बिड संख्या/Bid Number: GEM/2025/B/6378655

दिनांक /Dated: 25-06-2025

बिड दस्तावेज़ / Bid Document

बिड विवरण/Bid Details	
बिड बंद होने की तारीख/समय /Bid End Date/Time	15-07-2025 16:00:00
बिड खुलने की तारीख/समय /Bid Opening Date/Time	15-07-2025 16:30:00
बिड पेशकश वैधता (बंद होने की तारीख से)/Bid Offer Validity (From End Date)	180 (Days)
मंत्रालय/राज्य का नाम/Ministry/State Name	Ministry Of Health And Family Welfare
विभाग का नाम/Department Name	Department Of Health And Family Welfare
संगठन का नाम/Organisation Name	North Eastern Indira Gandhi Regional Institute Of Health And Medical Sciences (neigrihms)
कार्यालय का नाम/Office Name	Neigrihms, Shillong
कुल मात्रा/Total Quantity	16452
वस्तु श्रेणी /Item Category	Anti - A Blood Grouping Reagent (Q2) , Anti-B Blood Grouping Reagent (V2) (Q2) , Anti - AB Blood Grouping Reagent (V2) (Q2) , Anti - D Blood Grouping Reagent (Q2) , Anti-A1 Lectin Reagent (V2) (Q2) , Anti-Human Globulin (AHG) Reagent (Q2) , Malaria Rapid Test Kits (Q2) , HIV ELISA Test Kits (Q2)
बिडर का न्यूनतम औसत वार्षिक टर्नओवर (3 वर्षों का) /Minimum Average Annual Turnover of the bidder (For 3 Years)	1 Lakh (s)
मूल उपकरण निर्माता का औसत टर्नओवर (गत 3 वर्षों का)/OEM Average Turnover (Last 3 Years)	10 Lakh (s)
उन्हीं/समान सेवा के लिए अपेक्षित विगत अनुभव के वर्ष/Years of Past Experience Required for same/similar service	3 Year (s)
टर्नओवर के लिए एमएसई को छूट प्राप्त है / MSE Exemption for Turnover	Yes | Complete
टर्नओवर के लिए स्टार्टअप को छूट प्राप्त है / Startup Exemption for Turnover	Yes | Complete
विक्रेता से मांगे गए दस्तावेज़/Document required from seller	Experience Criteria,Past Performance,Bidder Turnover,Certificate (Requested in ATC),OEM Authorization Certificate,OEM Annual Turnover,Compliance of BoQ specification and supporting document *In case any bidder is seeking exemption from Experience / Turnover Criteria, the supporting documents to prove his eligibility for exemption must be uploaded for evaluation by the buyer

बिड विवरण/Bid Details	
क्या आप निविदाकारों द्वारा अपलोड किए गए दस्तावेज़ों को निविदा में भाग लेने वाले सभी निविदाकारों को दिखाना चाहते हैं? संदर्भ मेनू है/Do you want to show documents uploaded by bidders to all bidders participated in bid?	No
विगत प्रदर्शन /Past Performance	30 %
बिड से रिवर्स नीलामी सक्रिय किया/Bid to RA enabled	No
बिड का प्रकार/Type of Bid	Two Packet Bid
प्राथमिक उत्पाद श्रेणी/Primary product category	Anti - A Blood Grouping Reagent
तकनीकी मूल्यांकन के दौरान तकनीकी स्पष्टीकरण हेतु अनुमत समय /Time allowed for Technical Clarifications during technical evaluation	2 Days
निरीक्षण आवश्यक (सूचीबद्ध निरीक्षण प्राधिकरण /जेम के साथ पूर्व पंजीकृत एजेंसियों द्वारा)/Inspection Required (By Empanelled Inspection Authority / Agencies pre-registered with GeM)	No
अनुमानित बिड मूल्य /Estimated Bid Value	268585.8
मूल्यांकन पद्धति/Evaluation Method	Item wise evaluation/
मध्यस्थता खंड/Arbitration Clause	No
सुलह खंड/Mediation Clause	No

ईएमडी विवरण/EMD Detail

आवश्यकता/Required	No

ईपीबीजी विवरण /ePBG Detail

आवश्यकता/Required	No

विभाजन/Splitting

बोली विभाजन लागू नहीं किया गया/ Bid splitting not applied.

एमआईआई खरीद वरीयता/MII Purchase Preference

एमआईआई खरीद वरीयता/MII Purchase Preference	Yes

एमएसई खरीद वरीयता/MSE Purchase Preference

एमएसई खरीद वरीयता/MSE Purchase Preference	Yes

1. If the bidder is a Micro or Small Enterprise (MSE) as per latest orders issued by Ministry of MSME, the bidder shall be exempted from the eligibility criteria of "Bidder Turnover" as defined above subject to meeting of quality and technical specifications. If the bidder itself is MSE OEM of the offered products, it would be exempted from the "OEM Average Turnover" criteria also subject to meeting of quality and technical specifications. The bidder seeking exemption from Turnover, shall upload the supporting documents to prove his eligibility for exemption.
2. If the bidder is a DPIIT registered Startup, the bidder shall be exempted from the the eligibility criteria of "Bidder Turnover" as defined above subject to their meeting of quality and technical specifications. If the bidder is DPIIT Registered OEM of the offered products, it would be exempted from the "OEM Average Turnover" criteria also subject to meeting of quality and technical specifications. The bidder seeking exemption from Turnover shall upload the supporting documents to prove his eligibility for exemption.
3. The minimum average annual financial turnover of the bidder during the last three years, ending on 31st March of the previous financial year, should be as indicated above in the bid document. Documentary evidence in the form of certified Audited Balance Sheets of relevant periods or a certificate from the Chartered Accountant / Cost Accountant indicating the turnover details for the relevant period shall be uploaded with the bid. In case the date of constitution / incorporation of the bidder is less than 3-year-old, the average turnover in respect of the completed financial years after the date of constitution shall be taken into account for this criteria.
4. Experience Criteria: In respect of the filter applied for experience criteria, the Bidder or its OEM of the product offered in the bid {themselves or through reseller(s)} should have regularly, manufactured and supplied same or similar Category Products to any Central / State Govt Organization / PSU for number of Financial years as indicated above in the bid document before the bid opening date. Copies of relevant contracts and delivery acceptance certificates like CRAC to be submitted along with bid in support of having supplied some quantity during each of the Financial year. In case of bunch bids, the category of primary product having highest value should meet this criterion.
5. OEM Turn Over Criteria: The minimum average annual financial turnover of the OEM of the offered product during the last three years, ending on 31st March of the previous financial year, should be as indicated in the bid document. Documentary evidence in the form of certified Audited Balance Sheets of relevant periods or a certificate from the Chartered Accountant / Cost Accountant indicating the turnover details for the relevant period shall be uploaded with the bid. In case the date of constitution / incorporation of the OEM is less than 3 year old, the average turnover in respect of the completed financial years after the date of constitution shall be taken into account for this criteria.
6. Preference to Make In India products (For bids < 200 Crore):Preference shall be given to Class 1 local supplier as defined in public procurement (Preference to Make in India), Order 2017 as amended from time to time and its subsequent Orders/Notifications issued by concerned Nodal Ministry for specific Goods/Products. The minimum local content to qualify as a Class 1 local supplier is denoted in the bid document. If the bidder wants to avail the Purchase preference, the bidder must upload a certificate from the OEM regarding the percentage of the local content and the details of locations at which the local value addition is made along with their bid, failing which no purchase preference shall be granted. In case the bid value is more than Rs 10 Crore, the declaration relating to percentage of local content shall be certified by the statutory auditor or cost auditor, if the OEM is a company and by a practicing cost accountant or a chartered accountant for OEMs other than companies as per the Public Procurement (preference to Make-in -India) order 2017 dated 04.06.2020. Only Class-I and Class-II Local suppliers as per MII order dated 4.6.2020 will be eligible to bid. Non - Local suppliers as per MII order dated 04.06.2020 are not eligible to participate. However, eligible micro and small enterprises will be allowed to participate.The buyers are advised to refer the OM No.F.1/4/2021-PPD dated 18.05.2023 OM_No.1_4_2021_PPD_dated_18.05.2023 for compliance of Concurrent application of Public Procurement Policy for Micro and Small Enterprises Order, 2012 and Public Procurement (Preference to Make in India) Order, 2017.

