

File No.- BMSIC/40030/297-2024/5553

दिनांक:- 24/09/2024

बिहार चिकित्सा सेवाएं एवं आधारभूत संरचना निगम लि०, बिहार पटना

**BMSICL की निविदा संख्या- BMSIC/MEDICAL DEVICES/CONSUMABLES/24-05 से संबंधित प्राप्त ई-निविदाओं के तकनीकी मूल्यांकन विवरणी पर साक्ष्य सहित दावा/आपत्ति की माँग संबंधी सूचना**

बिहार चिकित्सा सेवाएं एवं आधारभूत संरचना निगम लि०, द्वारा **Medical Devices/Consumables** की अधिप्राप्ति हेतु ई-निविदा (निविदा संख्या- **BMSIC/MEDICAL DEVICES/CONSUMABLES/24-05**) आमंत्रित की गई थी, जिसके आलोक में निर्धारित समय सीमा के अन्तर्गत कुल 10 (दस) ई-निविदा प्राप्त हुई। उक्त 10 (दस) ई-निविदा के दस्तावेजों के प्राथमिक तकनीकी मूल्यांकन के उपरान्त तैयार की गई तकनीकी मूल्यांकन विवरणी के दावा/आपत्ति के आमंत्रण हेतु BMSICL के **website (www.bmsicl.gov.in)** एवं e-proc 2.0 के **website (www.eproc2.bihar.gov.in)** पर अपलोड की गई है।

निविदा में भाग लेने वाले निर्माता संस्थान अथवा अन्य आपूर्तिकर्ता अपलोड किये गए उपर्युक्त तकनीकी मूल्यांकन प्रपत्र में किसी प्रकार की विसंगति पाये जाने की स्थिति में, साक्ष्य सहित अपना दावा/आपत्ति दिनांक 01/10/2024 के अपराह्न 05:00 बजे तक केवल e-proc 2.0 के **website (www.eproc2.bihar.gov.in)** के माध्यम से कर सकते हैं।

e-proc 2.0 के अलावा अन्य किसी माध्यम से प्राप्त किसी प्रकार के दावा/आपत्ति पर कोई विचार नहीं किया जायेगा।

अनुलग्नक- यथोक्त

(रवीन्द्र कुमार)  
महाप्रबंधक (अधिप्राप्ति)



**TENDER NO. BMSIC/MEDICAL DEVICES/CONSUMABLE/24-05**

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

**Company Name:** Medsource Ozone Biomedicals Pvt. Ltd.

**Total Number of Pages Submitted in bid documents:** 1-262

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/- + GST @18%, Total Rs 11,800 shall be submitted online (On E-Proc-2). This fee is payable only once for one tender irrespective of items contained therein.	Yes	28	Yes	—
2	3.(b)	EMD shall be submitted ONLY in form of Bank Guarantee (Offline mode), drawn in favor of Managing Director, Bihar Medical Services and Infrastructure Corporation Limited from any Scheduled/Nationalized bank payable at Patna, as mentioned in Clause 2, as per following table:- S.N. No. of MEDICAL DEVICES/CONSUMABLE quoted EMD Amount 1 Upto 5 MEDICAL DEVICES/CONSUMABLE Rs 50,000/- (Fifty thousand only) 2 6 to 10 MEDICAL DEVICES/CONSUMABLE Rs 1,00,000 (One Lakhs only) 3 11 to 20 MEDICAL DEVICES/CONSUMABLE Rs 1,50,000 (One Lakhs fifty thousand only) 4 More than 20 MEDICAL DEVICES/CONSUMABLE Rs 2,50,000 (Two Lakhs fifty thousand only)	Yes	47-51	Yes	As per Bid document clause 3(b) BG Submitted for EMD must be Schedule/Nationalized Bank Payable at patna But firm has not Submitted the same.
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	05-24	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 <b>Annexure-V.</b>	Yes	248	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	01	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 <b>5 Crores</b> 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	29-36	Yes	—
7	3.(l)	Copy of Income Tax Return for any three of last four consecutive Assessment years should be submitted (Self Attested).	Yes	37-39	Yes	—
8	3.(o)	Copy of PAN Card of the bidder company should be submitted (self-attested).	Yes	41	Yes	—
9	3.(p)	Copy of certificate of valid GST registration of the bidder company should be submitted (self-attested).	Yes	43-45	Yes	—

