with original copy
5	3.(e)	Power of Attorney or Resolution of Board by which the authorised signatory has been authorised by bidder firm to sign the documents. As per Clause 3(e) of the NIT. Format to be used.	Yes	71	Yes	
6	3.(k)	Copies of the Audited Balance Sheet and Profit and Loss statement showing details of their annual average turnover not less than 5 Crores for any three of the last four consecutive financial years (Auditor/CA certificate of turnover will not be accepted). Self-attested copies are to be submitted.	Yes	110-116	Yes	
7	3.(l)	Copy of Income Tax Return for any three of last four Consecutive Assessment years should be submitted (self-attested).	Yes	-	Yes	confirmed with original copy
8	3.(o)	Copy of PAN Card of the bidder company should be submitted (self-attested).	Yes	119	Yes	
9	3.(p)	Copy of certificate of valid GST registration of the bidder company should be submitted (self-attested).	Yes	120-121	Yes	

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28/11/2021

Check list - II: Evaluation sheet to be used for preliminary evaluation of technical bids

Company Name: - M/s Iscon Surgical Limited. Total Number of Pages Submitted in bid documents: 01 to 122

Sl. No	SBD Clause serial No	Description of the Clause/ Technical Eligibility Criteria as per SBD, as mentioned in Check List	Document/ fees submission status (Yes/ No)	Page Number	Do the provided documents meet the eligibility criteria ? (Yes/ No)	Remarks	Clarification given by firm	TEC Recommendation
1	3.(d)	The details of Bidder Name, Address, Telephone Number, Fax. Number, e-mail address of the bidder and of the Managing Director / Partners / Proprietor should be submitted in Annexure-V.	Yes Page	9	Yes			
2	3.(e)	Power of Attorney or Resolution of Board by which the authorised signatory has been authorised by bidder firm to sign the documents. As per Clause 3(e) of the NIT. Format to be used.	Yes	71	Yes			
3	3.(f)	In case of manufacturer, the bidder firm must have a valid manufacturing license or duly acknowledged renewal application with old license issued by the state licensing authority/Central licensing approving authority under Medical Devices Rules 2017 where ever applicable.	Yes	73,76,77,84	Yes			
		Approved product list as per the license issued for quoted MEDICAL DEVICES/CONSUMABLE as Per Medical Devices Rules 2017.	Yes	73	Yes			
		• Manufacturing License along with approved product list must be valid till the last date of the submission of tender	Yes	79,76,77,84,79-80	Yes			
		In case of Importer, the bidder (importer) firm must have a valid import License with product registration certificate issued by the Drugs controller General of India as per Medical Device Rule 2017. All Quoted products should be accompanied by their invoices, statement and import License showing that the quoted product are being imported and sold in India by the bidder (Importer) firm minimum for Last three years. Import license must be valid on the last date of submission of tender.	NA		Yes			

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		In case of Non-drug item(s) where neither the D & C Act 1945 nor the Medical Device Rule 2017 is applicable the bidder must have a manufacturing license/import export certificate (IEC) with an undertaking/Self declaration in his letter pas as per Annexure-VII that the item(s) quoted by the bidder is/are non-drug item(s) i.e neither covered under D & C Act nor Under Medical Device Rule 2017 .	NA		Yes				
4	3.(g)	Bidder must have Market Standing Certificate of minimum three years issued by the concerned Licensing Authority from Drugs Control Department/Concerned Government Department for the quoted product. Self-attested copies are to be submitted	Yes	94	No	Pack size not mentioned in MSC certificate			
5	3.(h)	Non Conviction Certificate (NCC) issued by the concerned Licensing Authority from Drugs Control Administration/Concerned Government Department of the state for last three years should be submitted. It should be not more than one year old. Self-attested copies are to be submitted.	Yes	95	Yes				
6	3.(i)	WHO-GMP/GMP (Good Manufacturing Practice) as per revised Schedule-'M'/COPP Certificate of the manufacturing unit issued by the Licensing Authority/ Drugs Control Department/BIS/ISI certificate issued from the concerned department. The GMP certificate should remain valid till the last date of submission of tender. Self-attested copies are to be submitted.	Yes	97-101	No	GMP certificate valid up to 26.01.2020			
7	3.(j)	Maximum Batch Production Capacity Certificate (section wise) issued by concerned Licensing Authority from Drugs Control Department/Concerned government Department highlighting the quoted product section. Self-attested copies are to be submitted. Importers will have also to submit Invoices/Evidence of import in items of said product with quantity details.	Yes	103	Yes				
8	3.(m)	The tenderer should give an affidavit sworn before first class magistrate / Notary stating that the firm & its quoted product is not black listed currently (as on the date of submission of the tender)by Central Government / Central Government agencies/any state government or any of the state government agencies / or any Drug procurement agencies or by BMSICL as per Annexure-II .	Yes	104-105	Yes				
9	5.(k)	An Affidavit (with stamp) regarding acceptance of tender conditions to be submitted by the bidding firm as per Annexure-IV .	Yes	106-107	Yes				
10	5.(l)	Filled check list as per given Annexure-VI to be submitted at the time of uploading the bid.	Yes	10-13	Yes				