7. Purchase preference will be given to MSEs having valid Udyam Registration and whose credentials are validated online through Udyam Registration portal as defined in Public Procurement Policy for Micro and Small Enterprises (MSEs) Order, 2012 dated 23.03.2012 issued by Ministry of Micro, Small and Medium Enterprises and its subsequent Orders/Notifications issued by concerned Ministry. If the bidder wants to avail themselves of the Purchase preference, the bidder must be the manufacturer / OEM of the offered product on GeM. Traders are excluded from the purview of Public Procurement Policy for Micro and Small Enterprises and hence resellers offering products manufactured by some other OEM are not eligible for any purchase preference. In respect of bid for Services, the bidder must be the Service provider of the offered Service. Relevant documentary evidence in this regard shall be uploaded along with the bid in respect of the offered product or service and Buyer will decide eligibility for purchase preference based on documentary evidence submitted, while evaluating the bid. If L-1 is not an MSE and MSE Seller (s) has / have quoted price within L-1+ 15% (Selected by Buyer) of margin of purchase preference /price band defined in relevant policy, such MSE Seller shall be given opportunity to match

L-1 price and contract will be awarded for 25% (selected by Buyer) percentage of total quantity. The buyers are advised to refer the OM No. F.1/4/2021-PPD dated 18.05.2023 OM_No.1_4_2021_PPD_dated_18.05.2023 for compliance of Concurrent application of Public Procurement Policy for Micro and Small Enterprises Order, 2012 and Public Procurement (Preference to Make in India) Order, 2017. Benefits of MSE will be allowed only if seller is validated on-line in GeM profile as well as validated and approved by Buyer after evaluation of documents submitted.
8. Estimated Bid Value indicated above is being declared solely for the purpose of guidance on EMD amount and for determining the Eligibility Criteria related to Turn Over, Past Performance and Project / Past Experience etc. This has no relevance or bearing on the price to be quoted by the bidders and is also not going to have any impact on bid participation. Also this is not going to be used as a criteria in determining reasonableness of quoted prices which would be determined by the buyer based on its own assessment of reasonableness and based on competitive prices received in Bid / RA process.
9. Past Performance: The Bidder or its OEM {themselves or through re-seller(s)} should have supplied same or similar Category Products for 30% of bid quantity, in at least one of the last three Financial years before the bid opening date to any Central / State Govt Organization / PSU. Copies of relevant contracts (proving supply of cumulative order quantity in any one financial year) to be submitted along with bid in support of quantity supplied in the relevant Financial year. In case of bunch bids, the category related to primary product having highest bid value should meet this criterion.

मूल्यांकन विधि(मदवार मूल्यांकन विधि) / Evaluation Method (Item Wise Evaluation Method)

Contract will be awarded schedulewise and the determination of L1 will be done separately for each schedule. The details of item-consignee combination covered under each schedule are as under:

मूल्यांकन अनुसूचियां / **Evaluation Schedules**	अनुमानित मूल्य / **Estimated Value**	वस्तु/श्रेणी / **Item/Category**	मात्रा / **Quantity**
Schedule 1	7200	Anti - A Blood Grouping Reagent	1200
Schedule 2	8280	Anti-b Blood Grouping Reagent (v2)	1200
Schedule 3	18540	Anti - Ab Blood Grouping Reagent (v2)	1200
Schedule 4	21228	Anti - D Blood Grouping Reagent	1200
Schedule 5	19800	Anti - D Blood Grouping Reagent	1200
Schedule 6	44880	Anti-a1 Lectin Reagent (v2)	1200
Schedule 7	42012	Anti-human Globulin (ahg) Reagent	1200
Schedule 8	4183.2	Anti-human Globulin (ahg) Reagent	120
Schedule 9	2397.6	Anti-human Globulin (ahg) Reagent	48
Schedule 10	96225	Malaria Rapid Test Kits	7500
Schedule 11	3840	Hiv Elisa Test Kits	384

Anti - A Blood Grouping Reagent (1200 milliliter)

(क्रमशः श्रेणी 1 और श्रेणी 2 के स्थानीय आपूर्तिकर्ता के रूप में अर्हता प्राप्त करने के लिए आवश्यक/Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively)

तकनीकी विशिष्टियाँ /Technical Specifications

[* जेम केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification]

विवरण/Specification	विशिष्टि का नाम /Specification Name	बिड के लिए आवश्यक अनुमत मूल्य /Bid Requirement (Allowed Values)
GENERAL FEATURES	Type of Blood Grouping Sera/Reagent	Anti-A Blood Grouping Sera IgM
	Antibody Type	Monoclonal
	Reagent should meet the standards approved by CDSCO/NIB for blood bank reagents with respect to appearance, color, sensitivity, specificity, avidity, affinity and titer strength	Yes
	Reagent should meet the standards mentioned in the technical manual for blood banks approved by the MOHFW, GOI	Yes
PACKAGING AND LABELING	Pack size	10 ml
CERTIFICATIONS & REPORTS	Compliance with Medical Device Rules (MDR) 2017 as amended till date	Yes
	Availability of valid drug license for the product issued from the competent authority defined under Drugs and Cosmetic Act 1940 and Rules made there under as amended till date	Yes
	Manufacturing unit certification	ISO:13485 (Latest)
	Availability of Test Report for each supplied batch/product as per Medical Device Rules (MDR) 2017 as amended till date	Yes
	Submission of all necessary certifications, licenses and test reports to the buyer at the time of bid submission or along with supplies as per buyer requirement	Yes
SHELF LIFE	Minimum shelf life of the product at the time of delivery to the consignee	3/4th of Total Shelf Life
ADVANCE SAMPLE	Agree to provide advance sample of the product for buyer's approval before commencement of supply in case of bidding	Yes

परेषिती/रिपोर्टिंग अधिकारी तथा मात्रा/Consignees/Reporting Officer and Quantity

क्र.सं./S.No.	परेषिती/रिपोर्टिंग अधिकारी /Consignee Reporting/Officer	पता/Address	मात्रा /Quantity	डिलीवरी के दिन/Delivery Days
1	Rudolf Lyngdoh	793018,P.O. NEIGRIHMS, Mawdiangdiang, Shillong	1200	15

Anti-B Blood Grouping Reagent (V2) (1200 milliliter)

(क्रमशः श्रेणी 1 और श्रेणी 2 के स्थानीय आपूर्तिकर्ता के रूप में अर्हता प्राप्त करने के लिए आवश्यक/Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively)

तकनीकी विशिष्टियाँ /Technical Specifications

* जेम केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

विवरण/Specification	विशिष्टि का नाम /Specification Name	बिड के लिए आवश्यक अनुमत मूल्य /Bid Requirement (Allowed Values)
General Features	Product Description	Anti-B Blood Grouping Reagent
Product Informations	Type of Blood Grouping Sera/Reagent	Anti-B Blood Grouping Sera IgM
	Antibody Type	Monoclonal
	Ready to use reagent containing antibodies specific to the 'B' antigen on RBC	Yes
	It should give easily observable agglutination reaction with antigen positive cells and clear absence of agglutination reaction in antigen negative cells	Yes
	Reagent should meet the standards approved by CDSCO/NIB for blood bank reagents with respect to appearance, color, sensitivity, specificity, avidity, affinity and titer strength	Yes
	Reagent should meet the standards mentioned in the technical manual for blood banks approved by the MOHFW, GOI with latest amendments	Yes
Packaging & Labelling	Pack size (in ml)	10.0 **(milliliter)**

विवरण/Specification	विशिष्टि का नाम /Specification Name	बिड के लिए आवश्यक अनुमत मूल्य /Bid Requirement (Allowed Values)
Certifications & Reports	Compliance to Medical Device Rules (MDR) 2017 as amended till date	Yes
	Availability of valid drug license for the product issued from the competent authority defined under Drugs and Cosmetic Act 1940 and Rules made there under as amended till date	Yes
	Manufacturing unit certification	ISO:13485 (Latest)
	Availability of Test Report for each supplied batch/product as per Medical Device Rule (MDR) 2017 as amended till date	Yes
	Submission of all necessary certifications, licenses and test reports to the buyer at the time of bid submission or along with supplies as per buyer requirement	Yes
Shelf Life	Minimum shelf life of the product at the time of delivery to the consignee	3/4 th of Total Shelf Life
ADVANCE SAMPLE	Agree to provide advance sample of the product for buyer's approval before commencement of supply in case of bidding	Yes