*Archan Singh* *[Signature]*

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**TENDER NO. BMSIC/MEDICAL DEVICES/CONSUMABLE/24-05**

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

**Company Name: - M/s Medsource Ozone Biomedicals Pvt. Ltd. Total Number of Pages Submitted in bid documents: 262**

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
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 <b>Annexure-V.</b>	Yes	248	Yes	
2	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	1 & 2	Yes	
3	3.(f)	(I) Minimum three years old valid Manufacturing License of the quoted product.	Yes	14-22	No	(i) Less than 3 year for NIT sr. no. 3 & 5. (ii) All of the specification as per annexure of NIT not mentioned in submitted product approval certificate. (iii) Not highlighted the quoted item.
4		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	14-22	No	
5		Approved product list as per the license issued for quoted MEDICAL DEVICES/CONSUMABLE as Per Medical Devices Rules 2017.	Yes	14-22	No	
6		Manufacturing License along with approved product list must be valid till the last date of the submission of tender.	Yes	14-22	No	
7		Valid Pollution Control Clearance Certificate in accordance with Water [Prevention and control of Pollution] Act, 1974 & Air [Prevention and control of Pollution] Act, 1981 and Hazardous Wastes (Management, Handling & Trans Boundary Movement) Rules 2008 (Self Attested Copy of Certificate to be enclosed) (as applicable).	Yes	23	Yes	Exemption certificate submitted
8		Bidders shall submit self-attested copies of required manufacturing license and approved product list in support of above-mentioned condition and they are required to specify the quoted product in their approved product list by highlighting it.	Yes	14-22	No	Quoted product not highlighted

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9		(II) 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	NA	NA	
10		(III) 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	NA	NA	
11	3.(g)	Bidder must have <b>Market Standing Certificate</b> 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	102-122	No	Less than 3 year and not highlighted the quoted item
12	3.(h)	<b>Non-Conviction Certificate (NCC)</b> issued by the concerned Licensing Authority from Drugs Control Administration of the state for last three years should be submitted (wherever applicable). It should be not more than one year old. Self-attested copies are to be submitted.	Yes	52-89	No	Not highlighted the quoted item
13	3.(i)	<b>WHO-GMP/GMP</b> (Good Manufacturing Practice) as per revised Schedule- 'M'/COPP Certificate of the manufacturing unit issued by the Licensing Authority/Drugs Control Department, (wherever applicable). The GMP certificate must not be older than one year from the date of publication of tender. Self-attested copies are to be submitted. <b>Explanation-</b> Generally the GMP Certificate is issued for one-year validity. Hence the provision that it should not be older than one year from the date of publication of tender implies mutatis mutandis that the GMP certificate should remain valid till the date of submission of tender.	NA	NA	NA	ISO:13485:2016 certificate submitted (page no. 246)
14	3.(j)	<b>Maximum Production Capacity Certificate</b> (Section wise) issued by concerned Licensing Authority from Drugs Control Department highlighting the quoted product section (wherever applicable). Self-attested copies are to be submitted. In case of Importer, an affidavit (with Stamp) sworn before first class magistrate/ Notary stating the batch production capacity of the firm and also that said production (Importing) capacity shall be adequate for requirement laid in NIT. Importer will have also to submit Invoices/evidence of import in items of said product with quantity details.	Yes	25	Yes	
15	3.(m)	The tenderer should give an affidavit sworn before first class magistrate / Notary stating that the firm & its quoted product is not <b>black listed/Debarred currently</b> (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 <b>Annexure-II</b> .	Yes	4	Yes	

