

बिड दस्तावेज़ / Bid Document

बिड विवरण/Bid Details	
बिड बंद होने की तारीख/समय /Bid End Date/Time	16-03-2026 15:00:00
बिड खुलने की तारीख/समय /Bid Opening Date/Time	16-03-2026 15:30:00
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	Directorate General Of Health Services
संगठन का नाम/Organisation Name	Bcg Vaccine Laboratory
कार्यालय का नाम/Office Name	Chennai
कुल मात्रा/Total Quantity	1
वस्तु श्रेणी /Item Category	Horizontal Customised Steam Steriliser
GeMARPTS में खोजी गई स्ट्रिंग्स / Searched Strings used in GeMARPTS	HORIZONTAL CUSTOMISED STEAM STERILISER
GeMARPTS में खोजा गया परिणाम / Searched Result generated in GeMARPTS	Horizontal Autoclave, Continuous Dyeing Machine
अधिसूचना के लिए चयनित प्रासंगिक श्रेणियाँ / Relevant Categories selected for notification	<ul style="list-style-type: none"> Vertical Autoclave Autoclave (Horizontal) Steam Sterilizer (V2)
बिडर का न्यूनतम औसत वार्षिक टर्नओवर (3 वर्षों का) /Minimum Average Annual Turnover of the bidder (For 3 Years)	17 Lakh (s)
मूल उपकरण निर्माता का औसत टर्नओवर (गत 3 वर्षों का)/OEM Average Turnover (Last 3 Years)	50 Lakh (s)
उन्हीं/समान सेवा के लिए अपेक्षित विगत अनुभव के वर्ष/Years of Past Experience Required for same/similar service	3 Year (s)
वर्षों के अनुभव एवं टर्नओवर से एमएसई को छूट प्राप्त है / MSE Relaxation for Years Of Experience and Turnover	Yes Complete
स्टार्टअप के लिए अनुभव के वर्षों और टर्नओवर से छूट प्रदान की गई है / Startup Relaxation for Years Of Experience and Turnover	Yes Partial Experience - 1 year (s) Turn over value - 4.25 (in lakhs)

बिड विवरण/Bid Details	
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
क्या आप निविदाकारों द्वारा अपलोड किए गए दस्तावेजों 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?	Yes (Documents submitted as part of a clarification or representation during the tender/bid process will also be displayed to other participated bidders after log in)
बिड लगाने की समय सीमा स्वतः नहीं बढ़ाने के लिए आवश्यक बिड की संख्या। / Minimum number of bids required to disable automatic bid extension	3
दिनों की संख्या, जिनके लिए बिड लगाने की समय-सीमा बढ़ाई जाएगी। / Number of days for which Bid would be auto-extended	7
ऑटो एक्सटेंशन अधिकतम कितनी बार किया जाना है। / Number of Auto Extension count	1
विगत प्रदर्शन /Past Performance	70 %
बिड से रिवर्स नीलामी सक्रिय किया/Bid to RA enabled	No
वार्षिक रखरखाव शुल्क आवश्यक / Annual Maintenance Charges Required	Yes
बिड का प्रकार/Type of Bid	Two Packet Bid
तकनीकी मूल्यांकन के दौरान तकनीकी स्पष्टीकरण हेतु अनुमत समय /Time allowed for Technical Clarifications during technical evaluation	3 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
मूल्यांकन पद्धति/Evaluation Method	Total value wise evaluation
मध्यस्थता खंड/Arbitration Clause	No
सुलह खंड/Mediation Clause	No

ईएमडी विवरण/EMD Detail

एडवाइजरी बैंक/Advisory Bank	Bank Of Baroda
ईएमडी राशि/EMD Amount	70000

ईपीबीजी विवरण /ePBG Detail

एडवाइजरी बैंक/Advisory Bank	Bank Of Baroda
ईपीबीजी प्रतिशत (%) /ePBG Percentage(%)	5.00
ईपीबीजी की आवश्यक अवधि (माह) /Duration of ePBG required (Months).	38

(a). जेम की शर्तों के अनुसार ईएमडी छूट के इच्छुक बिडर को संबंधित कटेगरी के लिए बिड के साथ वैध समर्थित दस्तावेज़ प्रस्तुत करने है। एमएसई कटेगरी के अंतर्गत केवल वस्तुओं के लिए विनिर्माता तथा सेवाओं के लिए सेवा प्रदाता ईएमडी से छूट के पात्र हैं। व्यापारियों को इस नीति के दायरे से बाहर रखा गया है।/EMD EXEMPTION: The bidder seeking EMD exemption, must submit the valid supporting document for the relevant category as per GeM GTC with the bid. Under MSE category, only manufacturers for goods and Service Providers for Services are eligible for exemption from EMD. Traders are excluded from the purview of this Policy.

(b). ईएमडी और संपादन जमानत राशि, जहां यह लागू होती है, लाभार्थी के पक्ष में होनी चाहिए। / EMD & Performance security should be in favour of Beneficiary, wherever it is applicable.

लाभार्थी /Beneficiary :

Director

Director, BCG Vaccine Laboratory, No. 110, 33 Feet Road, Manickam Lane, Mount Road, Guindy, Chennai 600032 (Director)

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

एमआईआई खरीद वरीयता / MII Purchase Preference

एमआईआई खरीद वरीयता / MII Purchase Preference	Yes
मेक इन इंडिया विक्रेताओं को खरीद में प्राथमिकता, यदि उनका मूल्य L1+X% तक की सीमा में है / Purchase Preference to MII sellers available upto price within L1+X%	20
मेक इन इंडिया खरीद में प्राथमिकता के लिए बिड की मात्रा का अधिकतम प्रतिशत / Maximum Percentage of Bid quantity for MII purchase preference	50
सार्वजनिक खरीद (मेक-इन-इंडिया को प्राथमिकता) आदेश 2017 के अनुसार केवल क्लास 1/क्लास 2 के स्थानीय आपूर्तिकर्ताओं को ही भागीदारी की अनुमति है दिनांक 16.09.2020 (समय-समय पर संशोधित एवं लागू) / Allow participation only from Class 1/Class 2 local suppliers as per the Public procurement(Preference to Make-in-india) order 2017 date 16.09.2020(as amended and applicable time to time)	Yes, in compliance with the MII ORDER : DPIIT Order(as amended and applicable time to time)

एमएसई खरीद वरीयता/MSE Purchase Preference

एमएसई खरीद वरीयता/MSE Purchase Preference	Yes
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सूक्ष्म और लघु उद्यम मूल उपकरण निर्माताओं को खरीद में प्राथमिकता, यदि उनका मूल्य L1+X% तक की सीमा में हो / Purchase Preference to MSE OEMs available upto price within L1+X%	15
सूक्ष्म और लघु उद्यम को खरीद में प्राथमिकता के लिए बिड की मात्रा का अधिकतम प्रतिशत / Maximum Percentage of Bid quantity for MSE purchase preference	25