परेषिती/रिपोर्टिंग अधिकारी तथा मात्रा/Consignees/Reporting Officer and Quantity

क्र.सं./S.No.	परेषिती/रिपोर्टिंग अधिकारी /Consignee Reporting/Officer	पता/Address	मात्रा /Quantity	डिलीवरी के दिन/Delivery Days
1	Rudolf Lyngdoh	793018,P.O. NEIGRIHMS, Mawdiangdiang, Shillong	1200	15

Anti - AB Blood Grouping Reagent (V2) (1200 milliliter)

(क्रमशः श्रेणी 1 और श्रेणी 2 के स्थानीय आपूर्तिकर्ता के रूप में अर्हता प्राप्त करने के लिए आवश्यक/Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively)

तकनीकी विशिष्टियाँ /Technical Specifications

* जेम केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

विवरण/Specification	विशिष्टि का नाम /Specification Name	बिड के लिए आवश्यक अनुमत मूल्य /Bid Requirement (Allowed Values)
GENERAL FEATURES	Type of Blood Grouping Sera/Reagent	Anti-AB Grouping Sera IgM
	Clinical Purpose	Anti-AB reagent is a laboratory reagent that is used in blood typing to determine an individual's ABO blood type
	Antibody Type	Monoclonal
	Suitable for	Tube Method, Slide Method, Microplate method
	Ready to use reagent containing antibodies specific to the 'A' and 'B' antigens on RBC	Yes
	Reagent should meet the standards approved by CDSCO/NIB for blood bank reagents with respect to appearance, color, sensitivity, specificity, avidity, affinity and titer strength	Yes
PACKAGING AND LABELING	Pack size	10 ml
CERTIFICATIONS & REPORTS	Compliance to Medical Device Rules (MDR) 2017 as amended till date	Yes
	Availability of valid drug license for the product issued from the competent authority defined under Drugs and Cosmetic Act 1940 and Rules made there under as amended till date	Yes
	Manufacturing unit certification	ISO:13485 (Latest)
	Availability of Test Report for product as per Medical Device Rules (MDR) 2017 as amended till date	Yes
	Submission of all necessary certifications, licenses and test reports to the buyer at the time of bid submission and/or along with supplies as per buyer requirement	Yes
ADVANCE SAMPLE	Agree to provide advance sample of the product for buyer's approval before commencement of supply in case of bidding	Yes

परेषिती/रिपोर्टिंग अधिकारी तथा मात्रा/Consignees/Reporting Officer and Quantity

क्र.सं./S.No.	परेषिती/रिपोर्टिंग अधिकारी /Consignee Reporting/Officer	पता/Address	मात्रा /Quantity	डिलीवरी के दिन/Delivery Days
1	Rudolf Lyngdoh	793018,P.O. NEIGRIHMS, Mawdiangdiang, Shillong	1200	15

Anti - D Blood Grouping Reagent (1200 milliliter)

(क्रमशः श्रेणी 1 और श्रेणी 2 के स्थानीय आपूर्तिकर्ता के रूप में अर्हता प्राप्त करने के लिए आवश्यक/Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively)

तकनीकी विशिष्टियाँ /Technical Specifications

* जेम केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

विवरण/Specification	विशिष्टि का नाम /Specification Name	बिड के लिए आवश्यक अनुमत मूल्य /Bid Requirement (Allowed Values)
GENERAL FEATURES	**Type of Blood Grouping Sera/Reagent**	Anti-D Blood Grouping Sera IgM
	Antibody Type	Monoclonal
	Anti-D reagent should be capable of detecting all weak and partial D	Yes
	Ready to use reagent containing antibodies specific to the 'D' antigen on RBC	Yes
	Should not hemolyze cells or produce rouleux	Yes
	It should give easily observable agglutination reaction with antigen positive cells and clear absence of agglutination reaction in antigen negative cells	Yes
	Reagent should meet the standards approved by CDSCO/NIB for blood bank reagents with respect to appearance, color, sensitivity, specificity, avidity, affinity and titer strength	Yes
	Reagent should meet the standards mentioned in the technical manual for blood banks approved by the MOHFW, GOI	Yes
PACKAGING	Pack size	10 ml

विवरण/Specification	विशिष्टि का नाम /Specification Name	बिड के लिए आवश्यक अनुमत मूल्य /Bid Requirement (Allowed Values)
CERTIFICATIONS & REPORTS	Compliance with Medical Device Rules (MDR) 2017 as amended till date	Yes
	Availability of valid drug license for the product issued from the competent authority defined under Drugs and Cosmetic Act 1940 and Rules made there under as amended till date	Yes
	Manufacturing unit certification	ISO:13485 (Latest)
	Availability of Test Report for each supplied batch/product as per Medical Device Rules (MDR) 2017 as amended till date	Yes
	Submission of all necessary certifications, licenses and test reports to the buyer at the time of bid submission or along with supplies as per buyer requirement	Yes
ADVANCE SAMPLE	Agree to provide advance sample of the product for buyer's approval before commencement of supply in case of bidding	Yes, No

परेषिती/रिपोर्टिंग अधिकारी तथा मात्रा/Consignees/Reporting Officer and Quantity

क्र.सं./S.No.	परेषिती/रिपोर्टिंग अधिकारी /Consignee Reporting/Officer	पता/Address	मात्रा /Quantity	डिलीवरी के दिन/Delivery Days
1	Rudolf Lyngdoh	793018,P.O. NEIGRIHMS, Mawdiangdiang, Shillong	1200	15

Anti - D Blood Grouping Reagent (1200 milliliter)

(क्रमशः श्रेणी 1 और श्रेणी 2 के स्थानीय आपूर्तिकर्ता के रूप में अर्हता प्राप्त करने के लिए आवश्यक/Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively)

तकनीकी विशिष्टियाँ /Technical Specifications

* जेम केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

विवरण/Specification	विशिष्टि का नाम /Specification Name	बिड के लिए आवश्यक अनुमत मूल्य /Bid Requirement (Allowed Values)
GENERAL FEATURES	**Type of Blood Grouping Sera/Reagent**	Anti-D Blood Grouping Sera (IgM + IgG)
	It should give easily observable agglutination reaction with antigen positive cells and clear absence of agglutination reaction in antigen negative cells	Yes
	Reagent should meet the standards approved by CDSCO/NIB for blood bank reagents with respect to appearance, color, sensitivity, specificity, avidity, affinity and titer strength	Yes
	Reagent should meet the standards mentioned in the technical manual for blood banks approved by the MOHFW, GOI	Yes
CERTIFICATIONS & REPORTS	Compliance with Medical Device Rules (MDR) 2017 as amended till date	Yes
	Availability of valid drug license for the product issued from the competent authority defined under Drugs and Cosmetic Act 1940 and Rules made there under as amended till date	Yes
	Manufacturing unit certification	ISO:13485 (Latest)
	Availability of Test Report for each supplied batch/product as per Medical Device Rules (MDR) 2017 as amended till date	Yes
	Submission of all necessary certifications, licenses and test reports to the buyer at the time of bid submission or along with supplies as per buyer requirement	Yes
ADVANCE SAMPLE	Agree to provide advance sample of the product for buyer's approval before commencement of supply in case of bidding	Yes

परेषिती/रिपोर्टिंग अधिकारी तथा मात्रा/Consignees/Reporting Officer and Quantity

क्र.सं./S.No.	परेषिती/रिपोर्टिंग अधिकारी /Consignee Reporting/Officer	पता/Address	मात्रा /Quantity	डिलीवरी के दिन/Delivery Days
1	Rudolf Lyngdoh	793018,P.O. NEIGRIHMS, Mawdiangdiang, Shillong	1200	15

Anti-A1 Lectin Reagent (V2) (1200 milliliter)

(क्रमशः श्रेणी 1 और श्रेणी 2 के स्थानीय आपूर्तिकर्ता के रूप में अर्हता प्राप्त करने के लिए आवश्यक/Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively)

