

All India Institute of Medical Sciences
Rishikesh-249203



Tender Document for Procurement of
Portable ECMO Machine for Department of CTVS
AIIMS, Rishikesh

Ref. No. : 24/RT/CTVS/ECMO/550/2020-Rish(Admn)
Publishing Date :
Pre-Bid Meeting :
Bid Submission Start Date :
Last Date of Bid Submission :
Bid Opening :

Tender documents may be downloaded from institute's web site www.aiimsrishikesh.edu.in
(for reference only) and CPPP site <https://eprocure.gov.in/eprocure/app>

TENDER NOTICE

for

Portable ECMO Machine for Department of CTVS at

AIIMS, Rishikesh

Dated:

1. E-tenders in Two Bids (Technical & Financial) basis are invited on behalf of the Director, All India Institute of Medical Sciences, Rishikesh from interested and eligible manufacturer or their authorised distributors/dealers, for providing **Portable ECMO Machine for Department of CTVS** at AIIMS Rishikesh.
2. Bids shall be submitted online only at CPPP website: <https://eprocure.gov.in/eprocure/app>.
3. The complete bidding process is online. Bidders should be in possession of valid digital Signature Certificate (DSC) for online submission of bids. Prior to bidding DSC need to be registered on the website mentioned above. For any assistance for e-bidding process, if required, bidder may contact to the helpdesk at 0135-2462915.
4. Tenderer/Contractor/Bidders are advised to follow the instructions provided in the 'Instructions to the Contractors/Tenderer/Bidders for the e-submission of the bids online through the Central Public Procurement Portal for e Procurement at <https://eprocure.gov.in/eprocure/app>'.
5. Bid documents may be scanned with 100 dpi with black and white option which helps in reducing size of the scanned document.
6. Hard Copy of earnest money deposit and tender fee etc. must be delivered to AIIMS, Rishikesh on or before last date/time of Bid Submission as mentioned above. The bid without EMD and tender fee will be summarily rejected. The scanned copy of the EMD and Tender fee should be attached in the technical bid.
7. The tender shall be submitted online in two part, viz., technical bid and financial bid. All the pages of bid being submitted must be signed and sequentially numbered by the bidder irrespective of nature of content of the documents before uploading.

The offers submitted by Telegram/Fax/email shall not be considered. No correspondence will be entertained in this matter.

8. Any future clarification and/or corrigendum(s) shall be communicated through the Central Public Procurement Portal for e Procurement at <https://eprocure.gov.in/eprocure/app> or AIIMS, Rishikesh website: www.aiimsrishikesh.edu.in. The bidders are required to regularly check the website to know about any/all such corrigendum(s) as only these bids, taking care of such corrigendum(s) shall be considered for finalisation of the tender.
9. Bidder should necessarily enclose a covering letter mentioning a summary of applied document with proper numbering. Secondly, bid should also attach a compliance sheet as per specification mentioning that they are complying to all specification or have any variation.
10. The pre bid conference would be held on-2019 at 03.00 PM in the office of Tender Opening Room, AIIMS, Rishikesh. All firm's representative who are attending the pre bid meeting, shall produce an authorization letter from their firm on the firm's letter head. They are required to put their query in writing before the committee and submit the same in writing on its letter head.
11. All the duly filled/completed pages of the tender should be given serial /page number on each page and signed by the owner of the firm or his Authorized signatory. In case the tenders are signed by the Authorized signatory, a copy of the power of attorney/authorization may be enclosed along with tender. A copy of the terms & conditions shall be signed on each page and submitted with the technical bid as token of acceptance of terms & conditions. Tender with unsigned pages/incomplete/partial/part of tender if submitted will be rejected out rightly.

12. Any omission in filling the columns of Financial Bid form (Schedule of Rates) shall debar a tender from being considered. Rates should be filled up carefully by the tenderer. All corrections in this schedule must be duly attested by full signature of the tenderers. The corrections made by using fluid and overwriting will not be accepted and tender would be rejected.

13.(i) **Bid Security:** -The bidder shall pay the respective amount of Bid Security (EMD) as mentioned in Table-I along with the Technical Bid by way of demand FD/TD/CD in favor of "AIIMS, Rishikesh" drawn on any Nationalized Bank/ Scheduled Bank and payable at Rishikesh and must be valid for (6) six month. Bids received without tender fees and Earnest Money deposit (EMD) shall stand rejected and thus shall not be considered for evaluation etc. at any stage. The original EMD will be put in cover-I containing with Technical bid.

- a) The Public Sector Undertaking of the Central/State Govt./MSEs/MSME/Registered with Central Purchase Organization are exempted from furnishing Earnest Money along with tender, subject to submission of its valid proof.
- b) The firms Registered with DGS & D/SSI and any approved source of Centre/States Govt. are not exempted from furnishing Earnest Money in so far as this institute is concerned.
- c) Earnest Money deposited with AIIMS, Rishikesh in connection with any other tender enquiry even if for same/similar material / Stores by the tenderer will not be considered against this tender.
- d) Declaration of Udyog Aadhar Memorandum (UAM) number by the vendors on CPPP is mandatory. The bidders who fail to submit the UAM number shall not be able to avail benefits available to MSE's.

(ii) EMD is required to protect the purchaser against the risk of Bidders conduct. The EMD will be forfeited if the bidder withdraws or amends its tender or impairs or derogates from the tender in any respect within the period of validity of its tender or if it comes to the notice that the information/ documents furnished in its tender is incorrect or false.

14. The bid security (EMD) without interest shall be returned to the unsuccessful bidders after finalization of contract with successful bidder.

15. Bidders are not allowed to submit more than one bid for the same/similar tendered item else all his bids shall be cancelled thereby making him disqualified in addition to the forfeiture of the EMD.

16. The successful bidders have to execute a contract on Indian non judicial stamp paper of Rs.100/- (Rupees one hundred only) within twenty-one (21) days from the date of award of this tender in his favour and also required to furnish the **Security Deposit @ 5%** of contract value in the form of FD/BG/TD/CD for **Six months extra of the contract period** from any Nationalised/Schedule bank duly pledged in favour of AIIMS, Rishikesh & payable at Rishikesh only. The EMD deposited by successful bidder may be adjusted towards Security Deposit as demanded above after its validation for the required period. If the successful bidder fails to furnish the full security deposit or difference amount between Security Deposit and EMD within 21 (twenty-one) days after the issue of **Letter of Award** of Work, his bid security (EMD) shall be forfeited and award of tender in suppliers favour automatically stands terminated at his cost & liability, unless time extension has been granted by AIIMS, Rishikesh.