1. If the bidder is a Micro or Small Enterprise as per latest orders issued by Ministry of MSME, the bidder shall be relaxed from the eligibility criteria of "Experience Criteria" as defined above subject to meeting of quality and technical specifications. The bidder seeking Relaxation from Experience Criteria, shall upload the supporting documents to prove his eligibility for Relaxation.
2. If the bidder is a Micro or Small Enterprise (MSE) as per latest orders issued by Ministry of MSME, the bidder shall be relaxed 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 relaxed from the "OEM Average Turnover" criteria also subject to meeting of quality and technical specifications. The bidder seeking Relaxation from Turnover, shall upload the supporting documents to prove his eligibility for Relaxation.
3. If the bidder is a DPIIT registered Startup, the bidder shall be relaxed from the the eligibility criteria of "Experience Criteria" as defined above subject to their meeting of quality and technical specifications. The bidder seeking Relaxation from Experience Criteria, shall upload the supporting documents to prove his eligibility for Relaxation.
4. If the bidder is a DPIIT registered Startup, the bidder shall be relaxed 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 relaxed from the "OEM Average Turnover" criteria also subject to meeting of quality and technical specifications. The bidder seeking Relaxation from Turnover shall upload the supporting documents to prove his eligibility for Relaxation.
5. 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.
6. 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.
7. 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.
8. 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.

9. 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.

10. Past Performance: The Bidder or its OEM {themselves or through re-seller(s)} should have supplied same or similar Category Products for 70% 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.

Pre Bid Detail(s)

मूल्य भिन्नता खंड दस्तावेज़/Pre-Bid Date and Time	प्री-बिड स्थान/Pre-Bid Venue
25-02-2026 11:00:00	BCG Vaccine Laboratory, No. 110, 33 Feet Road, Manickam Lane, Mount Road, Guindy, Chennai 600032

Horizontal Customised Steam Steriliser (1 pieces)

(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

क्रेता विशिष्टि दस्तावेज़ /Buyer Specification Document	Download
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Annual Maintenance	
Warranty of required product	3 Year
Annual Maintenance Charges Duration (Post Warranty)	5 Year
Annual Maintenance Charges Frequency	Bi-annually

*Warranty displayed under the AMC/CMC Details section will supersede the warranty displayed under the catalog specification

उपरोक्त मद के लिए इंस्टॉलेशन कमीशनिंग एंड टेस्टिंग (आईसीटी) का विवरण / Installation Commissioning and Testing (ICT) details for the above item:

% of Product Cost Payable on Product Delivery	70%
Min Cost Allocation for ICT as a % of product cost	25%
Number of days allowed for ICT after site readiness communication to seller	60 Days

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

क्र.सं./S.N o.	परेषिती/रिपोर्टिंग अधिकारी /Consignee Reporting/Officer	पता/Address	मात्रा /Quantity	डिलीवरी के दिन/Delivery Days
1	M K Gurumurthy	600032, No.110, 33 Feet Road, Mount Road, Guindy, Chennai	1	45

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. **Scope of Supply**

Scope of supply (Bid price to include all cost components) : Supply Installation Testing Commissioning of Goods and Training of operators and providing Statutory Clearances required (if any)

5. **Generic**

Bidder financial standing: The bidder should not be under liquidation, court receivership or similar proceedings, should not be bankrupt. Bidder to upload undertaking to this effect with bid.

6. **Generic**

Data Sheet of the product(s) offered in the bid, are to be uploaded along with the bid documents. Buyers can match and verify the Data Sheet with the product specifications offered. In case of any unexplained mismatch of technical parameters, the bid is liable for rejection.

7. **Generic**

Experience Criteria: The Bidder or its OEM {themselves or through reseller(s)} should have regularly, manufactured and supplied same or similar Category Products to any Central / State Govt Organization / PSU for 3 years before the bid opening date. Copies of relevant contracts to be submitted along with bid in support of having supplied some quantity during each of the year. In case of bunch bids, the primary product having highest value should meet this criterion.

8. **Generic**

Installation, Commissioning, Testing, Configuration, Training (if any - which ever is applicable as per scope

of supply) is to be carried out by OEM / OEM Certified resource or OEM authorised Reseller.

9. **Warranty**

Bidder / OEM has to give an undertaking that after expiry of warranty period, it will provide AMC Service for next 5 years for the offered products at the rate not more than 5 % of contract price per annum. Buyer reserves the right to enter into an AMC agreement (covering preventive maintenance and servicing)with the Successful Bidder / OEM after expiry of the Warranty period at rate as mentioned above and the payment for the AMC charges would be made Biannually after rendering of the AMC Services of the relevant AMC period. Performance Security of the successful bidder shall be forfeited if it fails to accept the AMC contract when called upon by the buyer. The original Performance Security of contract will be returned only after submission and verification of AMC Performance Security for 3% of total AMC value valid up to AMC period plus 2 months (if there is no other claim). (Undertaking of acceptance to be uploaded with bid).

10. **Warranty**

Warranty period of the supplied products shall be 3 years from the date of final acceptance of goods or after completion of installation, commissioning & testing of goods (if included in the scope of supply), at consignee location. OEM Warranty certificates must be submitted by Successful Bidder at the time of delivery of Goods. The seller should guarantee the rectification of goods in case of any break down during the guarantee period. Seller should have well established Installation, Commissioning, Training, Troubleshooting and Maintenance Service group in INDIA for attending the after sales service. Details of Service Centres near consignee destinations are to be uploaded along with the bid.

11. **Forms of EMD and PBG**

Bidders can also submit the EMD with Account Payee Demand Draft in favour of

The Pay & Accounts Officer, Ministry of Health & Family Welfare, Chennai
payable at
Chennai

.
Bidder has to upload scanned copy / proof of the DD along with bid and has to ensure delivery of hardcopy to the Buyer within 5 days of Bid End date / Bid Opening date.

12. **Forms of EMD and PBG**

Successful Bidder can submit the Performance Security in the form of Account Payee Demand Draft also (besides PBG which is allowed as per GeM GTC). DD should be made in favour of

The Pay & Accounts Officer, Ministry of Health & Family Welfare, Chennai
payable at
Chennai

. After award of contract, Successful Bidder can upload scanned copy of the DD in place of PBG and has to ensure delivery of hard copy to the original DD to the Buyer within 15 days of award of contract.

13. **Buyer Added Bid Specific ATC**

Buyer Added text based ATC clauses

Micro and Small Enterprises (MSEs) are exempt from submission of EMD (Bid security). Bidders claiming exemption of EMD under this rule (170 of GFR) are however required to submit a signed Bid securing declaration (format enclosed) along with the relevant and valid exemption certificate issue by the appropriate authorities. The Micro and Small Enterprises (MSEs) bidders to note and ensure that nature of service and goods/ items manufactured mentioned in MSE certificate matches with the nature of the service and goods/item to be supplied as per tender for claiming EMD exemption.