तकनीकी विशिष्टियाँ /Technical Specifications

* जेम केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

विवरण/Specification	विशिष्टि का नाम /Specification Name	बिड के लिए आवश्यक अनुमत मूल्य /Bid Requirement (Allowed Values)
General Features	Type of Blood Grouping Sera/Reagent	Anti-A1 Lectin Reagent
Product Information	Antibody Type	Monoclonal
	It should give easily observable agglutination reaction with antigen positive cells and clear absence of agglutination reaction in antigen negative cells	Yes
	Reagent should meet the standards approved by CDSCO/NIB for blood bank reagents with respect to appearance, color, sensitivity, specificity, avidity, affinity and titer strength	Yes
	Reagent should meet the standards mentioned in the technical manual for blood banks approved by the MOHFW, GOI	Yes
Packaging & Labelling	Pack size (in ml)	5 ml
Certification & Reports	Compliance to Medical Device Rules (MDR) 2017 as amended till date	Yes
	Availability of valid drug license for the product issued from the competent authority defined under Drugs and Cosmetic Act 1940 and Rules made there under as amended till date	Yes

विवरण/Specification	विशिष्टि का नाम /Specification Name	बिड के लिए आवश्यक अनुमत मूल्य /Bid Requirement (Allowed Values)
	Manufacturing unit certification	ISO:13485 (Latest)
	Availability of Test Report for each supplied batch/product as per Medical Device Rules (MDR) 2017 as amended till date	Yes
	Submission of all necessary certifications, licenses and test reports to the buyer at the time of bid submission or along with supplies as per buyer requirement	Yes
Advance Sample	Agree to provide advance sample of the product for buyer's approval before commencement of supply in case of bidding	Yes

परेषिती/रिपोर्टिंग अधिकारी तथा मात्रा/Consignees/Reporting Officer and Quantity

क्र.सं./S.No.	परेषिती/रिपोर्टिंग अधिकारी /Consignee Reporting/Officer	पता/Address	मात्रा /Quantity	डिलीवरी के दिन/Delivery Days
1	Rudolf Lyngdoh	793018,P.O. NEIGRIHMS, Mawdiangdiang, Shillong	1200	15

Anti-Human Globulin (AHG) Reagent (1200 milliliter)

(क्रमशः श्रेणी 1 और श्रेणी 2 के स्थानीय आपूर्तिकर्ता के रूप में अर्हता प्राप्त करने के लिए आवश्यक/Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively)

तकनीकी विशिष्टियाँ /Technical Specifications

* जेम केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

विवरण/Specification	विशिष्टि का नाम /Specification Name	बिड के लिए आवश्यक अनुमत मूल्य /Bid Requirement (Allowed Values)
GENERAL FEATURES	Product Description	Anti-Human Globulin (AHG) Reagent
PRODUCT INFORMATION	**Type of Anti Human Globulin (AHG) Sera**	Polyspecific (Anti-IgG + Anti C3d)
	Antibody Type	Polyclonal
PACKAGING AND LABELING	Pack size (in ml)	5 ml, 10 ml

विवरण/Specification	विशिष्टि का नाम /Specification Name	बिड के लिए आवश्यक अनुमत मूल्य /Bid Requirement (Allowed Values)
CERTIFICATIONS & REPORTS	Compliance to Medical Device Rules (MDR) 2017 as amended till date	Yes
	Availability of valid drug license for the product issued from the competent authority defined under Drugs and Cosmetic Act 1940 and Rules made there under as amended till date	Yes
	Manufacturing unit certification	ISO:13485 (Latest)
	Availability of Test Report for each supplied batch/product as per Medical Device Rules (MDR) 2017 as amended till date	Yes
	Meets the standards as mentioned in the technical manual for blood banks approved by the MOHFW, GOI	Yes
	Meets the standards approved by CDSCO/NIB for blood bank reagents with respect to appearance, color, sensitivity, specificity, avidity, affinity and titre strength	Yes
	Submission of all necessary certifications, licenses and test reports to the buyer at the time of bid submission or along with supplies as per buyer requirement	Yes
ADVANCE SAMPLE	Agree to provide advance sample of the product for buyer's approval before commencement of bulk supply	Yes

परेषिती/रिपोर्टिंग अधिकारी तथा मात्रा/Consignees/Reporting Officer and Quantity

क्र.सं./S.No.	परेषिती/रिपोर्टिंग अधिकारी /Consignee Reporting/Officer	पता/Address	मात्रा /Quantity	डिलीवरी के दिन/Delivery Days

क्र.सं./S.No.	परेषिती/रिपोर्टिंग अधिकारी /Consignee Reporting/Officer	पता/Address	मात्रा /Quantity	डिलीवरी के दिन/Delivery Days
1	Rudolf Lyngdoh	793018,P.O. NEIGRIHMS, Mawdiangdiang, Shillong	1200	15

Anti-Human Globulin (AHG) Reagent (120 milliliter)

(क्रमशः श्रेणी 1 और श्रेणी 2 के स्थानीय आपूर्तिकर्ता के रूप में अर्हता प्राप्त करने के लिए आवश्यक/Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively)

तकनीकी विशिष्टियाँ /Technical Specifications

* जेम केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

विवरण/Specification	विशिष्टि का नाम /Specification Name	बिड के लिए आवश्यक अनुमत मूल्य /Bid Requirement (Allowed Values)
PRODUCT INFORMATION	**Type of Anti Human Globulin (AHG) Sera**	Polyspecific (Anti-IgG + Anti C3d), Monospecific (Anti-IgG), Monospecific (Anti-C3d)
	Antibody Type	Monoclonal
CERTIFICATIONS & REPORTS	Compliance to Medical Device Rules (MDR) 2017 as amended till date	Yes
	Availability of valid drug license for the product issued from the competent authority defined under Drugs and Cosmetic Act 1940 and Rules made there under as amended till date	Yes
	Manufacturing unit certification	ISO:13485 (Latest)
	Availability of Test Report for each supplied batch/product as per Medical Device Rules (MDR) 2017 as amended till date	Yes
	Meets the standards as mentioned in the technical manual for blood banks approved by the MOHFW, GOI	Yes
	Meets the standards approved by CDSCO/NIB for blood bank reagents with respect to appearance, color, sensitivity, specificity, avidity, affinity and titre strength	Yes
	Submission of all necessary certifications, licenses and test reports to the buyer at the time of bid submission or along with supplies as per buyer requirement	Yes

Additional Specification Parameters - Anti-Human Globulin (AHG) Reagent (120 milliliter)

Specification Parameter Name	Bid Requirement (Allowed Values)
type	Monospecific - IgG, packed size 2ml or 5ml

* Bidders offering must also comply with the additional specification parameters mentioned above.

परेषिती/रिपोर्टिंग अधिकारी तथा मात्रा/Consignees/Reporting Officer and Quantity

क्र.सं./S.No.	परेषिती/रिपोर्टिंग अधिकारी /Consignee Reporting/Officer	पता/Address	मात्रा /Quantity	डिलीवरी के दिन/Delivery Days
1	Rudolf Lyngdoh	793018,P.O. NEIGRIHMS, Mawdiangdiang, Shillong	120	15

Anti-Human Globulin (AHG) Reagent (48 milliliter)

(क्रमशः श्रेणी 1 और श्रेणी 2 के स्थानीय आपूर्तिकर्ता के रूप में अर्हता प्राप्त करने के लिए आवश्यक/Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively)

तकनीकी विशिष्टियाँ /Technical Specifications

* जेम केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

विवरण/Specification	विशिष्टि का नाम /Specification Name	बिड के लिए आवश्यक अनुमत मूल्य /Bid Requirement (Allowed Values)
GENERAL FEATURES	Product Description	Anti-Human Globulin (AHG) Reagent
PRODUCT INFORMATION	**Type of Anti Human Globulin (AHG) Sera**	Polyspecific (Anti-IgG + Anti C3d), Monospecific (Anti-IgG), Monospecific (Anti-C3d)
	Antibody Type	Monoclonal
CERTIFICATIONS & REPORTS	Compliance to Medical Device Rules (MDR) 2017 as amended till date	Yes
	Availability of valid drug license for the product issued from the competent authority defined under Drugs and Cosmetic Act 1940 and Rules made there under as amended till date	Yes
	Manufacturing unit certification	ISO:13485 (Latest)
	Availability of Test Report for each supplied batch/product as per Medical Device Rules (MDR) 2017 as amended till date	Yes

विवरण/Specification	विशिष्टि का नाम /Specification Name	बिड के लिए आवश्यक अनुमत मूल्य /Bid Requirement (Allowed Values)
	Meets the standards as mentioned in the technical manual for blood banks approved by the MOHFW, GOI	Yes
	Meets the standards approved by CDSCO/NIB for blood bank reagents with respect to appearance, color, sensitivity, specificity, avidity, affinity and titre strength	Yes
	Submission of all necessary certifications, licenses and test reports to the buyer at the time of bid submission or along with supplies as per buyer requirement	Yes
ADVANCE SAMPLE	Agree to provide advance sample of the product for buyer's approval before commencement of bulk supply	Yes

Additional Specification Parameters - Anti-Human Globulin (AHG) Reagent (48 milliliter)

Specification Parameter Name	Bid Requirement (Allowed Values)
Type	Monospecific - C3D, packed size 2ml or any, bidders needs to specify in the compliance sheet

* Bidders offering must also comply with the additional specification parameters mentioned above.

