TENDER NO. BMSIC/MEDICAL DEVICES/CONSUMABLE/18-03

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

Company Name:-Plasti Surge Industries. **Total Number of Pages Submitted in bid documents:-1 to 174**

Sl. No	SBD clause serial No	Descrption 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	124-125	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	122-123	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	69-96	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	54	YES	–

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**	**97-98**	**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**	**131-146-164**	**YES**	–
7	3.(l)	Copy of **Income Tax Return for any three of last four Consecutive Assessment years** should be submitted **(self-attested)**.	**YES**	**165-167**	**YES**	–
8	3.(o)	**Copy of PAN Card of the bidder company should be submitted (self-attested).**	**YES**	**118**	**YES**	–
9	3.(p)	**Copy of certificate of valid GST registration of the bidder company should be submitted (self-attested).**	**YES**	**169-171**	**YES**	–

Archana Singh
5/3/2019

TENDER NO. BMSIC/MEDICAL DEVICES/CONSUMABLE/18-03

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

Company Name: - M/s Plasti Surge Industries Pvt. Ltd. **Total Number of Pages Submitted in bid documents: 176**

Sl. No	SBD Clause serial No	Descrption 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
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	54	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	97-98	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.	No	No	No	License is Not Submitted
		Approved product list as per the license issued for quoted MEDICAL DEVICES/CONSUMABLE as Per Medical Devices Rules 2017.	No	No	No	Product list not submitted as per medical device 2017.
		• Manufacturing License along with approved product list must be valid till the last date of the submission of tender	Yes	114-117	No	Original license not Submitted only product list Submitted

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		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.	**Yes**	**102**	**Yes**	
		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 .	**No**	**No**	**No**	
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**	**103-106**	**No**	**Market standing certificate not issued by concerned Govt. Department**
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**	**109**	**No**	**Non conviction certificate (NCC) not issued by concerned Govt. department**
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**	**111**	**No**	**Not submitted**
7	**3.(j)**	Maximum Batch Production Capacity Certificate (section wise) issued by concerned Licensing Authority form 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**	**113**	**No**	**Product NIT seriol No-2 Hb testing Kits (Haemo globin colour Kits is not mention in Maximum Batch product certificate Page No.-114**

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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**	**120-121**	**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**	**175-176**	**Yes**	
10	5.(l)	Filled check list as per given Annexure-VI to be submitted at the time of uploading the bid.	**Yes**	**9-12**	**Yes**	
11	7.(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**	**97-98**	**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.	**Yes**	**102, 103, 109, 111, 113**	**Yes**	

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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**	**20-24**	**Yes**	**ISO, CE**
14	**ANNEXURE-VIII**	Affidavit regarding Higher Price/ Lower Price Certificate.	**Yes**	**55-56**	**Yes**	

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TENDER NO. BMSIC/MEDICAL DEVICES/CONSUMABLE/18-03

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

Company name: - M/s Plasti Surge Industries Pvt. Ltd. Total Number of Pages Submitted in bid documents:

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	(Drug/Non Drug)	First Approval	Approved Upto	Approved in Brand /Generic Name	
1	1	Salt Testing Kits	Salt testing Kits	**SALT TESTING KITS** **Annexure- X** **1.** the salt testing Kit should be ready in use, liquid from. Each salt testing Kit shouldd have 20 ml testing solution or testing capacity of 75-100 samples. Supply should be in plastic screwed cap vial and able and relative humidity (20-90%) in any part of the country. **2.** The Kit should be able to differentiate :- Salt with Iodine. Salt with inadequate iodine in the range of 05 to less than 15ppm. Salt with adequate levels of iodine 15ppm and above. **3.** The test Kit should be able to detect Iodine levels in the salt from various sources and characteristics e.g.- salts that are alkaline / acide in nature and with varying sodium choloride content in the country. **4.** The test Kit should have been evaluated and validated by at least one International agencies like WHO, UNICEF, MI, and / or national level Laboratories such as National Institute of Nutrition, Hydrabad, National Centre for Disease Control Delhi; All India Institute of Medical Sciences , New Delhi; All India Institute of Hygine & Public Health, Kolkata; Central Food Technological Research Institute, Mysore; Indian Council of Medical Research & Council of Scientific and Industrial Research Laboratories. The validation should include test for the qwality, packaging, ready to use testing (drop by drop), stability at various places, shelf life under sealed condition as well as open condition as as all these parameters are interlinked. The testing Laboratory should submit detail report about all the test parameters including how they vary under different field conditions. **5.** The offered Manufacturer/Bidders should have manufacturing and marketing experience minimum of 2 years and should be supported by documentary evidence. **6.** The shelf life of the salt testing KIT should be at least one year and when the vial is opened, it shoukd not be less than 4-6 months. 7. Pack Size: Each salt testing KIT should be independenly packed and not more than kiss in a bigger package, for the purpose of ease of transportation/distribution. **8.** Bidders are required to submit documentart proof in support of above quoted specification and requirements along with their bids. **9.** Bidders are also required to submit the three packets having ten Kits each of independent packaging as per technical specifications at S.N.-1 to 6 of salt testing KIT as samples along with their bids.Specification of Salt Testing Kit 1. 2-3 Ampoules of 10 ml each containing test solution. 2. In some cases, I red ampoule containing recheck solution. 3. A detailed instruction sheet in the local language. 4. A colour chari with circular colour spots. 5. One small container. 6. All fiting into a handy pocket size kit.	Not Mention	Per test per Kit	Not Mention	Non Drug	18-11-2010	Not Submitted	Generic	Not Submitted
				TECHNICAL SPECIFICATION OF HEMOGLOBIN COLOUR SCALE KIT **1. The technology of the system should be Colour Scale Based.** **2. The Colour Scale for Hemoglobin should have a calibrated and dully validated laminated Hemoglobin Scale booklet with measurement of Hb in g/dl marked in 4,6,8,10,12 & 14 range for easy & accurate detection of Hemoglobin levels.** **3. The Validation document from Confederation of American Pathologist Accrediated (CAP)/National Accreditation Board for Testing and Calibration Laboratories (NABL) must be attached with the tender otherwise the tenderer would be disqualified. The validation must be of the current batch to be supplied by the supplier.** **4. The kit must contain one each of Colour Scale Card and 1x200 strips in a dispenser box that must contain 100 strips on each side of the box having 2 openings dispensing sides containing 100 strips on each side totaling to 200 strips. Kit should contain 200 lancets for finger prick.** **5. Users list would not be treated as validation for this product. The manufacturer must have a CE certificate for the quoted product.** **6. The supplier can be importer or direct manufacturer with an ISO certification.**	Not Mention	Per KIT	Not Mention	Non Drug	18-11-2010	Not Submit	Generic	Not Submitted

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2	2	Hb Testing Kits (Haemoglobin Colour Scale Kits)	Hemoglobin Check Kit / Starter Kit	7. Packaging: a) The kit must have a weather proof packaging for easy carrying and storage. A sample must be deposited along the tender. b) The colour scale booklet & test kits must have NHM Logo at the time of supply with the year of supply inscribed on the pack. c) Instruction for use should be included with the box pack. d) Steps to be followed for using colour Scale must be printed on the colour scale book both in English & Hindi. e) Guideline with sketch must be there with each test kit pack. f) Manufacturer details with production batch & expiry details must be printed on the test box along with shelf life after opening of the box. g) All Refill Kit sketch must be laminated or covered with plastic. 8. Colour scale range should be as follows with an indication of Haemoglobin (in equivalent g/dl), (i) 4g/dl- Colour grade (ii) 6g/dl- Colour grade (iii) 8g/dl- Colour grade (iv) 10 g/dl- Colour grade (v) 12g/dl- Colour grade (vi) 14g/dl- Colour grade 9. Storage Conditions: - Dry, room temperature. The strip must be kept in their closed dispenser to avoid becoming damp when not actually being used. 10. Final Packaging:- Store shall be securely packed in normal trade packing of corrugated boxes to avoid loss or damage during the transit by rail/road.										

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TENDER NO. BMSIC/MEDICAL DEVICES/CONSUMABLE/18-03

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

Company name: - M/s Plasti Surge Industries Pvt. Ltd. **Total Number of Pages Submitted in bid documents:**

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	1	Salt Testing Kits	Not Submitted	Not Submitted	No	No	No	No	No	No
2	2	Hb Testing Kits (Haemoglobin Colour Scale Kits)	Not Submitted	Not Submitted	No	No	No	No	No	No

Note:- Assisted in tecjhnical evaluation in refernce to letter no. BMSIC/40015/21-2018/5473, dated 13.02.2019 on the basis of document provided by BMSICL checklist II, III,&IV. Provided chedklist complied with due deligence and care. Inspite, some in advertent discrepencies could have been crept in humble request to all concern to bring to the notice indue time if any discrepenceies are observed for rectification.

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