Successful Bidder has to submit an agreement in Rs. 100/- Stamp Paper to be signed by both parties.

Bidder has to submit Technical Compliance in the prescribed format attached with this tender without fail

.
Pre bid meeting will be held on 25.02.2026 at 11:00 AM at BCGVL, Chennai to clarify queries from all potential bidders. Potential bidders are advised to send their queries sufficiently in advance by email to bcgvlst

ores@gmail.com. A Corrigendum will be issued based on pre-bid meeting clarifications and shall form part of the Tender.

14. Buyer Added Bid Specific ATC

Buyer uploaded ATC document [Click here to view the file.](#)

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.

Additional Clause For Annual Maintenance Charges

1. AMC charges to be indicated as percentage of cost of Product/Equipment quoted for each year after the warranty period.
2. GST shall be included in the AMC Charges quoted.
3. The AMC functionality shall be available in bid only and no direct RA shall be applicable. In case of bid to RA decrement rules shall be applicable on total price inclusive of AMC charges.
 - 3.1 Buyer shall indicate number of years of warranty by selecting option of 1- 10 Years available in the field depending on warranty parameter applicable in category parameters for the equipment. The Seller while participating in Bid/RA will get fields to indicate AMC charges as percentage depending on number of years of AMC selected by Buyer. The following shall be applicable If 5 year AMC selected.
 - 3.1.1 AMC charges for first year after warranty period – Percentage to be indicated- A1.
 - 3.1.2 AMC charges for second year after warranty period – Percentage to be indicated A2.
 - 3.1.3 AMC charges for third year after warranty period – Percentage to be indicated A3.
 - 3.1.4 AMC charges for fourth year after warranty period – Percentage amount to be indicated A4.
 - 3.1.5 AMC charges for 5th year after warranty period – Percentage to be indicated A5.
 - 3.2 The calculation of AMC Charges shall take in to account of number of years of warranty and duration of AMC as specified while creating bid.
 - 3.3 AMC charges to be indicated for each subsequent year should be same or higher than preceding year.
 - 3.4 The AMC charges shall be offered within range of 3 to 25% of cost of equipment.
4. Since AMC charges are to be paid only later for each year during AMC period , applicable performance guarantee amount after placement of contract shall be based on the cost of product/equipment and not on basis of cost of equipment along with AMC Charges.
5. Performance bank guarantee applicable for AMC is to be submitted at start of the AMC and shall be applicable as 3.0% on the total contract value including AMC Charges The PBG submitted after award of contract shall be released only after new PBG for the AMC period is submitted and accepted by buyer/consignee after due verification. Bank guarantee for AMC is to remain valid till completion of AMC period plus one year .The bank guarantee for AMC shall be submitted to buyer directly.
6. In case of splitting of quantity product/equipment cost and AMC charges offered by L-1 in the evaluated cost shall be matched by higher quoting eligible bidders on one to one basis .The equipment cost shall be matched and AMC charges shall be matched year to year.
7. The AMC Contract shall be an offline contract to be handled by buyer. The payment of AMC will be made on AMC frequency (as indicated above) basis after satisfactory completion of said period, duly certified by end user and scope of AMC will be as per para 1 above.

All GeM Sellers/Service Providers shall ensure full compliance with all applicable labour laws, including the provisions, rules, schemes and guidelines under the four Labour Codes i.e. the Code on Wages, 2019; the Industrial Relations Code, 2020; the Occupational Safety, Health and Working Conditions Code, 2020; and the Code on Social Security, 2020 as and when notified and brought into force by the Government of India.

For all provisions of the Labour Codes that are pending operationalisation through rules, schemes or notifications, the corresponding provisions of the pre-existing labour enactments (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. and relevant State Rules) shall continue to remain applicable.

The Seller/ Service Providers shall, therefore, be responsible for ensuring compliance under:

- **All notified and enforceable provisions of the new Labour Codes as mentioned hereinabove; and**
- **All operative provisions of the erstwhile Labour Laws until their complete substitution.**

All obligations relating to wages, social security, safety, working conditions, industrial relations etc. and any other statutory requirements shall be strictly met by the Seller/ Service Provider. Any non-compliance shall constitute a breach of the contract and shall entitle the Buyer to take appropriate

action in accordance with the contract and applicable law.

[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---

Bid NO.: GEM/2026/B/7152360 dated 29.01.2026

Item: Horizontal customized steam sterilizer (Horizontal Autoclave)

The following changes are issued as corrigendum for the above bid.

Sl No.	Page No.	Description	Instead of	To be Read as
1.	1	Chamber Capacity and Dimension	Capacity - 540 liters (W) 600mm X (H) 600mm X (D) 1500mm	Capacity - 540 liters (Minimum)
2.	1	Outer Dimension	The external dimension of the autoclave should not exceed 1200 mm (Width) and 2200 mm (Height)	The external dimensions of the autoclave should be Approximately 1200mm (Width) and 2200mm (Height).
3.	1	Temperature	The sterilization temperature band and uniformity should be as per HTM 2010 & EN 285.	The sterilization temperature band and uniformity should be as per EN 285.
4.	1	Chamber minimum Features	Thickness 6 mm	Minimum Thickness- 6mm.
5.	1	Pressure Gauge	Pressure gauge should be provided for both chamber and jacket with glycerine filled compound gauge. Should be provided on loading side for chamber and jacket. Also, Should be provided on Unloading Side for chamber and unloading side gasket	Pressure gauge should be provided for chamber, Jacket and Steam generator with the glycerine filled compound gauge. Pressure gauge should be provided for the chamber and gasket on both sides (loading and unloading).
6.	1	Data access/ Storage	The system should have the capacity to store inbuilt cycle programs after every cycles.	The system should have the capacity to store Minimum Cycles As per FDA, cGMP and other leading Guidelines.
7.	1,2	Construction of Chamber	<ul style="list-style-type: none"> The chamber should be square design with rounded edge corner. It should be certified as per PED (Pressure Equipment Directive) (2014/68/EU) for design, safety and manufacturing practices. A copy of the certificate should be enclosed with the technical bid. 	<ul style="list-style-type: none"> The chamber should have square/Rectangle design with rounded corners. It must be certified as per PED (Pressure Equipment Directive) (2014/68/EU) for design, safety and manufacturing practices. A copy of the certificate should be enclosed with the technical bid.