परेषिती/रिपोर्टिंग अधिकारी तथा मात्रा/Consignees/Reporting Officer and Quantity

क्र.सं./S.No.	परेषिती/रिपोर्टिंग अधिकारी /Consignee Reporting/Officer	पता/Address	मात्रा /Quantity	डिलीवरी के दिन/Delivery Days
1	Rudolf Lyngdoh	793018,P.O. NEIGRIHMS, Mawdiangdiang, Shillong	48	15

Malaria Rapid Test Kits (7500 Test)

(क्रमशः श्रेणी 1 और श्रेणी 2 के स्थानीय आपूर्तिकर्ता के रूप में अर्हता प्राप्त करने के लिए आवश्यक/Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively)

तकनीकी विशिष्टियाँ /Technical Specifications

[* जेम केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification]

विवरण/Specification	विशिष्टि का नाम /Specification Name	बिड के लिए आवश्यक अनुमत मूल्य /Bid Requirement (Allowed Values)
GENERAL FEATURES	Product Description	Malaria Rapid Test Kit
PRODUCT INFORMATION	**Test differentially detects**	Antigen of P.Falciparum (HRP-2/ LDH) and Pan Plasmodia against P.falciparum, P.vivax, P.ovale, P.malariae (LDH) from human serum or plasma or whole blood
	Type of Sample	Whole Blood
	Sensitivity	?99% Or higher
	Specificity	?98% Or higher
	Declared sensitivity and specificy shall be claimed by the manufacturer in the kit literature	Yes
	Contains an internal control dot/band for the confirmation that the test has been performed correctly	Yes
KIT CONTENTS	Kit Contents	Test Card/Cassette with Desiccant, Sample Dropper, Assay Buffer (if any)
	Positive and negative controls provided with each pack of kit	Yes, No
CERTIFICATIONS & REPORTS	Compliance with Medical Device Rules (MDR) 2017 as amended till date	Yes
	Availability of valid drug license for the product issued from the competent authority defined under Drugs and Cosmetic Act 1940 and Rules made there under as amended till date	Yes
	Manufacturing unit certification	ISO:13485 (Latest)
	Availability of Test Report for each supplied batch/product as per Medical Device Rules (MDR) 2017 as amended till date	Yes
	Submission of all necessary certifications, licenses and test reports to the buyer at the time of bid submission or along with supplies as per buyer requirement	Yes
SHELF LIFE	Shelf life in months from the date of manufacture	18, 24, 36 Or higher
	Minimum shelf life of the product at the time of delivery to the consignee	3/4 th of Total Shelf Life

विवरण/Specification	विशिष्टि का नाम /Specification Name	बिड के लिए आवश्यक अनुमत मूल्य /Bid Requirement (Allowed Values)
ADVANCE SAMPLE	Agree to provide advance sample of the product for buyer's approval before commencement of supply in case of bidding	Yes

परेषिती/रिपोर्टिंग अधिकारी तथा मात्रा/Consignees/Reporting Officer and Quantity

क्र.सं./S.No.	परेषिती/रिपोर्टिंग अधिकारी /Consignee Reporting/Officer	पता/Address	मात्रा /Quantity	डिलीवरी के दिन/Delivery Days
1	Rudolf Lyngdoh	793018,P.O. NEIGRIHMS, Mawdiangdiang, Shillong	7500	15

HIV ELISA Test Kits (384 Test)

(क्रमशः श्रेणी 1 और श्रेणी 2 के स्थानीय आपूर्तिकर्ता के रूप में अर्हता प्राप्त करने के लिए आवश्यक/Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively)

तकनीकी विशिष्टियाँ /Technical Specifications

* जेम केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

विवरण/Specification	विशिष्टि का नाम /Specification Name	बिड के लिए आवश्यक अनुमत मूल्य /Bid Requirement (Allowed Values)
PRODUCT INFORMATION	**Type of Kit**	HIV1 & HIV2 Antibodies and HIV1 p24 Antigen Detection ELISA Test Kit
	Testing Principle	Sandwich ELISA
	Sensitivity (%)	?99%, 100% Or higher
	Specificity (%)	?98% Or higher
	HIV positive and negative serum controls provided with the kit	Yes
	Quantity of controls provided	Sufficient for at least 4 runs for the number of tests provided in the pack size
	Maintenance of cold chain by the supplier during storage and transportation of Kits at 2°C to 8°C and placement of cumulative time temperature indicator technology on every pack of kits	Yes

विवरण/Specification	विशिष्टि का नाम /Specification Name	बिड के लिए आवश्यक अनुमत मूल्य /Bid Requirement (Allowed Values)
	Cumulative time/temp indicator shall indicate exposure to high temperature above 8°C and indicator changes color uniformly, irreversibly & color change shall have a well defined start & end point that can be correlated to heat stability of the kit	Yes
	Adequate Document detailing principle, component, antigen detail for antibody detection of HIV1&2, biosafety,methodologies,validity criteria,result interpretation, performance characteristic, assay limitation, mfg,exp date, storage condition provided	Yes
	Kit shall be compatible with all common ELISA readers and washers	Yes
	Original kit literature (not photocopy) provided with each kit	Yes
PACKAGING	Pack size of the kit	96 Tests (in strips of 12 x 8 wells)
CERTIFICATIONS & REPORTS	Compliance with Medical Device Rules (MDR) 2017 as amended till date	Yes
	Manufacturing unit certification	ISO:13485 (Latest)
	Availability of Test Report for each supplied batch/product as per Medical Device Rules (MDR) 2017 as amended till date	Yes
	Submission of all necessary certifications, licenses and test reports to the buyer at the time of bid submission or along with supplies as per buyer requirement	Yes
ADVANCE SAMPLE	Agree to provide advance sample of the product for buyer's approval before commencement of supply in case of bidding	Yes

परेषिती/रिपोर्टिंग अधिकारी तथा मात्रा/Consignees/Reporting Officer and Quantity

क्र.सं./S.No.	परेषिती/रिपोर्टिंग अधिकारी /Consignee Reporting/Officer	पता/Address	मात्रा /Quantity	डिलीवरी के दिन/Delivery Days
1	Rudolf Lyngdoh	793018,P.O. NEIGRIHMS, Mawdiangdiang, Shillong	384	15

Special terms and conditions-Version:1 effective from 04-05-2023 for category Anti - A Blood Grouping Reagent

1. SPECIAL TERMS AND CONDITIONS (STC)

    1. All Provisions of Drugs and Cosmetics Act, 1940 and Rules (including Medical Device Rule 2017) made there under as amended till date will always be applicable. This will include all notifications issued by Central Drugs Standard Control Organization (CDSCO), Ministry of Health & Family Welfare (MoHFW) and Department of Pharmaceuticals (DOP), Ministry of Chemicals & Fertilizers time to time in this regard.
    2. The sellers are registered on GeM based on self-declaration of valid Drug License, product certification, test reports etc. However, buyers must check and validate the details at their end for all applicable licenses and certifications e.g., validity and authenticity/genuineness of drug license, product certification, manufacturer certification/licenses, test reports etc.
    3. In case of authorized resellers/distributors, it will be the legal & regulatory liability of the manufacturer to ensure that their resellers/distributors are operating in compliance with all relevant laws and regulations and are properly licensed to sell the manufacturer's products, including verifying the validity and authenticity of drug license held by them.
    4. The price offered by the seller/bidder shall not, in any case exceed the DPCO/NPPA controlled price or price fixed by State Government, if any. The seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government, if any.
    5. Any other Terms and Conditions which is not included or at variance with the conditions specified in STC/GTC, may be added by the buyer through Additional Terms and Conditions (ATC) in the bid to ensure items are procured from authentic/validated source with appropriate and applicable quality. The above terms and conditions are in reverse order of precedence i.e. ATC shall supersede specific STC which shall supersede General Terms and Conditions (“GTC”), whenever there are any conflicting provisions.