17. The EMD/PBG shall be forfeited if successful bidder fails to supply the goods/equipment in stipulated time or fails to comply with any of the terms & conditions of the contract or fail to sign the contract.

18. The bid shall be valid and open for acceptance by the competent authority of AIIMS Rishikesh for a period of 180 (one hundred eighty) days from the published date of opening of the tenders and no request for any variation in quoted rates and / withdrawal of tender on any ground by bidders shall be entertained. The unilateral withdraw at any stage will cause forfeiture of EMD in addition to any remedy that the purchaser may have under the law.

19. To assist in the analysis, evaluation and computation of the bids, the Competent Authority, may ask bidders individually for clarification of their bids. The request for Clarification and the response shall be in writing but no change in the price or substance of the bid offered shall be permitted.
20. After evaluation, the work shall be awarded normally to the Agency fulfilling all the conditions of the contract and who has quoted the lowest rate as per financial bid after complying with the all the Acts / provisions stated / referred to for adherence in the tender.
21. The competent authority of AIIMS, Rishikesh reserves all rights to accept or reject any/ all tender(s) without assigning any reason. It can also impose/relax any administrative term and condition/specifications of the tender enquiry after due discussion in pre-bid conference. This will be communicated and shown over the website of the Institute. No representation will be considered after pre-bid meeting and **bidders may ensure its queries only in pre-bid meeting.** AIIMS, Rishikesh also reserves the right to reject any bid which in his opinion is non-responsive or violating any of the conditions/specifications without any liability to any loss whatsoever it may cause to the bidder in the process.
22. Tender must be submitted on the prescribed Tender Form otherwise tender will be cancelled straightway.
23. The tender form is not transferable.
24. Canvassing in any form is strictly prohibited and the tenderers who are found canvassing are liable to have their tenders rejected out rightly.
25. It is required by all concerned, namely the Bidders/Suppliers, as the case may be to observe highest standard of ethics during the procurement and execution of this Tender.
26. Installation at consignee's site should be free of cost immediately on arrival of equipment at consignee's site.
27. In case the quality of goods supplied are not in conformity with the standard given in tender and as per the samples supplied or the supplies are found defective at any stage these goods shall immediately will be taken back by the supplier and will be replaced with the tender quality goods, without any delay. The competent authority reserves all rights to reject the goods if the same are not found in accordance with the required description / specifications and liquidates damages shall be charged in addition to the cost of re- tender. The supplier is required to provide the demonstration of equipment at AIIMS premises to the AIIMS representatives for its evaluation as per the specification & desired functionality standard. However, a submission of videography displaying functionality as per tender specification may also be considered by the AIIMS, representative.
28. In case the bidder on whom the supply order has been placed, fails to make supplies within the delivery schedule and the purchaser has to resort risk purchase, the purchaser (AIIMS, Rishikesh) may recover from the tender the difference between the cost calculated on the basis of risk purchase price and that calculated on the basis of rates quoted by tenderer. In case of repeated failure in supplying the order goods the supply order may be cancelled and bid security deposit will be forfeited.
29. Where the specifications are as per tenderer's range of products the tenderer's offer should mention that the item meets all specifications as per the tender enquiry and if there are improvements/deviations the same should be brought out on separate Letter Head of the firm. It would be discretion of the competent authority of the institute to accept or reject such deviations which are not in accordance with our required specifications as given below the financial bid.

30. It must be mentioned clearly whether bidder is a manufacturer/sole distributor/ sole agent for the items for which he is quoting.

- a. **Manufacturer** must add a certificate that item(s) is manufactured by them as per range of products.
- b. **Sole Manufacturers** must add a certificate that they are the sole manufacturer of the Item for which they are quoting in this tender enquiry & item is /are their proprietary Item in India. The rate certificate is also required from the sole manufactures that the Rates quoted are the same as they quote to other State/Centre Govt./reputed Private Organisation and DGS&D rate for the similar item(s) and these are not higher than those quoted by them.
- c. **Authorized agents** must add authority letter from their Manufacturer/Principals on the letter head of the manufacturer/principals signed by a competent person and comes in Proforma given in attach must duly supported by a notarised affidavit on Indian Non Judicial Stamp Paper of Rs.10/- (Rupees ten only) that they are quoting Rates on behalf of them. The authorization letter must give/mention the purpose for which it is allowed. The validity period of the authorization letter must be mentioned in the authority letter otherwise tender will be liable to rejection.

31. The bidders should have furnished a copy of GST/S.T. /C.S.T./VAT registration number, the State / U.T. of registration and the date of such registration. Tenders not complying with this condition will be rejected.

32. **Turnover provisions:** - (i) The tenderers should submit along with the tender, a photo state copy of the last three years Annual Accounts with Audit certificate by Chartered Accountant, Income Tax returns and a copy of current valid income tax clearance certificate (IT CC), otherwise bidder will not be considered for administrative evaluation (in evaluation of Technical bid) and will be declared **disqualified** in technical evaluation.

(ii) In case of bidder falls under Section 44AD/44ADA/44AE of Income Tax shall be required to submit turnover certificate verified by Chartered Accountant with his Registration number issued by Institute of Chartered Accountants of India.

(iii) In case of supplier is an Indian Agent, the firm can submit copies of purchase orders issued in favour of firm (*As the payment is made through LC directly to foreign manufacturer and equipment payment does not exist in the book of account of the supplier*) in support to its turnover whatever amount is getting short.

(iv) There will be relaxation on turnover on *case to case* basis for **Start-up firms** registered by Government of India under Start-ups scheme as per orders of Ministry of Commerce, Government of India.

33. **Sample/demonstration:** - In case, the item required prior submission of sample/ performing demonstration, tenderer will have to submit sample/perform demonstration of the equipment/item to the competent authority of the institute, the bidder will have to born all the expenses for the same. Non submission of sample/non performing demonstration will **disqualify** the bidder in the technical bidding process and financial bid of the bidder will not be opened.