			<ul style="list-style-type: none"> The PED Certificate issuing body should be notified from European Commission and should be traceable with the Certificate number and the notifying body at the Commission. 	<ul style="list-style-type: none"> The PED/ASME Certificate issuing body must be notified from European Commission and should be traceable with the Certificate number and the notifying body at the Commission.
8.	2	MOC	<ul style="list-style-type: none"> The chamber should be made of SS 316 L 	<ul style="list-style-type: none"> The Inner chamber, Inbuilt Steam Generator and Connecting pipe should be made of SS 316 L.
9.	2	Flange	Flange	CNC Flange
10.	3	Sterilization cycle	<ul style="list-style-type: none"> The critical parameters should be displayed on the HMI controller placed at the loading side. The control to start/stop sterilization cycle should be provided with IPC based 21 CFR (Code of Federal Regulation) Software. 	<ul style="list-style-type: none"> The critical parameters should be displayed on the HMI/IPC/SCADA controller, placed at the loading side. The control to start/stop sterilization cycle should be provided with IPC based 21 CFR (Code of Federal Regulation) Software requirements; The system should include Software updates from time to time in accordance with FDA regulatory changes for a total period of 8 years.(3 years Warranty + 5 Years AMC)
11.	3	Vacuum system	VLT leak rate should be as per HTM 2010.	VLT leak rate should be as per EN 285.
12.	3	Steam Connection	<ul style="list-style-type: none"> To be provided with an option to connect external steam source. 	<ul style="list-style-type: none"> Inbuilt Steam generator with minimum heater capacity of 36 kVA
13.	3	Pre-Warming	<ul style="list-style-type: none"> To be provided with 1-3 pre-warming pulses option of pressure cycles to reduce lag time. 	<ul style="list-style-type: none"> To be provided with minimum of 3 pre-warming pulses option of pressure cycles to reduce lag time.
14.	5	Vacuum Pump	Should be provided with Inbuilt Liquid-Ring type vacuum Pump for negative pulses and with heat exchanger, drying with minimum 2HP	Should be provided with Inbuilt Liquid-Ring type vacuum Pump for negative pulses and with heat exchanger, drying with minimum 2-3HP.

15.	5	Water Conservation for Vacuum Pump should be in supplier scope	The autoclave should be provided with a system to supply water to cool vacuum pump during operation. The system should require less than or equal to 300 Liters per year only for vacuum pump cooling. The Vacuum Pump should also be circulated with water having temperature less than 10° c in order to increase the life of the vacuum pump. The system should be integrated with the autoclave and should not require any additional water/electrical connections.	The autoclave should be provided with a system to supply water to cool vacuum pump during the operation with necessary /Appropriate Cooling Technology. The system should be integrated with the autoclave and should not require any additional water/electrical connections.
16.	5,6	Safety valve	European CE Certified Spring Loaded safety valves should be provided for both Jacket & Chamber.	European CE Certified Spring Loaded safety valves should be provided for Jacket, Chamber and Steam Generator.
17.	6	Temperature Control	The Sterilization temperature band should maintain the set temperature not more than +3 degree C variation. The temperature should not drop below the set temperature.	The Sterilization temperature band should maintain the set temperature within ±3°C. The temperature must not drop below the set temperature. Additionally the temperature sensor should have an accuracy of ±0.1°C
18.	6	HMI and PLC details	<ul style="list-style-type: none"> IPC Make : Schneider Electric 15.6 Inch, Touch Screen - with Intel Core i5, 8GB RAM, 500 GB SSD, Intel Core i5, Windows 10 Iiot Embedded Operation Software 	<ul style="list-style-type: none"> IPC Make: Schneider/ Allen Bradley. <ol style="list-style-type: none"> Minimum requirements for the IPC : Display size -15.6 Inch, Touch Screen type- Capacitive/Resistive Minimum CPU configuration- Intel Core i5, 11th Generation, 8GB LPDDR4 RAM, 512 GB SSD, Windows 11 with 64 bit and IOT Embedded Operational Software.

19.	6,7	The following section and features are applicable	Appropriate Software up-gradation / updation should be done on no additional cost whenever applicable or required.	Appropriate Software up-gradation / updation should be done on no additional cost whenever applicable or required up to the Period of AMC.
20.	12	Qualification Reports To be provided with the stated Qualification reports	<ul style="list-style-type: none"> • Qualification Reports To be provided with the stated Qualification reports • Design Qualification – DQ Document should be supplied once the contract is released to the concern vendor within 7 working days (Receivable to the Committee). The manufacturing of the autoclave should commence only after the approval from the tender committee. 	<ul style="list-style-type: none"> • Qualification documents to be provided with the reports. • Design Qualification – DQ Document should be supplied once the contract is released to the concern vendor within 3 Weeks. (Receivable to the Committee). The manufacturing of the autoclave should commence only after the approval from the Technical committee.
21.	13	Training	Training to be given regarding Operation and Maintenance Trouble shooting	Training to be given regarding the operation, maintenance and trouble shooting.
22.	13	Inspection at Vendors End	FAT request minimum 15 days in advance	FAT request minimum 15 days in advance (Max 5 Members).
23.	13	Technical Support	To be provided with 3 years warranty and 7 years AMC post warranty	To be provided with 3 years warranty and 5 years AMC post warranty. Note: Preventive maintenance- Yearly once and Breakdown visits must be conducted whenever required. (AMC agreement will be made/finalized after successful installation).
24.	13	Critical Spare Parts	<ul style="list-style-type: none"> • The first set should be supplied during the autoclave supply and the second supply should be supplied post completion of 3 years warranty. 	<ul style="list-style-type: none"> • The first set should be supplied along with the autoclave. The second and third sets should be supplied after completion of 3- year warranty period, during the AMC period.

			<ul style="list-style-type: none"> • The list of spares that shall be supplied should be enclosed with the technical bid. 	<ul style="list-style-type: none"> • The list of spares that shall be supplied should include Heaters, Temperature Sensors, Pressure Gauge, Pneumatic Valves, Gaskets and other critical parts to be enclosed with the technical bid itself.
25.	13,14	Supplier Scope	<ul style="list-style-type: none"> • The supplier should handle the below in their scope • Civil related changes required, demolition and re-construction as per the site challenges. • The site should be visited, scaled and a proposal should be enclosed with the technical bid with the changes and the actions proposed which will be part of technical qualification. 	<ul style="list-style-type: none"> • The supplier's scope should include handling the following points. • Civil related works : <ol style="list-style-type: none"> 1. Demolition of side wall 2. Removal of existing instruments 3. Installation of new Equipment 4. Rearrangement of panels with required changes 5. Flooring and Epoxy work 6. Other required Civil works to make the Instrument area comply with the guidelines. • The site should be visited, scaled and a proposal should be enclosed with the technical bid with the changes and the actions proposed which will be part of technical qualification. <p>*Note: Site visit report to be enclosed with the Technical Bid. (Site visit should be done on or before 13th March 2026 during the office hours only).</p>

*Technical compliance sheet, incorporating the above corrigendum, is provided below. The same shall be submitted by the vendors, duly signed and sealed on their letter head.

