

TENDER NO. BMSIC/MEDICAL DEVICES/CONSUMABLE/19-04

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

Company Name : Isens Biosensors India Private Limited., Total Number of Pages Submitted in bid documents: 1 TO 194

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	194	YES	-
2	3.(b)	A bidder is required to submit Earnest Money Deposit in the form of Demand Draft/ Bank Guarantee of Rs. 5,00,000/- (Five Lakh) drawn in favor of Managing Director, Bihar Medical Services and Infrastructure Corporation Limited from any Scheduled/Nationalized bank payable at Patna.	YES	147	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	30-52	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	21	YES	-
5	3.(e)	Power of Attorney or Resolution of the Board by which the authorized signatory has been authorized by the bidder firm to sign the documents should be submitted.	YES	59-60	YES	-
6	3.(m)	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	109-118-137	YES	-

7	3.(n)	Copy of Income Tax Return for any three of last four Consecutive Assessment years should be submitted (self-attested).	YES	149-151	YES	-
8	3.(q)	Copy of PAN Card of the bidder company should be submitted (self-attested).	YES	190	YES	-
9	3.(r)	Copy of certificate of valid GST registration of the bidder company should be submitted (self-attested).	YES	148	YES	Along with GSTIN Number, Copy of Nature of Business of Bidder must be attached with these Documents.

Archana Singh
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TENDER NO. BMSIC/MEDICAL DEVICES/CONSUMABLE/19-04

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

Company Name:- Isens Bioscience India Private Limited., Unit No.: 1116-1117, 11th Floor, JMD Megapolls, Sohna Road, Sector-48, Gurgaon.
Total Number of Pages Submitted in bid documents:- 195

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 as numbered by BMSICL	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	21	Yes	
2	3.(e)	Power of Attorney or Resolution of Board by which the authorised signatory has been authorized by the bidder firm to sign the documents. Should be submitted.	-	-	-	
3	3.(f)	•Minimum three years old valid Manufacturing/ import License with latest license renewal certificate.	Yes	63,67,69	Yes	
		•Must have three years of experience in manufacturing / Importing of the quoted item.	Yes	74-90	No	Import invoices for Lancet from Tianjin Huahong Co. Ltd. (89,90) (For two year) submitted but authorisation of manufacturer certificate submitted for M/s ISENS Inc. Gangwan-Republic of Korea. For Glucose strip & Glucometer submitted for three years
		•Must have three years of experience in supplying the quoted items to Central Government/ any state government/ Government corporation/ any Central Government or State Government PSU.	Yes	91-104	No	Submitted P.O. copies not clearly readable.

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		• Bidder who are manufactures for all the floated items or bidder who are direct importers for all the floated items or bidder who are manufacturer for some of the floated items as well as importer for the remaining floated items are allowed to participate in the bidding process.	Yes	63-67 69	No	Import License having product approval for only Glucose Strip
		Bidders shall submit self-attested copies of their manufacturing license (for manufacturer)/ import License (for direct importer)/ manufacturing& import license (for manufacturer as well as direct importer), invoices raised against the executed supply order/ orders of the quoted items in support of above mentioned conditions.	Yes	63-67 69	No	No invoices against submitted P.O.
		• In case of Importer, they will have to furnish the manufacturer's authorization form from the original equipment manufacturer (OEM) as per Annexure IX.	Yes	65	No	Not Submitted for M/s Tianjin Huahong Submitted only for M/s Isens Inc. South Korea
4	3 (g)	The manufacturer must have Valid ISO 13485 certificate for quality standards. Self-attested copies are to be submitted.	Yes	68	Yes	
5	3.(h)	The Glucometer machine must have valid CE certificate as per Invitro Diagnostic Devices (IVD) or US FDA certificate or BIS Certificate.	Yes	24-28	No	Submitted EC instead of CE.
6	3.(i)	The Glucose test strips should be certified by the National Institutes of Biological (NIB), Govt. of India.	Yes	53-54	Yes	
7	3.(j)	The Auto disable lancets should be CE or USFDA certified or BIS Certified.	No		No	Not Submitted
8	3.(k)	In case of Importer, the bidder (importer) firm must have valid import License. All Quoted products should be accompanied by their invoices and statements showing that the quoted product is 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	63-67,69,74-90	No	Import invoices for Lancet from Tianjin Huahang Tech. Co. Ltd. but authorisation of manufacture submitted for M/s ISENS Inc. Gangwan- Republic of Korea