34. The tenderer hereby guarantees that the equipment supplied to the Institute (purchaser) under the Contract shall be of the best quality/latest version and workmanship and new in all respects and shall be strictly in accordance with the specification and particulars contained/ mentioned in the Tender Document. The date of manufacturing of the equipment/goods supplied will not be more than 3 (Three months) old. The tenderer will have further guarantees that the said equipment would continue to conform to the description and quality aforesaid for a period of five (5) years guarantee period (As per MoH&FW guidelines), from the date of installation of the said equipment to the purchaser and notwithstanding the fact that the Purchaser (Inspector) may have inspected and /or approved the said equipment, if during the aforesaid period of five years the said equipment be discovered not to conform to the description and quality as required as per specification or not giving satisfactory performance or have deteriorated, the decision of the Purchaser in that behalf shall be final and binding on the tenderer and the Purchaser shall be entitled to call upon the tenderer to rectify the equipment or such portion thereof as is found to be defective by the purchaser within a reasonable period or such specified period as may be allowed by the purchaser in his discretion on/an application made thereof by the tenderer and in such an event, the above mentioned warranty period shall apply to the equipment replaced from the date of replacement thereof. In case of failure of the tenderer to rectify or replace the equipment, within specified time,

the purchaser shall be entitled to recover the cost with all expenses from the tenderer for such defective equipment.

35. Full description & specifications, make/brand and name of the manufacturing firm must be clearly mentioned in the tender, failing which, the tender will not be considered. The tenderer must also mention whether the goods are imported / indigenous. Descriptive literature / catalogues must be attached with the tender in original, failing which, tender may be disqualified.

36. Force Majeure: Any failure or omission to carryout of the provisions of this supply by the supplier shall not give right for any claim by supplier and purchaser to one against the other, if such failure or omission arise from an act of God which shall include all acts of natural calamities from civil strikes compliance with any statistics and or requisitions of the Government lockout and Strikes, riots, embargoes or from any political or other reasons beyond the suppliers control including war (whether declared or not) civil war or state of incarceration provided that notice of the occurrence of any event by either party to the other shall be within two weeks from the date of occurrence of such an event which could be attributed to force majeure. Any delay due to Force Majeure will not be attributable to the either of the parties.

37. The equipment installed should be up for 95% of the total warranty time. If the equipment is down for more than 5% suitable action shall be taken against the supplier including imposition of penalty as deemed fit.

38. If there is a close system the tenderer shall ensure and will have to submit an affidavit on Indian Non Judicial stamp paper of Rs.10/- along with technical bid that spare parts and consumables for these equipment's/instruments/item will be available at reasonable fixed rates for next 10 (ten) years, such rates should not be more than the rates supplied to institutes of national importance.

39. The successful Bidder shall at all times agree to indemnify and keep indemnified the purchaser against all losses, damages which may arise in respect of action/inactions of such Bidder or breach of any term of this tender by such Bidder. All claims regarding indemnity shall survive the termination of the contract with such Bidder.

40. In case the vendor fails to supply the spare parts or fails to provide the agreed maintenance during the prescribed period, as per the terms of contract, the purchaser is automatically entitled to procure the required parts and hire services from the market at the risk and cost of the vendor, such inability of bidder will entail forfeiture the security deposit. The purchaser also reserves the right to terminate the contract on immediate notice, if the vendor fails to comply with this clause for more than one instance.

41. Liquidated damage/demerge: - The time for the date of delivery/ dispatch stipulated in supply order shall be deemed to be the essence of the contract and if the supplier fails to deliver or dispatch any consignment within the period prescribed for such delivery or dispatch in the supply order, liquidated damages may be deducted from the bill @ 0.5% per week subject to maximum of 10% of the value of the delayed goods or services under the contract. The competent authority of the institute may also cancel the supply at the cost & liability of the supplier. In such a case, bid security of the supplier shall stand forfeited. The supply of equipment must be in single consignment, inclusive of all parts & accessories in adherence to the specification so as to make the equipment fully functional at the time of the installation. No installation repeat shall be signed in case of absence of any part as per the specification.

42. Legal Jurisdiction: -The Courts at Rishikesh/ Dehradun alone and no other Court will have the jurisdiction to try the matter, dispute or reference between the parties arising out of this tender/supply Order/contract.

Applicable Law:

43. The contract shall be governed by the laws and procedures established by Govt. of India, within the framework of applicable legislation and enactment made from time to time concerning such Commercial dealings / processing.

44. Any disputes are subject to exclusive jurisdiction of Competent Court and Forum in Rishikesh/Dehradun, Uttarakhand India only.

45. Except as otherwise provided under this Contract for immediate termination of the Contract, in the event of a disputes which may be arising out of the execution of the tender contract, the matter will be referred to the Deputy Director (Administration). Appeal against the decision of the DDA will lie to the Director, AIIMS Rishikesh and his decision shall be final and binding upon both the parties.

46. At the time of awarding the contract, the purchaser reserves the right to increase or decrease up to twenty-five (25%), the quantity of goods (round of to next whole number) without any change in the unit price and other terms & conditions quoted by the bidder.

I / We hereby accept the terms and Conditions given in the tender

(Signature & Stamp of the bidder)