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11	(c)	Power of Attorney or Resolution of the Board by which the authorized signatory has been authorized by the bidder firm should sign the documents in cases where person other than the Managing Director/Managing Partner or sole Proprietor signs the document.	Yes	71	Yes				
12	10.(c)	If a particular document/Certificate to be uploaded as specified in bid, is not applicable for a bidder, the bidder shall attach a scanned copy of declaration in the letter head stating that the specific document is not applicable/exempted for the bidder in connection to this tender.	No	No	No				
13	Corrigendum Point 17	Product standards for medical device.— (1) The medical device shall conform to the standards laid down by the Bureau of Indian Standards established under section 3 of the Bureau of Indian Standards Act, 1985 (63 of 1985) or as may be notified by the Ministry of Health and Family Welfare in the Central Government, from time to time. (2) Where no relevant Standard of any medical device has been laid down under sub-rule (1), such device shall conform to the standard laid down by the International Organisation for Standardisation (ISO) or the International Electro Technical Commission (IEC), or by any other pharmacopoeial standards. (3) In case of the standards which have not been specified under sub-rule (1) and sub-rule (2), the device shall conform to the validated manufacturer's standards.	Yes	17-18	Yes				
14	ANNEXURE-VIII	Affidavit regarding Higher Price/ Lower Price Certificate. Pollution Clearance Certificate	Yes	15-16	Yes				
			Yes	89-93	Yes				

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Check list - III: Evaluation sheet to be used for preliminary evaluation of technical bids

Company name: -M/s Iscon Surgical Limited Total Number of Pages Submitted in bid documents:01 to 122

Sheet to be used for verification of product approval and market standing

Sl. No	NIT Sl. No	Name of the Quoted MEDICAL DEVICES/CONSUMABLE		Specification		Pack Size		Product category	Approval Details			Last 3yrs market standing certificate/ New Drug
		As per NIT	As per Approval	As per NIT	As per Approval	As per NIT	As per Approval		First Approval	Approved Upto	Approved in Brand /Generic Name	
1	5	Disposable Syringe	Sterile Hypodermic syringe with needle attach for single use (Pg. 79)	Disposable Syringe-2 ml, with colour coded (as per BIS) needle Sterilised, Luer Mount, Non - toxic as per Drugs and Cosmetics Act 1940, IS No. 10258-2002 with BIS/ CE/ USFDA certification	Sterise hypodermic syringe with needle attach for single use	Per Piece	2ml	Drug	27.01.2003	26.01.2023	Generic	Pack size not mentioned
2	6	Disposable Syringe	Sterile Hypodermic syringe with needle attach for single use (Pg. 79)	Disposable Syringe-5 ml, with colour coded (as per BIS) needle Sterilised, Luer Mount, Non - toxic as per Drugs and Cosmetics Act 1940, IS No. 10258-2002 with BIS/ CE/ USFDA certification	Sterise hypodermic syringe with needle attach for single use	Per Piece	5ml	Drug	27.01.2003	26.01.2023	Generic	Pack size not mentioned
3	7	Disposable Syringe	Sterile Hypodermic syringe with needle attach for single use (Pg. 79)	Disposable Syringe-10 ml, with colour coded (as per BIS) needle Sterilised, Luer Mount, Non - toxic as per Drugs and Cosmetics Act 1940, IS No. 10258-2002 with BIS/ CE/ USFDA certification	10 ml, With colour coded (as per BIS) needle Sterilised, Luer Mount, Non - toxic CGS 2CC as per Drugs and Cosmetics Act 1940, IS No. 10258-2102 with CE certification.	Per Piece	10ml	Drug	27.01.2003	26.01.2023	Generic	Pack size not mentioned

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Check list - IV: Evaluation sheet to be used for preliminary evaluation of technical bids

Company name: -M/s Iscon Surgical Limited Total Number of Pages Submitted in bid documents: 01 to 122

Sheet for verification of licence details

Sl. No	NIT Sl. No	Name of the MEDICAL DEVICES/CONSUMABLE as per NIT	Manufacturer		Importer		Validity		GMP / WHO GMP / COPP (Import)/BIS/ISI	
			Forms Number	Manufacturing license Number	Forms Number	Import license Number	From	To	From	To
1	5	Disposable Syringe		RAJ-2164	-	-	27.01.2003	26.01.2023	24.01.2020	23.01.2023
2	6	Disposable Syringe	28	RAJ-2164	-	-	27.01.2003	26.01.2023	24.01.2020	23.01.2023
3	7	Disposable Syringe	28	RAJ-2164	-	-	27.01.2003	26.01.2023	24.01.2020	23.01.2023

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