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9	3.(l)	A self-declaration of Non-Conviction on a Judicial Stamp Paper of adequate value to be submitted which should be dully notarized (Annexure VIII). The date of self-declaration Non-Conviction Affidavit should be post the date of publication of this tender.	Yes	57	Yes	
10	3.(o)	The tenderer should give an affidavit as per Annexure-II sworn before first class magistrate / Notary stating that the firm & its quoted product is not black listed/debarred currently (as on the date of submission of the tender) by the Central Government / any Central Government agency/any state government or any of the state government agency / or any drug/PSU or by BMSICL.	Yes	55	Yes	
11	3.(p)	Duly signed list of items quoted in prescribed format as per Annexure-III.	Yes	29	Yes	
12	5.(g)	Affidavit declaration regarding acceptance of tender conditions to be submitted by the bidding firm as per Annexure-IV.	Yes	15	Yes	
13	5.(h)	Duly filled check list as per given Annexure-VI to be submitted at the time of uploading the bid.	Yes	191-193	Yes	
14	7.(c)	Power of Attorney supported by 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	59-60	Yes	
15	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.	NA			

Signature

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TENDER NO. BMSIC/MEDICAL DEVICES/CONSUMABLE/19-04

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

Company Name:- Isens Bioscience India Private Limited., Unit No.: 1116-1117, 11th Floor, JMD Megapolls, Sohna Road, Sector-48, Gurgaon.

Total Number of Pages Submitted in bid documents:- 195

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

Sl. No	NIT Sl. No	Name of the Quoted Items		Specification as per Annexure C		Pack Size as per Annexure B		Approval Details			Three years experience in supplying the quoted item
		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	1	Glucometer machine	Product approval not submitted.	1) Measurement range: 30 to 600 in mg/dl. 2) Accuracy should be as per International Standard ISO 15197: 2013 (Requirements for Blood-glucose monitoring systems for self-testing in managing diabetes mellitus). Supporting certificate or test reports from the National Institutes of Biologicals (NIB) must be furnished of last 2years with the technical bid. 3) Reproducibility/Precision: $\pm 5\%$ 4) Display should be 40mm ± 5 mm or better measured diagonally. 5) It should be battery operated electronic system and the battery life should be for atleast 500 tests.	20-600 mg/dl Yes(Page No.- 11) Certificate from NIB not submitted. Not Submitted Not Submitted Not Submitted	1 Piece/ pack	Not Submitted	Not Submitted	Not Submitted	Not Submitted	No (Not readable)
2	2	Glucose test strips	Blood Glucose test strips	6) Self life of strips: Minimum 6 months at the time of delivery to consignee. 7) Packing of strips should not be more than 50 strips in a pack. 8) Strips should work for minimum 3 months after opening of strips pack. 9) Operating temperature for both device and test strip should be 10 deg C to 40 deg C.	24 months Not Submitted Not Submitted 5-45 degree C	100 Strips/ pack	Not Submitted	23-02-16	27-05-24	Both	No (Not readable)
3	3	Auto Disable Lancets	Product approval not submitted.	10) A complete user operational guide shall have to be supplied along with each machine, printed in Hindi and English language.	Not Submitted	100 Nos/ pack	Not Submitted	Not Submitted	Not Submitted	Not Submitted	No (Not readable)

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TENDER NO. BMSIC/MEDICAL DEVICES/CONSUMABLE/19-04

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

Company Name:- Isens Bioscience India Private Limited., Unit No.: 1116-1117, 11th Floor, JMD Megapolls, Sohna Road, Sector-48, Gurgaon.

Total Number of Pages Submitted in bid documents:- 195

Sheet for verification of licence details

Sl No.	NIT Sl. No	Name of the Item as per NIT	Manufacturer		Importer		Validity		ISO 13485	
			Forms Number	Manufacturing license Number	Forms Number	Import license Number	From	To	From	To
1	1	Glucometer machine	—	—	Not Submitted	Not Submitted	Not Submitted	Not Submitted	01-04-17	31-03-20
2	2	Glucose test strips	—	—	Form 10 MD-15	NCD-31/16 IMP/IVD/2019/ 000186	23-2-16 28/5/19	22-02-2019 27/5/24	01-04-17	31-03-20
3	3	Auto Disable Lancets	—	—	Not Submitted	Not Submitted	Not Submitted	Not Submitted	01-04-17	31-03-20

Note:- Assisted in technical evaluation in reference to letter no.BMSIC/40015/44-2019 /6019 dt 07.01.2020 on the basis of documents provided by BMSICL as check list II,III & IV. Provided checklist compiled with due diligence and care.Inspite, some inadvertent discreprencies could have been crept in. Humble request to all concerned to bring to the notice in due time if any discreprencies are observed for rectification.