**Revised Technical Compliance Sheet for Horizontal Customized Steam Sterilizer
(Autoclave)**

DESCRIPTION	SPECIFICATION	Vendor Specification	Remarks
<p>NOTE: All the columns to be filled. Vendor has to provide detailed description/specification of the offered product in detail against each column. It may be noted that if marked, YES/NO/AGREED/COMPLIED, etc. may summarily be rejected. All the pages to be signed with seal/stamp.</p>			
A. PROCESS REQUIREMENTS			
Name of Equipment	Steam Sterilizer (Horizontal, Double Door)		
Chamber Capacity and Dimension	Capacity - 540 liters (Minimum)		
Outer Dimension	The external dimensions of the autoclave should be Approximately 1200mm (Width) and 2200mm (Height).		
Temperature	<p>Temperature control of 0.1°c in temperature display and print out with discrimination of 0.1°c.</p> <p>The sterilization temperature band and uniformity should be as per EN 285. Controlled using fixed RTD (PT 100) Sensor.</p>		
Temperature Sensor	<p>Platinum resistance types complying with class A of EN60751</p> <p>The Autoclave should be provided with 6no's of RTD PT100 sensors in total - 5 in chamber (4 in chamber + 1 in chamber drain) and 1 in jacket for effective cycle controlled</p>		
Chamber minimum Features	<p>Design temperature 150°c.</p> <p>Operating temperature 105°c to 135°c.</p> <p>Design pressure 2.31 kg/cm2.</p> <p>Hydraulic test pressure 3 kg/cm2.</p> <p>Minimum Thickness-6mm.</p>		
Jacket surrounding the chamber for uniform temperature distribution with minimum features	<p>Design temperature 150° c</p> <p>Maximum Operating temperature 121°c to 135° c</p> <p>Maximum Operating pressure 1.2 kg/cm2 to 2.15 kg/cm2</p> <p>Design pressure 2.31 kg/cm2</p> <p>Hydraulic test pressure 3 kg/cm2</p> <p>Minimum Thickness- 6mm</p>		

Pressure Gauge	Pressure gauge should be provided for chamber, Jacket and Steam generator with the glycerine filled compound gauge.		
	Chamber pressure should reflect in the printout with minimum of Three Decimals. (i.e. 0.001 Milli Bar) for all the cycles including vacuum leak test.		
	Pressure gauge should be provided for the chamber and gasket on both sides (loading and unloading).		
Data access/ Storage	The system should have the capacity to store Minimum Cycles As per FDA, cGMP and other leading Guidelines.		
Construction of Chamber	<ul style="list-style-type: none"> • The chamber should be as per ASME/PED Guidelines. • The chamber should have square/Rectangle design with rounded corners. It must be certified as per PED (Pressure Equipment Directive) (2014/68/EU) for design, safety and manufacturing practices. A copy of the certificate should be enclosed with the technical bid. • The PED/ASME Certificate issuing body must be notified from European Commission and should be traceable with the Certificate number and the notifying body at the Commission. • Drain should be provided with SS strainer 1 no removable strainer with sanitary type triclover fittings to protect any foreign particle entry in the drain with NRV. • The autoclave should perform the sterilization cycle & post drying wherever applicable. Should perform auto VLT and Bowie Dick Test. A copy of the VLT cycle report and Bowie Dick cycle report sample copy should be enclosed with the technical bid. 		

MOC	<ul style="list-style-type: none"> • The Inner chamber, Inbuilt Steam Generator and Connecting pipe should be made of SS 316 L. • Inbuilt Steam Generator and Connecting pipe should be made with SS316L. • The jacket should be made from SS 304 • SS316L for piping with TC fittings should be provided with swept piping design for critical pipelines to minimize dead legs. 		
Internal Surface	Mirror polished with Ra value ≤ 0.3 microns		
External Surface	Insulation required with minimum 50 mm thickness.		
Loading/ unloading	Movable trolley (2 nos) with appropriate Carriage should be provided as per the area layout space availability.		
Sliding doors	<ul style="list-style-type: none"> • Should be Double Door, Pass Through type. • Should be provided with vertical sliding doors (Down to up direction by operating pneumatic cylinder) SS316 mirror polished to Ra≤ 0.3 		
Door seal Gasket	Silicon rubber gasket (inflated) should be operated pneumatically and vacuumed for sealing/unsealing chamber and should be easy to replace and clean.		
CNC Flange	The chamber flange should be made from single metal with grooves without weld burs and should have pneumatic actuated gasket rubber type.		
Door controls	<ul style="list-style-type: none"> • Cannot be opened during process "ON" or chamber is under pressure. • Should not be possible to open unloading door, if Bowie Dick test is performed. • Both doors should not be openable at the same time except during maintenance. • Unloading door should open only at the end of a successful completion of full cycle. • The unloading door should not open when the cycle is aborted/fail. 		

	<ul style="list-style-type: none"> • Safety in stopping sliding door upward movement on detection of obstruction. 		
Sterilization cycle	<ul style="list-style-type: none"> • The critical parameters should be displayed on the HMI/IPC/SCADA controller placed at the loading side. • The control to start/stop sterilization cycle should be provided with IPC based 21 CFR (Code of Federal Regulation) • Software requirements; The system should include Software updates from time to time in accordance with FDA regulatory changes for a total period of 8 years.(3 years Warranty + 5 Years AMC) 		
Vacuum system	<ul style="list-style-type: none"> • Capable to evacuating sterilizing chamber to the required pressure for individual processes. • The air removal capacity should be minimum 27 m³/hr • Should be provided with the start of 3pulses Minimum. Configurable options for pre - vacuum air removal. • Should be provided with configurable number of pulses with specific time options for post vacuum drying stage • VLT leak rate should be as per EN 285. Leak rate limit achieved in the autoclave should be specified. 		
Steam Connection	<ul style="list-style-type: none"> • Inbuilt Steam generator with minimum heater capacity of 36 kVA. 		
Pre-Warming	<ul style="list-style-type: none"> • To be provided with minimum of 3 pre-warming pulses option of pressure cycles to reduce lag time. 		
Test connections	<ul style="list-style-type: none"> • To comply EN285. 		
Alarms	<ul style="list-style-type: none"> • All alarms should be logged and displayed and should be viewed in an alarm log with reports. • The alarm logs should be able to viewed and printed 		