Note- Please sign each page of document including terms & conditions & tender

(B) Financial terms and conditions

1. Bidders are requested to note that they should necessarily submit their financial bids in the format provided and no other format is acceptable. If the price bid has been given as a standard BoQ format with the tender document, then the same is to be downloaded and to be filled by all the bidders. Bidders are required to download the BoQ file, open it and complete the white coloured (unprotected) cells with their respective financial quotes and other details (such as name of the bidder). No other cells should be changed. Once the details have been completed, the bidder should save it and submit it online, without changing the filename. If the BoQ file is found to be modified by the bidder, the bid will be rejected.
2. Rates quoted should be inclusive of all applicable taxes, packing, forwarding, postage and transportation charges at for AIIMS Rishikesh (Site of installation/Use). Rates should be mentioned both in figures and in words.
3. The supplier has to submit a notarised affidavit on Indian Non Judicial Stamp Paper of Rs.10/- that the bidder has not quoted the price higher than previously supplied to any government Institute/Organisation/reputed Private Organisation or DGS&D rate in recent past. Therefore, if at any stage it has been found that the supplier has quoted lower rates than those quoted in this tender; the Institute (the purchaser) would be given the benefit of lower rates by the Supplier and any excess payment if any, will become immediately payable to the AIIMS, Rishikesh. If such affidavit is not submitted, tender will be out rightly rejected. **(Part of technical bid)**
4. **Guarantee / Warrantee Period:** The Tenderers must quote for 5 years' comprehensive warranty (Including all Spares, Accessories software application, if any and Labor) from the date of completion of the satisfactory installation. The warranty charges shall not be quoted separately otherwise the offer shall be summarily rejected. Also the bidders are requested to submit their quote (Rates) for subsequent 5 years Comprehensive Maintenance Contract (CMC) (Including All Spares, Accessories software application, if any and Labor). Failure to comply this condition will entail the rejection of the bids. The price comparison shall be taken into account on basic price and post warranty CMC.
4. **Custom Clearance:** For the Goods to be imported and supplied, the Institute will provide Custom Duty Exemption Certificate (CDEC) to successful bidder for availing concessional rate of duty as per prevailing Custom Tariff. In case, the bidder requires CDEC certificate, then the same should be specifically mentioned in the bid. The supplier is solely responsible for getting the material clearance from customs. Institute will provide all custom documents for custom clearance on the demand of supplier. The supplier undertakes to fully co-operate to avoid any fine, demurrage or other charges and shall indemnify AIIMS Rishikesh in case of any such failure. Transportation of goods up to AIIMS, Rishikesh and its successful installation and commissioning demonstration (and training, if required) is also the responsibility of the supplier. All charges/ expenses incurred in this process will be borne by the supplier and after submission of deposit slips of custom clearance and transportation charges will be reimbursed to the supplier if said provisions are to be shown separately in the financial bid.
5. **Payment terms:** -If the supplier supplied the requisite item within stipulated time and installation is pending on the part of AIIMS Rishikesh on various reasons, up to 90 *per cent* payment against supply can be made by the AIIMS Rishikesh on the case wise only, but will not be considered as precedence in all cases.
(A)Payment Term for Imported goods: For imported goods payment shall be made in the following manner:
 - a) On shipment: 50 % payment of the contract price shall be paid 60 days after presentation of shipping documents {goods shipped shall be paid through irrevocable, non-transferable Letter of Credit (LC) opened in favor of the supplier in a bank in his country} and upon the submission of the following documents: -

- I. Four copies of Supplier's invoice showing contract number, goods description, quantity, unit price and total amount;
- II. Original and four copies of the clean, on-board Bill of Lading/ Airway bill, marked freight prepaid and four copies of non-negotiable Bill of Lading/Airway bill.
- III. Insurance Certificate;
- IV. Certificate of origin by the chamber of commerce of the concerned country;
- V. Certificate of country of origin;
- VI. Manufacture's / Supplier's warranty certificate;
- VII. Manufacturer's own factory inspection report.

- i. **On Acceptance:** 50 % payment would be made after satisfactory installation, commissioning, demonstration and training, if required on issuance of Inspection certificate by the AIIMS, Rishikesh.

B) PAYMENT TERMS FOR INLAND GOODS

(Fifty) 50% Payment of the contract price shall be paid on receipt of goods condition and upon the submission of the following documents: -.

- (i) One Original and Four Copies of supplier's invoice showing contract number, goods description, quantity, unit price and total amount.
- (ii) Final Acceptance as per Inspection report issued by faculty.
- (iii) Two copies of packing list identifying contents of each package.
- (iv) Inspection Certificate issued by the user concerned department.
- (v) Final Acceptance Certificate issued by the Institute

On Acceptance: -

- (i) Balance Fifty (50) % payment would be made against 'Final Acceptance Certificate' as per Para (B) (i) &(v) of goods to be issued by the consignee's subject to recoveries, if any, either on account of non-rectification of defects/deficiencies not attended by the Supplier or otherwise.

6. **L1 Clause:** L1 firm will be decided on the basis of Total Price in addition with the CMC charges quoted by the firm. The CMC charges should be quoted separately in format provided in pdf.

NO DEMURRAGE / WHARFAGE CHARGES WILL BE PAYABLE BY THE INSTITUTE UNDER ANY CIRCUMSTANCES. NO ADVANCE PAYMENT WILL BE PAYABLE FOR CUSTOM CLEARANCE/ FREIGHT/INSURANCE ETC

Note: In case of any dispute regarding award of tender, decision of AIIMS Administration would be final.

I / We hereby accept the terms and Conditions given in the tender

(Signature & Stamp of the bidder)

Portable ECMO Machine
for Department of CTVS, AIIMS, Rishikesh
TECHNICAL BID
(Documents to be attached in the “Technical Bid”)

| | |
|--|---|
| 1. Name, full Address, telephone/mobile number, Email Id of the manufacturer and their authorised dealers/ distributors/Agency. | |
| 2. Specify your firm/company is a manufacturer/ authorised dealer/ distributor/ Agency. | |
| 3. Whether the signature on each page of the tender document and other relevant documents has been made by the bidder or not. (Signature on each page of tender document and other document is necessary) | |
| 4. Name, Address & designation of the authorized person(s) (Sole proprietor/partner /Director) | |
| 5. Clarification/declaration of Power of Attorney/authorization for signing the bid documents (It is not required in case of sole-proprietorship.) | |
| 6. PAN No. (Please attach scanned copy) | |
| 7. GST/VAT/Service Tax Registration Number. (Please attach copy) | |
| 8. Please attach copy of last three year’s Income Tax Return. | |
| 9. Turnover a. Please attach balance sheet (duly certified by Chartered Accountant) for last three (3) years (average minimum turnover for last three years should not be less than Rs 42 Lakhs (Rupees Forty-Two Lakhs only). Submit last three year’s turnover statement duly certified by the Chartered Accountant in the format shown in Annexure- A). b. The bidder falls under Section 44AD/44ADA/44AE of Income Tax Act shall be required to submit turnover certificate verified by Chartered Accountant with his Registration number issued by Institute of Chartered Accountants of India. c. Indian Agent can submit its copy of POs of LC cases, in support of its amount getting short in required turnover. d. Start-ups may submit its Start-up Registration for consideration (<i>Relaxation in turnover can be considered as the case may be, subject to fulfilment of other conditions. However, it will not be mandatory</i>) | |
| 10. Please provide a notarised affidavit on Indian Non Judicial stamp paper of Rs. 10/- in the format given in Annexure-1 that you have not quoted the price higher than previously supplied to any government Institute/Organisation/reputed Private Organisation or DGS&D/GeM rate in last two years . If you don’t fulfil this criterion, your tender will be out rightly rejected. | |
| 11. Please submit a notarised affidavit on Indian Non Judicial Stamp Paper of Rs.10/- in the format given in Annexure- 2 that they will provide complete warranty for all equipment/items for 5 (five) years followed by CMC for further 5 (five) years of these equipment/items. | |
| 12. Please furnish a notarised affidavit on Indian Non judicial stamp paper of Rs.10/- in the format given in Annexure- 3 that they will supply spare parts & consumables for next 10 years at reasonable price by submission of suitable benchmarks. | |
| 13. Please submit a notarised affidavit on Indian Non judicial stamp paper of Rs. 10/- in the format given in Annexure- 4 that no case is pending with the police against the Proprietor/firm/partner or the Company (Agency). Indicate any convictions in the past against the Company/firm/partner. | |
| 14. Please declare that proprietor/firm/company has never been blacklisted/debarred by any organization. An oath certificate to this effect may be enclosed on Rs.10 notarised Indian Non Judicial stamp paper in the format given in Annexure- 5 | |
| 15. Please submit a notarised affidavit for miscellaneous declarations on Indian Non Judicial stamp paper of Rs. 10/- in the format as given in Annexure- 6 . | |
| 16. Have you previously supplied these items to any government/ reputed private organization? If yes, attach the relevant poof. | |
| 17. Please submit two performance certificate from your two different customers to whom you have supplied such type of equipment in previous 3 years | |
| 18. Acceptance of terms & conditions attached (Yes/No). Please sign each page of terms and conditions as token of acceptance and submit as part of tender document with technical bid. Otherwise your tender will be rejected. | |
| 19. Details of the FD/DD/TD/CD of bid security (EMD) FD/DD/TD/CD No: Date: Payable at- | Detail of cost of Tender for Rs. 1180/- (if downloaded from website) DD No. Date: Payable at- |