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16	3.(n)	List of items quoted in prescribed format as per Annexure-III duly signed.	Yes	3	Yes	
17	5.(k)	Affidavit declaration regarding acceptance of tender conditions to be submitted by the bidding firm as per <b>Annexure-IV</b> .	Yes	90	Yes	
18	5.(l)	Filled check list as per given <b>Annexure-VI</b> to be submitted at the time of uploading the bid.	Yes	250-251	Yes	
19	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	1 & 2	Yes	
20	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	NA	NA	
21	2 (d)	The price quoted by the bidders must not exceed the ceiling price as fixed by NPPA (National Pharmaceutical Pricing Authority) as per the provision of "Drugs Price Control Order (wherever applicable)" and the quoted rate should be at least 20% less than its MRP. In extraordinary cases the Managing Director, BMSICL has discretion to take decision). <b>Explanation-</b> In order to ensure procurement of the tendered drugs at the most appropriate and competitive rate, the bidders are directed to quote their lowest price as compared to the Rate provided to their respective Distributors/ Dealers/Wholesalers/ Carrying and Forwarding Agents/Authorized depot sales point in the State of Bihar. A Notarized affidavit to this effect on a Rs 100/- Non-judicial Stamp Paper should be submitted with the Bid in the prescribed format as mentioned in <b>Annexure-X</b> .	Yes	249	Yes	
22	—	Performance Statement- <b>Annexure- IX</b>	Yes	123-221	Yes	
23	—	AFFIDAVIT FOR NON DRUG ITEM(S) <b>ANNEXURE-VII</b>	NA	NA	NA	

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TENDER NO. BMSIC/MEDICAL DEVICES/CONSUMABLE/24-05													
Check list - III: Evaluation sheet to be used for preliminary evaluation of technical bids													
Company Name: - M/s Medsource Ozone Biomedicals Pvt. Ltd.    Total Number of Pages Submitted in bid documents: 262													
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	(Medical Device/Non Drug)	Product Approval	Approved Upto	Approved in Brand /Generic Name		
1	1	HBsAg (Rapid Test) – whole blood	HBsAg Test (page no. 21)	1. Should be coated with monoclonal antibodies covering all subtypes and variants of HBsAg. 2. The assay should be able to detect surface antigen to Hepatitis B virus. 3. Should be compatible with whole blood. 4. Adequate documents detailing the principle, components, biosafety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit. 5. The kit should have approval of the statutory authority from the country of origin. 6. In case of imported kits, it should be registered and licensed by the DCG (I). 7. In case of indigenous manufactures, should be licensed by the competent authority/Licensing authority, defined under Drugs and Cosmetics Act (1940) and Medical Device Rules, 2017. 8. The kit should have minimum shelf life of 12 months at the port/place of discharge of consignees. 9. The total procedure time shall not be more than 30 minutes. 10. The assay component should include positive and negative controls, sufficient for conducting 20% of the tests (10% negative and 10% positive controls), which may be provided along with the kits, if not a part of the kit. 11. The assay should have sensitivity of more than 98% and specificity of more than or equal to 98% as per the office order of MoHFW vide F. No. 29/Misc./4/2016-DC(65) dated 13/06/2017. 12. The control dot/band should be able to detect the presence of human immunoglobulin and should not be just a “procedural control” or meant merely for checking the flow of reagents or integrity of antigens, except lateral flow technology. <b>General Specifications</b> 1. The manufacturer/authorized agent should ensure maintenance of cold chain during storage and transport of kits at 2-8°C. 2. The pack size should not be more than 50 tests, wherein each test is individually packed.	1. Not mentioned 2. Yes 3. Only for human specimen 4. Yes 5. Yes 6. N.A 7. Yes 8. 24 month 9. Not mentioned 10. Not mentioned 11. Sensitivity 100% Specificity 100% (page no. 236) 12. Not mentioned 1. Not mentioned 2. Not mentioned	Each Kit	Not mentioned	Medical Device	26.06.2020	25.06.205	Both	Submitted (page no. 102-122)	