Pipe joints & Fittings	<ul style="list-style-type: none"> • All piping should be fitted with tri-clover fitting clamps. 		
Visual display	<ul style="list-style-type: none"> • Visual display for parameters like Chamber temperature for all RTD sensors including drain - all 5 sensors. • Door gasket pressure • Cycle number, Batch number, Cycles parameters • Critical Process Parameters • I/O Status • Cycle end • Alarm 		
Test Cycle Provision	<ul style="list-style-type: none"> • Should be provided with options to create multiple cycles by authorized person as per the SOP requirements. 		
Maintenance Service Access	<ul style="list-style-type: none"> • The Autoclave service access should be only at any one side of the autoclave (according to the area layout availability). The service access panel should be entirely removable. Other end of the autoclave should not encompass any components/electrical of the autoclave. 		
• B.COMPONENT DETAILS			
Contact Parts	<ul style="list-style-type: none"> • SS316 L Mirror Finish with $Ra \leq 0.3$ except Jacket. 		
Non - Contact Parts	<ul style="list-style-type: none"> • SS304 Matt Finish 		
Gaskets	<ul style="list-style-type: none"> • Silicone Food Grade. 		
Cycle Reports	<ul style="list-style-type: none"> • The Cycle reports, alarm logs, audit trails, etc. should be printed through the software on any connected local or network printer. The cycle report should have all 5 temperature sensor readings, pressure reading, date & time, organization name, operator name, cycle number, batch number, cycle graphical data, minimum and maximum temperature difference, e-signature, approvals. A sample copy of cycle report and alarm log has to be submitted with the technical bid. 		

Electricity & Frequency	<ul style="list-style-type: none"> Electricity 415 V \pm 20% V, Three phase, 1 N,50 Hz + 2 Hz of frequency. 		
Compressed Air	<ul style="list-style-type: none"> Required to operate pneumatic control valve and minimum pressure 6.0kg/cm². Airline supply shall be supplied from site. 		
Vacuum Pump	<ul style="list-style-type: none"> Should be provided with Inbuilt Liquid-Ring type vacuum Pump for negative pulses and with heat exchanger, drying with minimum 2-3HP. 		
Water Conservation for Vacuum Pump should be in supplier scope	<ul style="list-style-type: none"> The autoclave should be provided with a system to supply water to cool vacuum pump during the operation with necessary/Appropriate Cooling Technology. The system should be integrated with the autoclave and should not require any additional water/electrical connections. 		
Steam Condenser	<ul style="list-style-type: none"> To be provided with steam condenser of SS 304 Shell & Tube type - before the medium passes into the vacuum pump 		
Drain in sterilizer	<ul style="list-style-type: none"> Should be provided with angular slope with minimum 2° slope. No water should retain in the chamber after each cycle. 		
Air Vent Filter	<ul style="list-style-type: none"> Should be provided with 0.2μ PTFE Membrane Capsule Filter Cartridge with 1" TC connection fitting on one end. Certificate of the Filter should be supplied with the autoclave during supply. 		
Insulation	<ul style="list-style-type: none"> Jacket should be insulated with minimum 50 mm thick glass-wool and SS304 sheet. 		
Validation port	<ul style="list-style-type: none"> Validation port to be leak-proof after insertion of validation probe. Should be provided with 2 no's suitable adapter of 1½" TC SS 316 for inserting probes during validation. 		
Safety valve	<ul style="list-style-type: none"> European CE Certified Spring Loaded safety valves should be provided for Jacket, Chamber and 		

	Steam Generator. A copy of the certificate should be enclosed with technical bid.		
Valves	<ul style="list-style-type: none"> All control valves to the chamber should be pneumatic valves only. 		
Others	<ul style="list-style-type: none"> CE Certificate for Autoclave and Safety Valves - To be submitted PED Certificate for Pressure Vessel Safety and manufacturing practices - To be submitted MOC declarations (wherever applicable) - To be submitted Calibration Certificate traceable up-to NABL. - to be submitted 		
C.CONTROL SYSTEM			
Cycle Control	<ul style="list-style-type: none"> All control parameters of the cycle should be controlled/ operated through HMI/IPC/SCDA only. 		
MCB, Over Load Relay and Contactor	<ul style="list-style-type: none"> Required 		
Emergency stop button on both sides (loading and unloading side)	<ul style="list-style-type: none"> Required 		
Temperature and Pressure Indicators(s)	<ul style="list-style-type: none"> Required 		
Temperature Control	<ul style="list-style-type: none"> The autoclave should maintain the temperature as per EN 285 in accordance with the below points, The Sterilization temperature band should maintain the set temperature within $\pm 3^{\circ}\text{C}$. The temperature must not drop below the set temperature. Additionally the temperature sensor should have an accuracy of $\pm 0.1^{\circ}\text{C}$ The Equilibrium time should not cross beyond the limit insisted by EN 285. The Equilibrium time of the quoted autoclave should be specified with the bid. 		

Data security	<ul style="list-style-type: none"> Multiple access group levels and multiple user levels should be available as per SOP at the time of Installation. 		
HMI and PLC details	<ul style="list-style-type: none"> HMI, Make: Siemens/ Weintek/ Beijer 3. IPC Make: Schneider/ Allen Bradley. 4. Minimum requirements for the IPC : Display size -15.6 Inch, Touch Screen type- Capacitive/Resistive Minimum CPU configuration- Intel Core i5, 11th Generation, 8GB LPDDR4 RAM, 512 GB SSD, Windows 11 with 64 bit and IOT Embedded Operational Software. PLC Make : Siemens/ABB/Allen Bradley 		
Program Backup 21 CFR Software	<ul style="list-style-type: none"> Required in Pen drive. 		
Electronic Signature	<ul style="list-style-type: none"> Required. 		
Data storage capacity	<ul style="list-style-type: none"> Required in IPC & server 		
Password protection	<ul style="list-style-type: none"> Required 		
Cycle Documentation	<ul style="list-style-type: none"> Cycle data for all 5 chamber temperature sensors with F0 summation of chamber value for drain sensor should be printed along with organization details, cycle set parameters, operator name, Batch number, recipe, hold time, temperature set point, Number of pulses (negative, positive), Electronic Signature provision and Graphical trends. A sample copy of the data report should be enclosed with the technical bid. 		
Others	<ul style="list-style-type: none"> Supplier to ensure a separate provision for wiring to connect UPS to controller. 		
	<ul style="list-style-type: none"> Only authorized person should create the recipe, data back-up/restore, retrieval, editing recipe/ system parameters, etc. 		
	<ul style="list-style-type: none"> Verification of I/O should be done during equipment installation. 		