ANNUAL TURNOVER STATEMENT
(At the Letter Head of Chartered Accountant)

I/We have examined the books of account and other relevant records of (bidding firm name), having its registered office at (full address of bidding firm) and do hereby certify that:

(1) Annual gross turnover as per Annual Accounts of the firm for last three years is as under-

| Sl. No. | Financial Year | Turnover (In INR) |
|----------------|-----------------------|--------------------------|
| 1. | 2016- 2017 | |
| 2. | 2017- 2018 | |
| 3. | 2019- 2020 | |

(2) Average turnover of the firm for last three financial years is Rs.

Signature of CA (with stamp of Firm)

Name-

(Registration No.-)

(Chartered Accountant)

Date-

Place-

Annexure -1

NOTARISED AFFIDAVIT

(On Rs. 10/- Non-Judicial Stamp Paper)

TENDER NO.

I, undersigned (name).....(designation)....., duly authorised representative of (name of Proprietorship/Firm/Company/Agency) hereby undertake, affirm, confirm and declare that-

Proprietorship/Firm/Company/Agency **has not quoted price in this Tender higher than one** at which goods/services were previously supplied to any government Institute/ Organisation/ reputed Private Organisation or DGS&D rate in last two years. If at any stage it is found that the firm (bidder) has quoted lower rates to any Govt./ Private Institute, Bidder shall be liable to payback access value to AIIMS Rishikesh. AIIMS Rishikesh further reserves right to impose suitable penalty shall be made by AIIMS Rishikesh.

Undersigned, on behalf of Proprietorship/Firm/Company/Agency does hereby solemnly declare and affirm that the above declaration is true and correct in all respects and we hold responsibilities for the same. No part of it is false and nothing has been concealed. Any false/incorrect submission shall make Proprietorship/Firm/Company/Agency as well as undersigned personally liable for all civil/criminal obligations including complaint to police and other authorities.

Deponent Signature:

Name:

Designation:

Aadhaar No:

Email Id:

Mobile No:

Landline No:

Fax No:

Address:

(Copy of Authorisation Letter from Proprietorship/Firm/Company/Agency enclosed)

NOTARISED AFFIDAVIT

(On Rs. 10/- Non-Judicial Stamp Paper)

TENDER NO.

I, undersigned (name).....(designation)....., duly authorised representative of (name of Proprietorship/Firm/Company/Agency) hereby undertake, affirm, confirm and declare that-

Undersigned undertake to provide **complete warranty** for all equipment / items for 5 (five) years followed by **CMC for further (5) five years (6th to 10th years)** for these equipment/ items.

Undersigned, on behalf of Proprietorship/Firm/Company/Agency does hereby solemnly declare and affirm that the above declaration is true and correct in all respects and we hold responsibilities for the same. No part of it is false and nothing has been concealed. Any false/incorrect submission shall make Proprietorship/Firm/Company/Agency as well as undersigned personally liable for all civil/criminal obligations including complaint to police and other authorities.

Deponent Signature:

Name:

Designation:

Aadhaar No:

Email Id:

Mobile No:

Landline No:

Fax No:

Address:

(Copy of Authorisation Letter from Proprietorship/Firm/Company/Agency enclosed)

NOTARISED AFFIDAVIT

(On Rs. 10/- Non-Judicial Stamp Paper)

TENDER NO.

I, undersigned (name).....(designation)....., duly authorised representative of (name of Proprietorship/Firm/Company/Agency) hereby undertake, affirm, confirm and declare that-

We undertake that we will supply spare parts and consumables for next 10 years at reasonable price by submission of suitable benchmark of Institute of national importance/ reputed institute.

Undersigned, on behalf of Proprietorship/Firm/Company/Agency does hereby solemnly declare and affirm that the above declaration is true and correct in all respects and we hold responsibilities for the same. No part of it is false and nothing has been concealed. Any false/incorrect submission shall make Proprietorship/Firm/Company/Agency as well as undersigned personally liable for all civil/criminal obligations including complaint to police and other authorities.

Deponent Signature:

Name:

Designation:

Aadhaar No:

Email Id:

Mobile No:

Landline No:

Fax No:

Address:

(Copy of Authorisation Letter from Proprietorship/Firm/Company/Agency enclosed)

NOTARISED AFFIDAVIT
(On Rs. 10/- Non-Judicial Stamp Paper)

TENDER NO.

I, undersigned (name).....(designation)....., duly authorised representative of..... (name of Proprietorship/Firm/Company/Agency) hereby undertake, affirm, confirm and declare that-

No criminal case is pending with the Police against our Proprietorship/Firm/Company/Agency or any of its authorized signatories.