Special terms and conditions-Version:1 effective from 30-05-2023 for category Anti-B Blood Grouping Reagent (V2)

1. 1. *A*ll Provisions of Drugs and Cosmetics Act, 1940 and Rules (including Medical Device Rule 2017) made there under as amended till date will always be applicable. This will include all notifications issued by Central Drugs Standard Control Organization (CDSCO), Ministry of Health & Family Welfare (MoHFW) and Department of Pharmaceuticals (DOP), Ministry of Chemicals & Fertilizers time to time in this regard.
    2. The sellers are registered on GeM based on self-declaration of valid Drug License, product certification, test reports etc. However, buyers must check and validate the details at their end for all applicable licenses and certifications e.g., validity and authenticity/genuineness of drug license, product certification, manufacturer certification/licenses, test reports etc.
    3. In case of authorized resellers/distributors, it will be the legal & regulatory liability of the manufacturer to ensure that their resellers/distributors are operating in compliance with all relevant laws and regulations and are properly licensed to sell the manufacturer's products, including verifying the validity and authenticity of drug license held by them.
    4. The price offered by the seller/bidder shall not, in any case exceed the DPCO/NPPA controlled price or price fixed by State Government, if any. The seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government, if any.
    5. Any other Terms and Conditions which is not included or at variance with the conditions specified in STC/GTC, may be added by the buyer through Additional Terms and Conditions (ATC) in the bid to ensure items are procured from authentic/validated source with appropriate and applicable quality. The above terms and conditions are in reverse order of precedence i.e. ATC shall supersede specific STC which shall supersede General Terms and Conditions (“GTC”), whenever there are any

conflicting provisions.

Special terms and conditions-Version:1 effective from 23-08-2023 for category Anti - AB Blood Grouping Reagent (V2)

1.

    1. All Provisions of Drugs and Cosmetics Act, 1940 and Rules (including Medical Device Rule 2017) made there under as amended till date will always be applicable. This will include all notifications issued by Central Drugs Standard Control Organization (CDSCO), Ministry of Health & Family Welfare (MoHFW) and Department of Pharmaceuticals (DOP), Ministry of Chemicals & Fertilizers time to time in this regard.
    2. The sellers are registered on GeM based on self-declaration of valid Drug License, product certification, test reports etc. However, buyers must check and validate the details at their end for all applicable licenses and certifications e.g., validity and authenticity/genuineness of drug license, product certification, manufacturer certification/licenses, test reports etc.
    3. In case of authorized resellers/distributors, it will be the legal & regulatory liability of the manufacturer to ensure that their resellers/distributors are operating in compliance with all relevant laws and regulations and are properly licensed to sell the manufacturer's products, including verifying the validity and authenticity of drug license held by them.
    4. The price offered by the seller/bidder shall not, in any case exceed the DPCO/NPPA controlled price or price fixed by State Government, if any. The seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government, if any.
    5. Any other Terms and Conditions which is not included or at variance with the conditions specified in STC/GTC, may be added by the buyer through Additional Terms and Conditions (ATC) in the bid to ensure items are procured from authentic/validated source with appropriate and applicable quality. The above terms and conditions are in reverse order of precedence i.e. ATC shall supersede specific STC which shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

Special terms and conditions-Version:1 effective from 04-05-2023 for category Anti - D Blood Grouping Reagent

1. SPECIAL TERMS AND CONDITIONS (STC)

    1. All Provisions of Drugs and Cosmetics Act, 1940 and Rules (including Medical Device Rule 2017) made there under as amended till date will always be applicable. This will include all notifications issued by Central Drugs Standard Control Organization (CDSCO), Ministry of Health & Family Welfare (MoHFW) and Department of Pharmaceuticals (DOP), Ministry of Chemicals & Fertilizers time to time in this regard.
    2. The sellers are registered on GeM based on self-declaration of valid Drug License, product certification, test reports etc. However, buyers must check and validate the details at their end for all applicable licenses and certifications e.g., validity and authenticity/genuineness of drug license, product certification, manufacturer certification/licenses, test reports etc.
    3. In case of authorized resellers/distributors, it will be the legal & regulatory liability of the manufacturer to ensure that their resellers/distributors are operating in compliance with all relevant laws and regulations and are properly licensed to sell the manufacturer's products, including verifying the validity and authenticity of drug license held by them.
    4. The price offered by the seller/bidder shall not, in any case exceed the DPCO/NPPA controlled price or price fixed by State Government, if any. The seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government, if any.
    5. Any other Terms and Conditions which is not included or at variance with the conditions specified in STC/GTC, may be added by the buyer through Additional Terms and Conditions (ATC) in the bid to ensure items are procured from authentic/validated source with appropriate and applicable quality. The above terms and conditions are in reverse order of precedence i.e. ATC shall supersede specific STC which shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

Special terms and conditions-Version:1 effective from 08-06-2023 for category Anti-A1 Lectin Reagent (V2)

1. 1. *A*ll Provisions of Drugs and Cosmetics Act, 1940 and Rules (including Medical Device Rule 2017) made there under as amended till date will always be applicable. This will include all notifications issued by Central Drugs Standard Control Organization (CDSCO), Ministry of Health & Family Welfare (MoHFW) and Department of Pharmaceuticals (DOP), Ministry of Chemicals & Fertilizers time to time

in this regard.
2. The sellers are registered on GeM based on self-declaration of valid Drug License, product certification, test reports etc. However, buyers must check and validate the details at their end for all applicable licenses and certifications e.g., validity and authenticity/genuineness of drug license, product certification, manufacturer certification/licenses, test reports etc.
3. In case of authorized resellers/distributors, it will be the legal & regulatory liability of the manufacturer to ensure that their resellers/distributors are operating in compliance with all relevant laws and regulations and are properly licensed to sell the manufacturer's products, including verifying the validity and authenticity of drug license held by them.
4. The price offered by the seller/bidder shall not, in any case exceed the DPCO/NPPA controlled price or price fixed by State Government, if any. The seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government, if any.
5. Any other Terms and Conditions which is not included or at variance with the conditions specified in STC/GTC, may be added by the buyer through Additional Terms and Conditions (ATC) in the bid to ensure items are procured from authentic/validated source with appropriate and applicable quality. The above terms and conditions are in reverse order of precedence i.e. ATC shall supersede specific STC which shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

Special terms and conditions-Version:1 effective from 08-06-2023 for category Anti-Human Globulin (AHG) Reagent

1. 1. *A*ll Provisions of Drugs and Cosmetics Act, 1940 and Rules (including Medical Device Rule 2017) made there under as amended till date will always be applicable. This will include all notifications issued by Central Drugs Standard Control Organization (CDSCO), Ministry of Health & Family Welfare (MoHFW) and Department of Pharmaceuticals (DOP), Ministry of Chemicals & Fertilizers time to time in this regard.
   2. The sellers are registered on GeM based on self-declaration of valid Drug License, product certification, test reports etc. However, buyers must check and validate the details at their end for all applicable licenses and certifications e.g., validity and authenticity/genuineness of drug license, product certification, manufacturer certification/licenses, test reports etc.
   3. In case of authorized resellers/distributors, it will be the legal & regulatory liability of the manufacturer to ensure that their resellers/distributors are operating in compliance with all relevant laws and regulations and are properly licensed to sell the manufacturer's products, including verifying the validity and authenticity of drug license held by them.
   4. The price offered by the seller/bidder shall not, in any case exceed the DPCO/NPPA controlled price or price fixed by State Government, if any. The seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government, if any.
   5. Any other Terms and Conditions which is not included or at variance with the conditions specified in STC/GTC, may be added by the buyer through Additional Terms and Conditions (ATC) in the bid to ensure items are procured from authentic/validated source with appropriate and applicable quality. The above terms and conditions are in reverse order of precedence i.e. ATC shall supersede specific STC which shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

Special terms and conditions-Version:1 effective from 04-05-2023 for category Malaria Rapid Test Kits

1. SPECIAL TERMS AND CONDITIONS (STC)

   1. All Provisions of Drugs and Cosmetics Act, 1940 and Rules (including Medical Device Rule 2017) made there under as amended till date will always be applicable. This will include all notifications issued by Central Drugs Standard Control Organization (CDSCO), Ministry of Health & Family Welfare (MoHFW) and Department of Pharmaceuticals (DOP), Ministry of Chemicals & Fertilizers time to time in this regard.
   2. The sellers are registered on GeM based on self-declaration of valid Drug License, product certification, test reports etc. However, buyers must check and validate the details at their end for all applicable licenses and certifications e.g., validity and authenticity/genuineness of drug license, product certification, manufacturer certification/licenses, test reports etc.
   3. In case of authorized resellers/distributors, it will be the legal & regulatory liability of the manufacturer to ensure that their resellers/distributors are operating in compliance with all relevant laws and regulations and are properly licensed to sell the manufacturer's products, including verifying the validity and authenticity of drug license held by them.
   4. The price offered by the seller/bidder shall not, in any case exceed the DPCO/NPPA controlled price

or price fixed by State Government, if any. The seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government, if any.