	<ul style="list-style-type: none"> • Protection class IP 65. Power sockets and emergency stop switch. 		
	<ul style="list-style-type: none"> • All wirings and Control systems should be provided on one side (servicing side) of the autoclave 		
	<ul style="list-style-type: none"> • Equipment and User Audit Trials should be available with printout. 		
D. SOFTWARE & HARDWARE FEATURES			
The following section and features are applicable	<ul style="list-style-type: none"> • Mention the details about the software program controlling/supporting the equipment like its name, version, and release. 		
	<ul style="list-style-type: none"> • Appropriate Software up-gradation / updation should be done on no additional cost whenever applicable or required up to the Period of AMC. 		
	<ul style="list-style-type: none"> • 21 CFR should be installed in the IPC and qualified 		
Access control and user authentication through:- <ul style="list-style-type: none"> ❖ Login ID ❖ Password 	<ul style="list-style-type: none"> • System should have unique user ID and password for individual user. 		
User Management: System should enforce:- <ul style="list-style-type: none"> ❖ Unique Login ID and prevent reuse of deactivated (due to person leaving organization) login IDs to maintain clear audit trail data. 	<ul style="list-style-type: none"> • Every user should have unique user ID and system should not allow to allot the same ID to different user. • Password should have configuration option from 1 to 99 months. • Password length should be minimum 8 characters and should be alpha- numeric complexity. • System should mask the password during login. • Auto logout time configuration option to be provided. • Expiry of passwords over time, preferably configurable. 		
Privilege management and different access levels (Multiple User Levels)	<ul style="list-style-type: none"> • Multiple user level creation options to be provided as per the company SOP at the time of installation. • System shall have the provision to configure user roles and privileges and same shall be captured 		

	<p>part of audit trail.</p> <ul style="list-style-type: none"> • System shall have the provision for default admin to access all the privileges. 		
<p>Ability to deactivate/ disable users:</p> <ul style="list-style-type: none"> ❖ By admin ❖ Due to repeated login failures 	<ul style="list-style-type: none"> • Only Admin can create / deactivate the user. • The number of unsuccessful attempt count should be configurable. After unsuccessful attempt system should block / deactivate the respective user. 		
<p>Audit Trails:</p> <ul style="list-style-type: none"> ❖ System-generated, time-stamped system log that records the date and time of all user entries and actions that create, modify, or delete electronic records. This feature should be always enabled and protected from any changes. 	<ul style="list-style-type: none"> • User creation / disable or any other login / logout event should come in audit trail. • Date and time along with the name of the user, old & new value (wherever applicable) should appear for all activity of creation, modification and deletion. • Set parameters change / deletion should come with old and new value along with the remarks for change or deletion. • There should be no option to turn off the Audit Trail. 		
<p>Ability to View entire or part of GxP impacted records/ Audit trail</p>	<ul style="list-style-type: none"> • Electronic records & Audit trail report should be available with search option with respect to date & batch No. 		
<p>Ability to Print/ Electronically copy entire/ part of GxP impacted records or Audit trail data.</p>	<ul style="list-style-type: none"> • Electronic records, reports and audit trail report should be available with search option with respect to date & batch no. and can be same in a non-editable format like PDF. 		
<p>Data Security:</p> <ul style="list-style-type: none"> ❖ Controls in place to prevent unauthorized/ unrecorded changes to system data. Audit trail data should be only read only mode and no changes should be allowed by any user including admin. 	<ul style="list-style-type: none"> • System should have functionality to assign the privilege for any data change. • Any generated record / audit trail should not be edited by any user including Admin. • System shall not allow the user to rename, delete or modify. 		
<p>Data Backup:</p>	<ul style="list-style-type: none"> • Complete data backup and 		

<ul style="list-style-type: none"> ❖ Ability to create backup files for the system/ audit trail data. Data should be retrievable during the storage period. 	<p>restoration functionality should be available in the system. Data should be easily retrievable throughout the life cycle.</p> <ul style="list-style-type: none"> ● Supplier shall have to provide the procedure for backup and data storage capacity. 		
<p>Electronic Signature Components:</p> <ul style="list-style-type: none"> ❖ These should be made up of at least two distinct identification components. All electronically signed records should contain the following information: ❖ Full printed name of the signer(This should be applied automatically by system based on login details) ❖ Date and time of signing (This should be applied automatically by system) ❖ Meaning of signature 	<ul style="list-style-type: none"> ● Login Name name of the signer(This should be applied automatically by system based on login details) ● Date and time of signing (This should be applied automatically by the system) ● Meaning of signature 		
<p>Security of Electronic Signatures:</p> <ul style="list-style-type: none"> ❖ Electronic signatures should be logged in audit trail and should be secured from any modifications. 	<ul style="list-style-type: none"> ● Electronic signatures for respective event in the system should logged in audit trail and the same should logged in audit trail and the same should be non - editable. 		
<p>Additional Security:</p> <ul style="list-style-type: none"> ❖ System data and audit trail data should be encrypted in case system access is not controlled or not closed system. 	<ul style="list-style-type: none"> ● Closed system is required. 		
<p>Admin controls:</p>	<ul style="list-style-type: none"> ● System should have 		

❖ Only Admin should have ability to enable/ disable/ expire users and reset the system.	functionality to define the privilege to Admin for any creation, disable and reset of password of any user.		
E. SAFETY FEATURES			
Lock /Tag out provision	<ul style="list-style-type: none"> Diagnostic mode should be provided to identify the fault in components such as temperature sensors, pressure transmitters, etc. and the operating procedures to be trained to the engineering department. 		
Emergency stop Button	<ul style="list-style-type: none"> Should be located on the loading side and unloading side on the Control panel 		
Power failure/ Recovery	<ul style="list-style-type: none"> In the event of a power failure, the Autoclave should have a restoration and reconditioning sequence on resumption of power. In case UPS, the blackout and electrical resumption events should get logged in the necessary prints and applicable electronic records and appropriate alarm messages should be displayed on the HMI/IPC/SCDA. 		
Alarms & Warnings	<ul style="list-style-type: none"> Audio & visual alarm system with, Visual light indication to be provided on machine wherever applicable Warning sings/displays Slow Exhaust alarm High temperature alarm All alarms should be reasoned by the operator and acknowledged by the supervisor wherever applicable in the software. 		
Earthing	<ul style="list-style-type: none"> No electrical shock to be observed during use. MCB of suitable ratings should be provided for protection Suitable body earthing to be provided for machine bonding to be ensured for machine accessories, parts. 		
Noise / Vibration Level	<ul style="list-style-type: none"> Should not exceed 70 dB at 1 m distance. 		