Undersigned, on behalf of Proprietorship/Firm/Company/Agency does hereby solemnly declare and affirm that the above declaration is true and correct in all respects and we hold responsibilities for the same. No part of it is false and nothing has been concealed. Any false/incorrect submission shall make Proprietorship/Firm/Company/Agency as well as undersigned personally liable for all civil/criminal obligations including complaint to police and other authorities.

Deponent Signature:

Name:

Designation:

Aadhaar No:

Email Id:

Mobile No:

Landline No:

Fax No:

Address:

(Copy of Authorisation Letter from Proprietorship/Firm/Company/Agency enclosed)

NOTARISED AFFIDAVIT

(On Rs. 10/- Non-Judicial Stamp Paper)

TENDER NO.

I, undersigned (name).....(designation)....., duly authorised representative of(name of Proprietorship/Firm/Company/Agency) hereby undertake, affirm, confirm and declare that-

Proprietorship/Firm/Company/Agency has never been **blacklisted/ debarred** by any organization.

Undersigned, on behalf of Proprietorship/Firm/Company/Agency does hereby solemnly declare and affirm that the above declaration is true and correct in all respects and we hold responsibilities for the same. No part of it is false and nothing has been concealed. Any false/incorrect submission shall make Proprietorship/Firm/Company/Agency as well as undersigned personally liable for all civil/criminal obligations including complaint to police and other authorities.

Deponent Signature:

Name:

Designation:

Aadhaar No:

Email Id:

Mobile No:

Landline No:

Fax No:

Address:

(Copy of Authorisation Letter from Proprietorship/Firm/Company/Agency enclosed)

NOTARISED AFFIDAVIT

(On Rs. 10/- Non-Judicial Stamp Paper)

TENDER NO.

I, undersigned (name).....(designation)....., duly authorised representative of (name of Proprietorship/Firm/Company/Agency) hereby undertake, affirm, confirm and declare that-

1. Undersigned is fully competent and authorised from Proprietorship/Firm/Company/Agency to make this Affidavit to bind such Proprietorship/Firm/Company/Agency.
2. All details/information/documents furnished by Proprietorship /Firm/ Company/Agency in bid document is true and correct.
3. Proprietorship/Firm/Company/Agency is fully solvent and legally/financially competent to perform terms and conditions of Tender.
4. Proprietorship/Firm/Company/Agency is duly registered under various relevant government notifications and all dues have been paid as on date.
5. Proprietorship/Firm/Company/Agency hereby agrees and fully understands that notwithstanding anything contrary contained in Tender document and without prejudice to any of the rights or remedies of AIIMS Rishikesh, AIIMS Rishikesh shall be entitled in its sole discretion to determine that a bidder is to be disqualified at any stage of the process and its participation in Tender process and/or its Technical Proposal and/or Financial Bid dropped from further consideration for any reasons.

Undersigned, on behalf of Proprietorship/Firm/Company/Agency does hereby solemnly declare and affirm that the above declarations are true and correct in all respects and we hold responsibilities for the same. No part of it is false and nothing has been concealed. Any false/incorrect submission shall make Proprietorship/Firm/Company/Agency as well as undersigned personally liable for all civil/criminal obligations including complaint to police and other authorities.

Deponent Signature:

Name:

Designation:

Aadhaar No:

Email Id:

Mobile No:

Landline No:

Fax No:

Address:

(Copy of Authorisation Letter from Proprietorship/Firm/Company/Agency enclosed

Undertaking

1. I/We have read and understood the contents of the Tender and agree to abide by the terms and conditions of this Tender.
2. I/We shall supply the items of requisite quality and quantity at given rate in timely manner.
3. I/We also confirm that in the event of my/our tender being accepted, I/we hereby undertake to furnish within 15 days, Bank Guarantee/ Performance Security after the issue of Purchase Order, as applicable, in the format to be provided by AIIMS Rishikesh in addition to execution of a Contract as pre-condition for obtaining the supply orders.
4. I/We further undertake that none of the Proprietor/Partners/Directors of the firm was or is Proprietor or Partner or Director of any firm with whom the Government have banned /suspended business dealings. I/We further undertake to report to the AIIMS Rishikesh immediately after we are informed but in any case not later 15 days, if any firm in which Proprietor/Partners/Directors are Proprietor or Partner or Director of such a firm which is banned/suspended in future during the currency of the Contract with you.
5. I/We undertake that the information given in this tender are true and correct in all respect and I/We hold the responsibility for the same.

(Signature of the Bidder)

Name:

Designation with Seal of the Firm:

**“Portable ECMO Machine
for Department of CTVS”**

AIIMS, Rishikesh

Chapter-II (Schedule of requirements& EMD)

Table-I

Details of items & their tentative quantity and EMD

The following items manufactured by Indian/International firms of repute are required.

| S.N. | Item | Quantity | EMD |
|-------------|--|-----------------|-------------------|
| 1 | Portable ECMO Machine for Department of CTVS | 01 (One) | 1,75,000/- |
| | In word: One Lakhs Seventy Five Thousands Only. | | |

MANUFACTURER's / PRINCIPAL's AUTHORIZATION FORM

(Clause 11 (c) of **other terms and conditions** of the tender)

To

The Administrative Officer,
All India Institute of Medical Sciences
Rishikesh

Dear Sir,

TENDER: _____.

we, _____, who are established and reputable manufacturers of _____, having factories at _____ and _____, hereby authorize Messrs. _____ (*name and address of agents*) to bid, negotiate and conclude the contract with you against Tender No. _____ for the above goods manufactured by us.

We hereby extend our full guarantee and warranty as per the conditions of tender contract for the goods offered for supply against this tender by the above firm.

The authorization is valid up to _____

Yours faithfully,

(Name)

For and on behalf of Messrs. _____
(*Name of manufacturers*)/Principal.

BANK GUARANTEE FORM FOR PERFORMANCE SECURITY/ CMC SECURITY

To

The Administrative Officer

All India Institute of Medical Sciences
Rishikesh,
Virbhadr Marg,
Rishikesh-249201

WHEREAS _____ (Name and address of the supplier) (Hereinafter called “the supplier”) has undertaken, in pursuance of contract no _____ dated _____ to supply (description of goods and services) (herein after called “the contract”). AND WHEREAS it has been stipulated by you in the said contract that the supplier shall furnish you with a bank guarantee by a scheduled commercial bank recognized by you for the sum specified therein as security for compliance with its obligations in accordance with the contract; AND WHEREAS we have agreed to give the supplier such a irrevocable bank guarantee;

NOW THEREFORE we hereby affirm that we are guarantors and responsible to you unconditionally, on behalf of the supplier, up to a total of _____ (Amount of the guarantee in words and figures), and we undertake to pay you, upon your first written demand declaring the supplier to be in default under the contract and without cavil or argument, any sum or sums within the limits of (amount of guarantee) as aforesaid, without your needing to prove or to show grounds or reasons for your demand or the sum specified therein.