5. Any other Terms and Conditions which is not included or at variance with the conditions specified in STC/GTC, may be added by the buyer through Additional Terms and Conditions (ATC) in the bid to ensure items are procured from authentic/validated source with appropriate and applicable quality. The above terms and conditions are in reverse order of precedence i.e. ATC shall supersede specific STC which shall supersede General Terms and Conditions (“GTC”), whenever there are any conflicting provisions.

Special terms and conditions-Version:2 effective from 19-05-2023 for category HIV ELISA Test Kits

1.

    1. All Provisions of Drugs and Cosmetics Act, 1940 and Rules (including Medical Device Rule 2017) made there under as amended till date will always be applicable. This will include all notifications issued by Central Drugs Standard Control Organization (CDSCO), Ministry of Health & Family Welfare (MoHFW) and Department of Pharmaceuticals (DOP), Ministry of Chemicals & Fertilizers time to time in this regard.
    2. The sellers are registered on GeM based on self-declaration of valid Drug License, product certification, test reports etc. However, buyers must check and validate the details at their end for all applicable licenses and certifications e.g., validity and authenticity/genuineness of drug license, product certification, manufacturer certification/licenses, test reports etc.
    3. In case of authorized resellers/distributors, it will be the legal & regulatory liability of the manufacturer to ensure that their resellers/distributors are operating in compliance with all relevant laws and regulations and are properly licensed to sell the manufacturer's products, including verifying the validity and authenticity of drug license held by them.
    4. The price offered by the seller/bidder shall not, in any case exceed the DPCO/NPPA controlled price or price fixed by State Government, if any. The seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government, if any.
    5. Any other Terms and Conditions which is not included or at variance with the conditions specified in STC/GTC, may be added by the buyer through Additional Terms and Conditions (ATC) in the bid to ensure items are procured from authentic/validated source with appropriate and applicable quality. The above terms and conditions are in reverse order of precedence i.e. ATC shall supersede specific STC which shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

क्रेता द्वारा जोड़ी गई बिड की विशेष शर्तें/Buyer Added Bid Specific Terms and Conditions

1. Experience Certificate for the supply of the same to any Govt/ PSU/ any renowned private organisation along with Supply/ Purchase Order.
2. If the agency is registered under MSME or NSIC, then EMD exemption certificate needs to be enclosed.
3. Make in india specific authorisation certificate needs to be enclosed.
4. **Turnover**

   Bidder Turn Over Criteria: The minimum average annual financial turnover of the bidder during the last three years, ending on 31st March of the previous financial year, should be as indicated in the bid document. Documentary evidence in the form of certified Audited Balance Sheets of relevant periods or a certificate from the Chartered Accountant / Cost Accountant indicating the turnover details for the relevant period shall be uploaded with the bid. In case the date of constitution / incorporation of the bidder is less than 3 year old, the average turnover in respect of the completed financial years after the date of constitution shall be taken into account for this criteria.

5. **Turnover**

   OEM Turn Over Criteria: The minimum average annual financial turnover of the OEM of the offered product during the last three years, ending on 31st March of the previous financial year, should be as indicated in the bid document. Documentary evidence in the form of certified Audited Balance Sheets of relevant periods or a certificate from the Chartered Accountant / Cost Accountant indicating the turnover details for the relevant period shall be uploaded with the bid. In case the date of constitution / incorporation of the OEM is less than 3 year old, the average turnover in respect of the completed financial years after the date of constitution shall be taken into account for this criteria. In case of bunch bids, the OEM of

CATEGORY RELATED TO primary product having highest bid value should meet this criterion.

6. **Purchase Preference (Centre)**

   Indian suppliers of this item are not allowed to participate and/ or compete in procurement by some foreign governments. Bidders / products from such countries are not eligible / not allowed to participate in this bid in terms of clause 1 (d) of Public Procurement (Preference to Make in India) Order, 2017

7. **Purchase Preference (Centre)**

   Purchase preference to Micro and Small Enterprises (MSEs): Purchase preference will be given to MSEs as defined in Public Procurement Policy for Micro and Small Enterprises (MSEs) Order, 2012 dated 23.03.2012 issued by Ministry of Micro, Small and Medium Enterprises and its subsequent Orders/Notifications issued by concerned Ministry. If the bidder wants to avail the Purchase preference, the bidder must be the manufacturer of the offered product in case of bid for supply of goods. Traders are excluded from the purview of Public Procurement Policy for Micro and Small Enterprises. In respect of bid for Services, the bidder must be the Service provider of the offered Service. Relevant documentary evidence in this regard shall be uploaded along with the bid in respect of the offered product or service. If L-1 is not an MSE and MSE Seller (s) has/have quoted price within L-1+ 15% of margin of purchase preference /price band defined in relevant policy, such Seller shall be given opportunity to match L-1 price and contract will be awarded for percentage of 30% of total value.

8. **Purchase Preference (Centre)**

   Purchase Preference linked with Local Content (PP-LC) Policy:

   The bid clause regarding “Preference to Make In India products” stands modified in this bid and shall be governed by the PPLC Policy No. FP-20013/2/2017-FP-PNG dated 17.11.2020 issued by MoP&NG as amended up to date. Accordingly, bidders with Local Content less than or equal to 20% will be treated as “Non Local Supplier”. The prescribed LC shall be applicable on the date of Bid opening. Sanctions on the bidders for false / wrong declaration or not fulfilling the Local Content requirement shall be as per the PPLC policy. Further following additional provisions are added in the certification and verification of local content provision of the Preference to Make in India clause:

   i. In case of foreign bidder, certificate from the statutory auditor or cost auditor of their own office or subsidiary in India giving the percentage of local content is also acceptable. In case office or subsidiary in India does not exist or Indian office/subsidiary is not required to appoint statutory auditor or cost auditor, certificate from practicing cost accountant or practicing chartered accountant giving the percentage of local content is also acceptable.
   ii. Along with Each Invoice: The local content certificate (issued by statutory auditor on behalf of procuring company) shall be submitted along with each invoice raised. However, the % of local content may vary with each invoice while maintaining the overall % of local content for the total work/purchase of the pro-rata local content requirement. In case, it is not satisfied cumulatively in the invoices raised up to that stage, the supplier shall indicate how the local content requirement would be met in the subsequent stages.
   iii. The bidder shall submit an undertaking from the authorized signatory of bidder having the Power of Attorney along with the bid stating the bidder meets the mandatory minimum LC requirement and such undertaking shall become a part of the contract.

9. **Purchase Preference (Centre)**

   Purchase Preference linked with Local Content (PP-LC) Policy:

   The bid clause regarding “Preference to Make In India products” stands modified in this bid and shall be governed by the PPLC Policy No. FP-20013/2/2017-FP-PNG dated 17.11.2020 issued by MoP&NG as amended up to date. Accordingly, bidders with Local Content less than or equal to 20% will be treated as “Non Local Supplier”. The prescribed LC shall be applicable on the date of Bid opening. Sanctions on the bidders for false / wrong declaration or not fulfilling the Local Content requirement shall be as per the PPLC policy. Further following additional provisions are added in the certification and verification of local content provision of the Preference to Make in India clause:

   i. In case of foreign bidder, certificate from the statutory auditor or cost auditor of their own office or subsidiary in India giving the percentage of local content is also acceptable. In case office or

subsidiary in India does not exist or Indian office/subsidiary is not required to appoint statutory auditor or cost auditor, certificate from practicing cost accountant or practicing chartered accountant giving the percentage of local content is also acceptable.

ii. Along with Each Invoice: The local content certificate (issued by statutory auditor on behalf of procuring company) shall be submitted along with each invoice raised. However, the % of local content may vary with each invoice while maintaining the overall % of local content for the total work/purchase of the pro-rata local content requirement. In case, it is not satisfied cumulatively in the invoices raised up to that stage, the supplier shall indicate how the local content requirement would be met in the subsequent stages.

iii. The bidder shall submit an undertaking from the authorized signatory of bidder having the Power of Attorney along with the bid stating the bidder meets the mandatory minimum LC requirement and such undertaking shall become a part of the contract.