Door Interlocks	<ul style="list-style-type: none"> • Autoclave door shall not open if it any program is running. • Autoclave steam cycle shall not start unless loading & unloading doors are closed & locked. • Unloading door shall open only after successful completion of sterilization & after autoclave temperature dropped below set limit. • Doors gaskets shall be sealed pneumatically then only cycle will start. • Both unloading or loading Doors shall not open if the Autoclave Chamber/Jacket is above/below • Atmospheric pressure • Specific Temperature. • Steam input valve should stop when temperature reaches high limit. • Autoclave shall not start if emergency stop activated, also should stop in case it is running • All safety functions should be handed by the PLC Program and should be provided with a cycle abort option of the process in case of critical safety alarms. 		
Control panel	<ul style="list-style-type: none"> • Required with exhaust fan and high/low voltage protection facility 		
Electrical panel	<ul style="list-style-type: none"> • To be properly grounded with secured parts 		
Others	<ul style="list-style-type: none"> • Every component to have identification tags/label • Warnings and Caution stickers where ever applicable. • Electrical wiring shall be numbered & concealed • Safety valves to be European CE Certified • All Hot pipe lines should be covered to prevent burn injuries(insulated) 		

F. DOCUMENTATION			
Vendor Training certificate	<ul style="list-style-type: none"> • Required 		
Certificates <ul style="list-style-type: none"> ❖ Safety Valve Test Certificate ❖ P&ID ❖ MOC Certificate for chamber, lid, flange, tray ❖ Pressure Vessel Integrity Test Certificate ❖ Calibration certificate for Pressure Gauge & Controller traceable up to NABL ❖ GA Drawing of autoclave with layout ❖ European CE and PED Certificate 	<ul style="list-style-type: none"> • Required 		
<ul style="list-style-type: none"> • Qualification documents to be provided with the reports. 	<ul style="list-style-type: none"> • Design Qualification – DQ Document should be supplied once the contract is released to the concern vendor within 3 Weeks. (Receivable to the Committee). The manufacturing of the autoclave should commence only after the approval from the Technical committee. • Installation Qualification • Operational Qualification • Performance Qualification • PQ to be performed with 36 Validation Cycles with suitable Data Logger. • Loads to be qualified are Media loads, Garment loads, Articles/accessories, Bowie Dick Cycle, VLT • All the required kits/consumables such as Biological indicators, Bowie Dick Test for performing PQ should be arranged by the supplier. 		

	<ul style="list-style-type: none"> • Qualification should be performed for 21CFR software as well and the necessary documents have to be enclosed during qualification activity. 		
Operation and Maintenance Manual	<ul style="list-style-type: none"> • Required 		
G. OTHERS			
Training	<ul style="list-style-type: none"> • Training to be given regarding the Operation, Maintenance and Trouble shooting 		
Inspection at Vendors End	<ul style="list-style-type: none"> • FAT request minimum 15 days in advance (Max 5 Members). 		
Technical Support	<ul style="list-style-type: none"> • To be provided with 3 years warranty and 5 years AMC post warranty. <p>Note: Preventive maintenance- Yearly once and Breakdown visits must be conducted whenever required. (AMC agreement will be made/finalized after successful installation).</p>		
Critical Spare Parts	<ul style="list-style-type: none"> • The autoclave should be supplied with minimum 3 sets of Critical Spare parts except. <p>The first set should be supplied along with the autoclave. The second and third sets should be supplied after completion of 3- year warranty period, during the AMC period.</p> <ul style="list-style-type: none"> • The list of spares that shall be supplied should include Heaters, Temperature Sensors, Pressure Gauge, Pneumatic Valves, Gaskets and other critical parts to be enclosed with the technical bid itself. 		
Supplier Scope	<ul style="list-style-type: none"> • The supplier's scope should include handling the following points. • Civil related works : <ol style="list-style-type: none"> 1. Demolition of side wall 2. Removal of existing instruments 3. Installation of new Equipment 		

4. Rearrangement of panels with required changes
5. Flooring and Epoxy work
6. Other required Civil works to make the Instrument area comply with the guidelines.

- The site should be visited, scaled and a proposal should be enclosed with the technical bid with the changes and the actions proposed which will be part of technical qualification.

***Note:** Site visit report to be enclosed with the Technical Bid. (Site visit should be done on or before 13th March 2026 during the office hours only).

- The supplier should ensure that the wall is demolished and construed including finishing and panel work until the product is installed and qualified successfully.
- Those who have not visited the site for site evaluation shall not be proceeded with technical qualification
- Transporting the material from the manufacturing facility to installation site/
- Unloading the material at site premises
- Handling and Positioning of Autoclave at the desired location (First Floor) including Crane, labor and other necessary arrangements
- Piping and Electricals wherever required.
- Installation, Qualification Performance and Documentations as per SOP
- Complete product operation and maintenance training to concern departments

RH
TS/ae

Amgen

Bid Security Declaration Format
(On Bidders Letterhead)

Date

Tender No: _____

To

The Director,
BCG Vaccine Laboratory,
No. 110, 33 Feet Road, Manickam Lane,
Mount Road, Guindy,
Chennai 600032

Sir,

I/We undersigned declare that:

- 1) I/We understand that, according to your conditions, bids must be supported by a Bid Securing Declaration.
- 2) I/We accept that I/We may be disqualified / debarred from bidding against BCG Vaccine Laboratory tenders for a period of one year from the date of notification, if, I/We are in a breach of any obligation under the bid conditions, because I/We
 - a) have withdrawn/modified/amended, impairs or derogates from the tender, my/our bid during the period of bid validity specified in the form of Bid; or
 - b) having been notified of the acceptance of our Bid by the purchaser during the period of bid validity (i) fail or refuse to execute the contract, if required, or (ii) fail or refuse to furnish the Performance Security within the timeline, in accordance with the instructions to Bidders & as per tender terms & conditions.
- 3) I/We understand this Bid Security Declaration shall cease to be valid on the Thirty First day from following,
 - a) If I am/we are not the successful Bidder, the receipt of your notification of the name of the successful Bidder; or
 - b) the expiration of the validity of my/our Bid or any extension thereof.

Signed: (insert signature of person whose name and capacity are shown)
In the capacity of (insert legal capacity of person signing the Bid Security Declaration)

Name: (insert complete name of person signing the Bid Security Declaration)
Duly authorised to sign the bid for an on behalf of (insert complete name of Bidder)

Dated on _____ day of _____ (insert date of signing)
Corporate Seal (where appropriate)

(Note: in case of a Joint Venture, the Bid Security Declaration must be in the name of all partners to the Joint Venture that submits the Bid)

Make in India Certificate

In line with Government Public Procurement (Preference to Make in India), Order 2017, P-45021/2/2017-PP (BE-II) dated 16.09.2020 and subsequent clarification No P-45021/102/2019-BE-II-Part(1) (E-50310) dated 04.03.2021, we hereby certify that we **M/s** _____, are local supplier meeting the requirement of minimum local content _____ (in %) as defined in above order for the material against **Enquiry No.** _____.

Details of location at which local value addition will be made is as follows:

_____ (Place).

We also understand, false declarations will be in breach of the Code of Integrity under Rule 175(1)(i)(h) of the General Financial Rules for which a bidder or its successors can be debarred for up to two years as per Rule 151 (iii) of the General Financial Rules along with such other actions as may be permissible under law.

The above declaration does not include services such as transportation, insurance, installation, commissioning, training and after sales service support like AMC/CMC etc as local value addition.

(Vendor's Seal & Sign)