2	2	Anti-HCV Antibody Kits (Rapid Test)- Whole blood	HCV Test (page no. 20)	<p>1. Should utilize recombinant and/or synthetic peptide antigens for core, NS3, NS4 and NS5.</p> <p>2. The assay should detect total anti HCV antibodies.</p> <p>3. Should be compatible with whole blood.</p> <p>4. Adequate documents detailing the principle, components, biosafety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assay, manufacturing and expiry dates should be provided in each kit.</p> <p>5. The kit should have approval of the statutory authority from the country of origin.</p> <p>6. In case of imported kits, it should be registered and licensed by the DCG (I).</p> <p>7. Indigenous manufactures should be licensed by the competent authority/Licensing authority, defined under Drugs and Cosmetics Act (1940) and Medical Device Rules, 2017.</p> <p>8. The kit should have minimum residual shelf life of 12 months at the port/place of discharge of consignees.</p> <p>9. The total procedure time shall not be more than 30 minutes.</p> <p>10. The assay component should include positive and negative controls sufficient for conducting 20% of the tests (10% negative and 10% positive controls), which may be provided along with the kits, if not a part of the kit.</p> <p>11. The assay should have sensitivity more than or equal to 99% and specificity of more than or equal to 98%, as per the office order of MoHFW vide F. No. 29/Misc./4/2016-DC(65) dated 12/07/2017.</p> <p>12. The control dot/band should be visible to the naked eye and be able to detect the presence of human immunoglobulin and should not be just a "procedural control" or meant merely for checking the flow of reagents or integrity of antigens except in lateral flow technology.</p> <p><b>General Specifications</b></p> <p>1. The manufacturer/authorized agent should ensure maintenance of cold chain during storage and transport of kits at 2-8°C.</p> <p>2. The pack size of kit should not be more than 50 tests, wherein each test is individually packed.</p>	<p>1. Not mentioned</p> <p>2. Yes</p> <p>3. Only for human specimen</p> <p>4. Yes</p> <p>5. Yes</p> <p>6. N.A</p> <p>7. Yes</p> <p>8. 24 month</p> <p>9. Not mentioned</p> <p>10. Not mentioned</p> <p>11. Sensitivity 100% Specificity 100% (page no. 238)</p> <p>12. Not mentioned</p> <p>1. Not mentioned</p> <p>2. Not mentioned</p>	Each Kit	Not mentioned	Medical Device	26.06.2020	25.06.2025	Generic	Submitted (page no. 102-122)
3	3	HIV- 4th Generation ELISA Kits	HIV Ag/Ab ELISA (page no. 15)	<p>1. Kit needs to detect antibodies against HIV 1+2 and p24 Ag against HIV-1.</p> <p>2. Kit needs to have specificity of more than 99.5% for both Antigen as well as Antibody without compromising the assay sensitivity</p> <p>3. Kit needs to have reactive and non reactive controls with separate positive control for Antigen and Antibody.</p> <p>4. The analytical Sensitivity of p-24 Ag detection needs to be less than 50 pg/ml or 1.0 IU/ml of WHO Standard</p> <p>5. Kit needs to have colour coded reagents (Optional).</p> <p>6. OD norms for reagents verification on automation as well as manual procedure.</p> <p>7. Kit needs to detect all the three classes of antibodies to HIV i.e. IgM, IgG and IgA simultaneously providing highest early sero-conversion sensitivity.</p> <p>8. Total Incubation time needs not to be more than 2 hrs.</p> <p>9. Sample volume needs not to be more than 100 µl without any predilution step.</p> <p>10. Supplier needs to provide the Certificate of Analysis/Quality from NIB/NARI for each supplied batch.</p> <p>11. Product needs to be CE approved and Certificate of Analysis should be provided for each batch of the product.</p> <p>12. Kit needs to be programmable &amp; compatible for automated / semi-automated systems.</p>	<p>1. Yes</p> <p>2. Sensitivity 100% Specificity 100% (page no. 241)</p> <p>3. Not mentioned</p> <p>4. Not mentioned</p> <p>5. Not mentioned</p> <p>6. Not mentioned</p> <p>7. Not mentioned</p> <p>8. Not mentioned</p> <p>9. Not mentioned</p> <p>10. Yes</p> <p>11. Not submitted</p> <p>12. Not mentioned</p> <p>Shelf life 18 month</p>	Each Kit	Not mentioned	Medical Device	19.02.2022 (Less than 3 year)	18.02.2027	Generic	Less than 3 year and not highlighted the quoted items (page no. 102-122)
4	5	Hep B 3rd Generation ELISA Kits	HBsAg ELISA Test (page no. 18)	<p>1. Kit needs to have a minimum analytical sensitivity of 0.060 ng/ml or 0.05 IU/ml for WHO Standard.</p> <p>2. Specificity of the Kit needs to be more than 99.5%.</p> <p>3. Kit needs to be able to detect all known major subtypes - adr, adw, ayr, ayw as well as most of the mutants.</p> <p>4. Kit needs to be based on one step sandwich Elisa.</p> <p>5. Kit needs to use combination of monoclonal &amp; polyclonal antibodies on solid phase and in the conjugate to enable best coverage of all the subtypes.</p> <p>6. Kit needs to have colour coded reagents (Optional).</p> <p>7. OD norms for reagents verification on automation as well as manual procedure.</p> <p>8. Total incubation time of the assay needs not to be more than 2 Hrs.</p> <p>9. Kit needs to be programmable &amp; compatible for automated / semi-automated systems.</p> <p>10. Sample volume need not to be more than 100 µl without any predilution step.</p> <p>11. Supplier needs to provide the Certificate of Analysis/Quality from NIB/NARI for each supplied batch.</p> <p>12. Product needs to be CE approved and Certificate of Analysis should be provided for each batch of the product.</p>	<p>1. Sensitivity 100%</p> <p>2. Specificity 99.8% (page no. 244)</p> <p>3. Not mentioned</p> <p>4. Yes</p> <p>5. Not mentioned</p> <p>6. Yes</p> <p>7. Not mentioned</p> <p>8. Not mentioned</p> <p>9. Not mentioned</p> <p>10. Not mentioned</p> <p>11. Yes</p> <p>12. Not submitted</p> <p>Shelf life 18 month</p>	Each Kit	Not mentioned	Medical Device	04.08.2021 (Less than 3 year)	03.08.2026	Both	Less than 3 year and not highlighted the quoted items (page no. 102-122)