We hereby waive the necessity of you to first demanding the said amount of guarantee from the supplier before raising the demand with us. You may directly raise the demand with us, without asking the supplier for the same.

We further agree that no change or addition to or other modification of the terms of the contract to be performed there under or of any of the contract documents which may be made between you and the supplier shall in any way release us from any liability under this guarantee and we hereby waive notice of any such change, addition or modification.

This guarantee will not be changed due to change in the constitution of the bank or the supplier.

This guarantee shall be valid up to 65 months from the date of satisfactory installation of the equipment i.e. up to ----- (indicate date).

.....
(Signature with date of the authorized officer of the Bank)

.....
Name and designation of the officer

.....
Seal, name & address of the Bank and address of the Branch

Instructions for Online Bid Submission:

The bidders are required to submit soft copies of their bids electronically on the CPP Portal, using valid Digital Signature Certificates. The instructions given below are meant to assist the bidders in registering on the CPP Portal, prepare their bids in accordance with the requirements and submitting their bids online on the CPP Portal.

More information useful for submitting online bids on the CPP Portal may be obtained at: <https://eprocure.gov.in/eprocure/app>.

REGISTRATION

- Bidders are required to enrol on the e-Procurement module of the Central Public Procurement Portal (URL: <https://eprocure.gov.in/eprocure/app>) by clicking on the link “Online bidder Enrolment” on the CPP Portal which is free of charge.
- As part of the enrolment process, the bidders will be required to choose a unique username and assign a password for their accounts.
- Bidders are advised to register their valid email address and mobile numbers as part of the registration process. These would be used for any communication from the CPP Portal.
- Upon enrolment, the bidders will be required to register their valid Digital Signature Certificate issued by any Certifying Authority recognized by CCA India (e.g. Sify / nCode / eMudhra etc.), with their profile.
- Only one valid DSC should be registered by a bidder. Please note that the bidders are responsible to ensure that they do not lend their DSC’s to others which may lead to misuse.
- Bidder then logs in to the site through the secured log-in by entering their user ID / password and the password of the DSC / e-Token.

SEARCHING FOR TENDER DOCUMENTS

- There are various search options built in the CPP Portal, to facilitate bidders to search active tenders by several parameters. These parameters could include Tender ID, Organization Name, Location, Date, Value, etc. There is also an option of advanced search for tenders, wherein the bidders may combine a number of search parameters such as Organization Name, Form of Contract, Location, Date, Other keywords etc. to search for a tender published on the CPP Portal.
- Once the bidders have selected the tenders they are interested in, they may download the required documents / tender schedules. These tenders can be moved to the respective ‘My Tenders’ folder. This would enable the CPP Portal to intimate the bidders through SMS / email in case there is any corrigendum issued to the tender document.
- The bidder should make a note of the unique Tender ID assigned to each tender, in case they want to obtain any clarification / help from the Helpdesk.

PREPARATION OF BIDS

- Bidder should take into account any corrigendum published on the tender document before submitting their bids.

- Please go through the tender advertisement and the tender document carefully to understand the documents required to be submitted as part of the bid.
- Please note the Number of covers in which the bid documents have to be submitted, the number of documents - including the names and content of each of the document that need to be submitted. Any deviations from these may lead to rejection of the bid.
- Bidder, in advance, should get ready the bid documents to be submitted as indicated in the tender document / schedule and generally, they can be in PDF / XLS / RAR / DWF/JPG Tender No.: formats. Bid documents may be scanned with 100 dpi with black and white option which helps in reducing size of the scanned document.
- To avoid the time and effort required in uploading the same set of standard documents which are required to be submitted as a part of every bid, a provision of uploading such standard documents (e.g. PAN card copy, annual reports, auditor certificates etc.) has been provided to the bidders. Bidders can use “My Space” or “Other Important Documents” area available to them to upload such documents. These documents may be directly submitted from the “My Space” area while submitting a bid, and need not be uploaded again and again. This will lead to a reduction in the time required for bid submission process.

SUBMISSION OF BIDS

- Bidder should log into the site well in advance for bid submission so that they can upload the bid in time i.e. on or before the bid submission time. Bidder will be responsible for any delay due to other issues.
- The bidder has to digitally sign and upload the required bid documents one by one as indicated in the tender document.
- Bidder has to select the payment option as “offline” to pay the tender fee / EMD as applicable and enter details of the instrument.
- Bidder should prepare the EMD as per the instructions specified in the tender document. The original should be posted/couriered/given in person to the concerned official, latest by the last date of bid submission or as specified in the tender documents. The details of the DD/any other accepted instrument, physically sent, should tally with the details available in the scanned copy and the data entered during bid submission time. Otherwise the uploaded bid will be rejected.
- Bidders are requested to note that they should necessarily submit their financial bids in the format provided and no other format is acceptable. If the price bid has been given as a standard BoQ format with the tender document, then the same is to be downloaded and to be filled by all the bidders. Bidders are required to download the BoQ file, open it and complete the white coloured (unprotected) cells with their respective financial quotes and other details (such as name of the bidder). No other cells should be changed. Once the details have been completed, the bidder should save it and submit it online, without changing the filename. If the BoQ file is found to be modified by the bidder, the bid will be rejected.
- The server time (which is displayed on the bidders’ dashboard) will be considered as the standard time for referencing the deadlines for submission of the bids by the bidders, opening of bids etc. The bidders should follow this time during bid submission.
- The documents being submitted by the bidders would be encrypted using PKI encryption all techniques to ensure the secrecy of the data. The data entered cannot be viewed by unauthorized persons until the time of bid opening. The confidentiality of the bids is maintained using the secured Socket Layer 128 Bit encryption technology. Data storage encryption of sensitive fields is done. Any bid document that is uploaded to the server is subjected to symmetric encryption using a system generated symmetric key
- Further this key is subjected to asymmetric encryption using buyers/bid opener’s public keys. Overall, the uploaded tender documents become readable only after the tender opening by the authorized bid openers.

