



ITI LIMITED

R&D

BENGALURU PLANT

DOORAVANINAGAR

BENGALURU-560016

**ISO 13485 Certification for Non-Invasive
Ventilator**

Tender Reference:

R212G0003

Dated: 20.07.2022

**R&D, ITI LIMITED,
BANGALORE
REQUEST FOR PROPOSAL**

**Invitation of Bids for ISO 13485 Certification for
Non-Invasive Ventilator**

IMPORTANT INFORMATION

e-Tender for R&D, ITI LIMITED, BANGALORE for R&D, ITI Limited,
Bengaluru - reg.

IMPORTANT INFORMATION

Sl.No	Items	Description
1	Scope of work	ISO 13485 Certification for Non-Invasive Ventilator for R&D, ITI Limited, Bangalore.
2	Tender Reference	R212G0003 Dated: 20.07.2022
3	Cost of bid documents	NIL
4	Date of uploading of Tender Document on website/ Portal	20 th July, 2022
5	Last Date & Time for upload/ submission of bid	3 rd August, 2022 @1600 HRS
6.	Date of opening of technical bid	4 th August, 2022@1000HRS
7	Date of opening of financial bid	Will be communicated to technically successful bidders

8	FORMING PART OF BID DOCUMENT I. Bidders/firms who fulfil the requirements as mentioned in this tender document shall be eligible to apply. II. On tender opening date, the bidders can login and see the bid opening process. III. Bidder can upload documents in the form of PDF format only IV. If any cell is left blank and no rate is quoted by the bidder, rate of such item shall be treated as "o" (ZERO). V. Technical bids shall be opened first on the date and time as mentioned above. Financial bids of Bidders/firms who qualified in technical evaluation will be opened on a later date.	
9.	Place of opening of bids	ITI Limited, Bengaluru Plant
10.	Address for communication	R&D Purchase , Bangalore Plant, ITI Limited, Bangalore-560016 Phone: 080-28503675 E-mail: mmr_bgp@itilttd.co.in

Note: In the case of non-submission of the Mandatory documents, the Bid would be rejected.

For any clarification / queries related to uploading in e-Tender Portal, kindly contact our e-tender partner Mr. Dhanraj (Antares) email: ghanraj.p@antaressystems.com; MOB: 9686115308

Certification required for Portable Non-Invasive Ventilator

Introduction:

ISO 13485 Certification to be carried out as per NABCB for Design & Development, Manufacturing and Supply of ITI Portable Non Invasive ventilator. The ISO13485 document will be uploaded in Central Drugs Standard Control Organisation (CDSCO) under Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India for obtaining the Registration Number and manufacturing License manufacturing License from CDSCO.

Scope of work:

Implementation of MDQMS ISO 13485 Certification for Manufacturing Portable Non Invasive Ventilator in M/s. ITI Ltd, Doorvani Nagar , Bangalore-560016. The vendor should prepare necessary process documents. All required documentation to be prepared along with ITI team for obtaining ISO 13485 and conducting the Audit by the vendor.

Audit:

- i. Initial Audit
 - a. Document Preparation: Vendor with ITI team
 - b. Document Review: Review of the documents and analysing gaps in the system.
 - c. Stage 1- Audit
 - d. Stage 2- Audit (Certification)
- ii. 1st Surveillance Audit: 1st Year
- iii. 2nd Surveillance Audit: 2nd Year

Organisational inputs (Design , Manufacturing , Marketing):

M/s.ITI Ltd (Central Public Sector Unit)
Doorvani Nagar
Bangalore-560016
Total Staff: 25
No. of Shifts: 01
No. of Sites: 01
Work completion time: 2 Months

Terms & Conditions of eligibility to participate in Tender:

- 1) The Vendor has to submit Technical and Commercial bids separately.
- 2) Payment terms to be clearly indicated.
- 3) The vendor should conduct the Audit (on-site/ off-site). Travelling or other expenses if any should be borne by the vendor.
- 4) The vendor should be listed in National Accreditation Board for Certification Bodies (NABCB) for MDQMS ISO 13485 and vendor should provide certificate in this regard.
- 5) The vendor should be valid certification body in CDSCO under the Ministry of Health and Family Welfare.
- 6) The vendor should submit valid copies of ISO 13485 Completion Certification issued to other customers
- 7) The vendor should give certification from their own organisation. No Third Party certification is accepted.
- 8) All the clarifications regarding the scope of work to be carried out in the technical evaluation time only.

TERMS AND CONDITIONS FOR SUBMISSION OF TENDER

1. Please specify your income Tax Account Number and name of I.T. Circle.
2. The quote must be for the quantity specified in the enquiry and should also indicate slab rates for multiples of the quantity enquired.
3. Liquidated Damages and risk purchase clauses: Time is the essence of contract and the materials against the order arising out of this enquiry must be delivered by the supplier according to the delivery schedule indicated in the purchase order. In case of any change, the supplier should inform us in advance and obtain approval to the revised delivery schedule. Should the supplier fail to deliver the material in full or part thereof as per the delivery schedule or any extension thereof, we shall be entitled at our option either to recover from the supplier as penalty, a sum equivalent to 0.5% per week for first four weeks and 1% per week thereafter for such delay or part there of subject to a maximum of 5% of the contract price of the item delayed or terminate the contract in respect of the balance supply so delayed and purchase materials elsewhere at the risk and cost of defaulting supplier.

4 FOR INDIGENEOUS OFFERS ONLY:

- (a) PRICES should always be quoted on F.O.R, ITI, BANGALORE basis including suitable packing.
- (b) Specify applicable statutory levies, e.g. Central excise duty, sales tax, etc.
In absence of these, the prices shall be treated as inclusive of all such levies & no subsequent claims will be entertained.

5 FOR FOREIGN OFFERS ONLY.

- (a) Prices must be quoted on F.O.B. Port of dispatch or airport and indicate estimated charges for dispatch by AIR FREIGHT/AIR POST PARCEL to BANGALORE.
- (b) Prices quoted must include Agency Commission (if any) to your Indian Agents. The same must be specified, which is payable to them in Indian Rupees.
- (c) Payment: Letter of credit or sight draft through the STATE BANK OF INDIA, BANGALORE- 560 016, as detailed below:
“ITI” will bear only LC establishment charges once & bank charges of State Bank of India. All foreign bank’s charges (i.e. charges while negotiating documents when the same are sent on the collection basis due to certain discrepancies in the presentation of documents (LCBCs etc.) are to be borne by Foreign Suppliers. In case of order placed on sight draft basis (FLCSAs) also, the invoice amount will be paid & all the foreign bank’s charges are to the supplier’s account.

Please furnish your Banker’s name and address for this purpose.