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## TENDER NO. BMSIC/MEDICAL DEVICES/CONSUMABLE/24-05

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

Company Name: - M/s Medsource Ozone Biomedicals Pvt. Ltd. Total Number of Pages Submitted in bid documents: 262

## 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/QMS	
			Forms Number	Manufacturing license Number	Forms Number	Import license Number	From	To	From	To
1	1	HBsAg (Rapid Test) – whole blood	MD- 9	MFG/IVD/2019/000057	NA	NA	04.08.2021	03.08.2026	05.12.2023	31.10.2025
2	2	Anti-HCV Antibody Kits (Rapid Test)- Whole blood	MD- 9	MFG/IVD/2019/000057	NA	NA	04.08.2021	03.08.2026	05.12.2023	31.10.2025
3	3	HIV- 4th Generation ELISA Kits	MD- 9	MFG/IVD/2019/000057	NA	NA	19.02.2022	18.02.2027	05.12.2023	31.10.2025
4	5	Hep B 3rd Generation ELISA Kits	MD- 9	MFG/IVD/2019/000057	NA	NA	04.08.2021	03.08.2026	05.12.2023	31.10.2025

Note:- Assisted in technical evaluation in reference to letter no. BMSIC/40030/297-2024/3888 dt 05.08.2024 on the basis of documents provided by BMSICL as check list II, III & IV. Provided checklist compiled with due diligence and care. In spite, some inadvertent discrepancies could have been crept in. Humble request to all concerned to bring to the notice in due time if any discrepancies are observed for rectification.

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