- The uploaded tender documents become readable only after the tender opening by the authorized bid openers.
- Upon the successful and timely submission of bids (i.e. after Clicking “Freeze Bid Submission” in the portal), the portal will give a successful bid submission message & a bid Tender No.: summary will be displayed with the bid no. and the date & time of submission of the bid with all other relevant details.
- The bid summary has to be printed and kept as an acknowledgement of the submission of the bid. This acknowledgement may be used as an entry pass for any bid opening meetings.

ASSISTANCE TO BIDDERS

- Any queries relating to the tender document and the terms and conditions contained therein should be addressed to the Tender Inviting Authority for a tender or the relevant contact person indicated in the tender.
- Any queries relating to the process of online bid submission or queries relating to CPP Portal in general may be directed to the 24x7 CPP Portal Helpdesk number 0120-4200462, 0120- 4001002.

Note:

-
As per clarification sought from ministry of MSME vide F.no.21(11)/2018- MA dated 31st December 2018, “Traders/Sole Agents/ Distributors are excluded to avail the facilities/ Benefits extended under the Public Procurement for Micro and Small Enterprises(MSMEs)

Ref: As circulated in Office Memorandum No. F.No.22(1)/2012-MA dated 24th October, 2016 in FAQs, Question No. 18.

Specification of Portable ECMO

1. Centrifugal Pump (Console with its Accessories)
 - a) Should work on power supply 100 V to 240 V, 50Hz to 60 Hz and 11V to 28 V DC
 - b) Should generate 0 to 50000 RPM
 - c) Should be able to flow 0.1 to 9.99 Litres per minute.
 - d) Should have compact, lightweight console (approx. 10 kg weight)
 - e) Should have LCD display screen (5 .5” -7”)
 - f) Should display following parameters or should provide additional monitor for monitoring
 - 04 no’s of External Pressures (Measuring Range – 50 to 900 mm Hg)
 - 03 no’s of Internal Pressures (Measuring Range – 50 to 900 mm Hg)
 - 02 no’s of External Temperatures (Measuring Range – 10 to 45°C)
 - 02 no’s of Internal Temperatures (Measuring Range – 10 to 45°C)
 - 01 no Venous Blood Oxygen Saturation (SvO₂) (measuring range – 40 to 100%)
 - 01 no Hemoglobin (Measuring Range 05 to 15 gm/d)
 - 01 no Hematocrit (Measuring range 15 to 50%)
 - 01 no flow sensor with integrated Bubble sensor which measures Blood Flow Rate and Bubbles respectively
 - 01 no Bubble sensor measuring Bubbles in the Blood Stream
 - g) Portable Emergency Hand Crank
 - h) Back Flow Prevention mode (Zero Flow Mode)
 - i) Recording of Data, I the unit (interval – 3 sec’s to 10 mins) and retrieval of the same into a USB memory stick or into a Computer.
 - j) 03 no’s of resettable Clock Timers.
 - k) 01 no of Countdown Timer
 - l) 03 modes of Application
 - Operating Room mode
 - Intensive Care Unit mode
 - Transport mode
 - m) 03 modes of Control
 - LPM mode
 - RPM mode
 - Night mode
 - n) Battery Backup 90 mins.
 - o) 01 no. connection for alarm output (Ward Call)
 - p) 01 no. connection for Ethernet Cable
 - q) 01 no. connection for External Drive
 - r) 01 no. connection for ECG signal
 - s) Should have Road and Air Transport Approval
2. Heating Unit with its accessories
 - a) Temperature range setting form 33°C to 39°C
 - b) Digital display for set temperature and outlet temperature
 - c) Compact & light weight console (9 kg weight)
 - d) To work on power supply 230 V, 50 Hz
 - e) Should generate 03 to 05 LPM, 0.34 bar pressures
 - f) Water Capacity 0.7 to 1.4 Ltrs.
 - g) Heat resistant Tubings with Hansen Coupling for quick connection
3. Sprinter Cart

- a) Advanced card design maximizing safety and convenience to move compete anywhere
- b) Infusion pole mast (Height adjustable)
- c) Gas Cylinder holder for better portability
4. Air-Oxygen Blender:
 - a) Mechanical air oxygen blender with hoses
5. Disposables:

Kit should include or should be provided with

 - a) Hollow fiber Diffusion membrane oxygenator (Poly Methyl Pentene Fiber) with 30 day CE certification for usage
 - b) Centrifugal Pump Head or any rotary pump
 - c) PVC tubing which make a circuit with 30 days CE certification of usage
 - d) Tip to tip Bioline Coating (Albumin + Heparin) or any Coating
 - e) Oxygenator unit includes a hollow fiber Heat Exchanger with very less pressure drop
 - f) Circuit minimized to its basic minimum components.
 - g) De-airing membrane in oxygenator
 - h) Integrated Sensors for Pressures (Venous Arterial and Internal) and Temperature (Arterial and Venous) monitoring.
 - i) Should have integrated Measuring Cell for Venous probe to measure Venous Oxygen saturation (SvO₂), Hemoglobin, Hematocrit and Venous Temperature
6. The quoted price should include the cost of the basic unit **and** cost of five set of disposable kit. (four full kit for use in an adult patient + one full kit for use in Paediatric patient)
7. Rates of the chargeable accessories should be quoted for the total period 5 years and should be frozen for that duration.
8. Five set of disposables should be supplied with machine for smooth starting of ECMO program.

General Conditions applicable to each tendered equipment:

- (i) There would be guarantee (with spares) for five years and additional warranty for five years.
- (ii) The product should be quoted with all the accessories. The price of all the accessories should also be quoted separately.
- (iii) The price of major spares parts should be quoted separately. The price would be fixed for the warranty period.
- (iv) The product or its earlier model should have been marketed in international market for at least 4 years.
- (v) If the equipment is software based, and new software is introduced within five years, the up gradation will be provided free of cost.
- (vi) The department may ask for demonstration of actual quoted product or even for trial use.
- (vii) If necessary, training of the personnel for the use of the equipment will be provided by the company vendor.
9. Compliance Statement: The vendor must provide, in tabular form a comparative chart of the required technical specification and technical specification of the quoted product. The vendor must give the relevant page number and paragraph number, in their literature regarding that technical information in the technical bid. Merely stating “complies” or meets requirement” will lead to assumption that the quoted product does not have the required feature.
10. We need FDA/CE/BIS approval.