10. **Purchase Preference (Centre)**

Procurement under this bid is reserved for purchase from Micro and Small Enterprises whose credentials are validated online through Udyog Aadhaar/URC for that product/service category. If the bidder wants to avail the reservation benefit, the bidder must be the manufacturer of the offered product in case of bid for supply of goods. Traders are excluded from the purview of Public Procurement Policy for Micro and Small Enterprises. In respect of bid for Services, the bidder must be the Service provider of the offered Service. Relevant documentary evidence in this regard shall be uploaded along with the bid in respect of the offered product or service.

11. **Certificates**

Bidder's offer is liable to be rejected if they don't upload any of the certificates / documents sought in the Bid document, ATC and Corrigendum if any.

12. **Certificates**

ISO 9001: The bidder or the OEM of the offered products must have ISO 9001 certification.

13. **Certificates**

Material Test Certificate Should Be Sent Along with The Supply. The Material Will Be Checked by Buyer’s Lab & the Results of the Lab will be the Sole Criteria for Acceptance of the Item.

14. **Certificates**

The bidder is required to upload, along with the bid, all relevant certificates such as BIS licence, type test certificate, approval certificates and other certificates as prescribed in the Product Specification given in the bid document.

15. **Past Project Experience**

Proof for Past Experience and Project Experience clause: For fulfilling the experience criteria any one of the following documents may be considered as valid proof for meeting the experience criteria:a. Contract copy along with Invoice(s) with self-certification by the bidder that service/supplies against the invoices have been executed.b. Execution certificate by client with contract value.c. Any other document in support of contract execution like Third Party Inspection release note, etc.Proof for Past Experience and Project Experience clause: For fulfilling the experience criteria any one of the following documents may be considered as valid proof for meeting the experience criteria:a. Contract copy along with Invoice(s) with self-certification by the bidder that service/supplies against the invoices have been executed.b. Execution certificate by client with contract value.c. Any other document in support of contract execution like Third Party Inspection release note, etc.

16. **Past Project Experience**

The Bidder / OEM {themselves or through reseller(s)}, should have executed project for supply and installation / commissioning of same or similar Category Products during preceding 3 financial years (i.e. current year and three previous financial years) as on opening of bid, as per following criteria:

(i) Single order of at least 35% of estimated bid value; or

(ii) Two orders of at least 20% each of estimated bid value; or
(iii) Three orders of at least 15% each of estimated bid value.
Satisfactory Performance certificate issued by respective Buyer Organization for the above Orders should be uploaded with bid. In case of bunch bids, the Category related to primary product having highest bid value should meet this criterion

17. **Buyer Added Bid Specific ATC**

    Buyer Added text based ATC clauses

    BIDDERS DECLARATION FORMAT

    RELATIONSHIP CERTIFICATE in Bidder's letter Head with detail declaration must be submitted in the following format

    "It is certified that I/We, the undersigned.do (With detail name & details)/do not have relationship with any of the employees working in NEIGRIHMS. The above statement is true and is submitted against the GeM Tender Enquiry No ._____dated_____

    Dated:_____

    (Signature) Name of the Company/Firm Seal

    The compliance sheet must be formatted correctly in a tabular form, including ITEM NAME, OFFERED SPECIFICATIONS (supported by relevant catalogues, brochures, photographs, certificates), MAKE, CATALOGUE NO., QUANTITY, and PACKED SIZE. S/N ITEM NAME Quantity Packed size Offered specifications CATALOGUE NO MAKE *Supporting documents are to be attached 4. Failure to submit a properly formatted compliance sheet with relevant product details may result in rejection by the TEC.

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अस्वीकरण/Disclaimer

The additional terms and conditions have been incorporated by the Buyer after approval of the Competent Authority in Buyer Organization, whereby Buyer organization is solely responsible for the impact of these clauses on the bidding process, its outcome, and consequences thereof including any eccentricity / restriction arising in the bidding process due to these ATCs and due to modification of technical specifications and / or terms and conditions governing the bid. If any clause(s) is / are incorporated by the Buyer regarding following, the bid and resultant contracts shall be treated as null and void and such bids may be cancelled by GeM at any stage of bidding process without any notice:-

1. Definition of Class I and Class II suppliers in the bid not in line with the extant Order / Office Memorandum issued by DPIIT in this regard.
2. Seeking EMD submission from bidder(s), including via Additional Terms & Conditions, in contravention to exemption provided to such sellers under GeM GTC.
3. Publishing Custom / BOQ bids for items for which regular GeM categories are available without any Category item bunched with it.
4. Creating BoQ bid for single item.
5. Mentioning specific Brand or Make or Model or Manufacturer or Dealer name.
6. Mandating submission of documents in physical form as a pre-requisite to qualify bidders.
7. Floating / creation of work contracts as Custom Bids in Services.
8. Seeking sample with bid or approval of samples during bid evaluation process. (However, in bids for attached categories, trials are allowed as per approved procurement policy of the buyer nodal Ministries)
9. Mandating foreign / international certifications even in case of existence of Indian Standards without specifying equivalent Indian Certification / standards.
10. Seeking experience from specific organization / department / institute only or from foreign / export experience.

11. Creating bid for items from irrelevant categories.
12. Incorporating any clause against the MSME policy and Preference to Make in India Policy.
13. Reference of conditions published on any external site or reference to external documents/clauses.
14. Asking for any Tender fee / Bid Participation fee / Auction fee in case of Bids / Forward Auction, as the case may be.
15. Buyer added ATC Clauses which are in contravention of clauses defined by buyer in system generated bid template as indicated above in the Bid Details section, EMD Detail, ePBG Detail and MII and MSE Purchase Preference sections of the bid, unless otherwise allowed by GeM GTC.
16. In a category based bid, adding additional items, through buyer added additional scope of work/ additional terms and conditions/or any other document. If buyer needs more items along with the main item, the same must be added through bunching category based items or by bunching custom catalogs or bunching a BoQ with the main category based item, the same must not be done through ATC or Scope of Work.

Further, if any seller has any objection/grievance against these additional clauses or otherwise on any aspect of this bid, they can raise their representation against the same by using the Representation window provided in the bid details field in Seller dashboard after logging in as a seller within 4 days of bid publication on GeM. Buyer is duty bound to reply to all such representations and would not be allowed to open bids if he fails to reply to such representations.

All GeM Sellers / Service Providers are mandated to ensure compliance with all the applicable laws / acts / rules including but not limited to all Labour Laws such as The Minimum Wages Act, 1948, The Payment of Wages Act, 1936, The Payment of Bonus Act, 1965, The Equal Remuneration Act, 1976, The Payment of Gratuity Act, 1972 etc. Any non-compliance will be treated as breach of contract and Buyer may take suitable actions as per GeM Contract.

यह बिड सामान्य शर्तों के अंतर्गत भी शासित है /This Bid is also governed by the General Terms and Conditions

जेम की सामान्य शर्तों के खंड 26 के संदर्भ में भारत के साथ भूमि सीमा साझा करने वाले देश के बिडर से खरीद पर प्रतिबंध के संबंध में भारत के साथ भूमि सीमा साझा करने वाले देश का कोई भी बिडर इस निविदा में बिड देने के लिए तभी पात्र होगा जब वह बिड देने वाला सक्षम प्राधिकारी के पास पंजीकृत हो।बिड में भाग लेते समय बिडर को इसका अनुपालन करना होगा और कोई भी गलत घोषणा किए जाने व इसका अनुपालन न करने पर अनुबंध को तत्काल समाप्त करने और कानून के अनुसार आगे की कानूनी कार्रवाई का आधार होगा।/In terms of GeM GTC clause 26 regarding Restrictions on procurement from a bidder of a country which shares a land border with India, any bidder from a country which shares a land border with India will be eligible to bid in this tender only if the bidder is registered with the Competent Authority. While participating in bid, Bidder has to undertake compliance of this and any false declaration and non-compliance of this would be a ground for immediate termination of the contract and further legal action in accordance with the laws.

---धन्यवाद/Thank You---