Notice Inviting e-Tender

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SUPPLY OF VENTILATOR STANDARD FOR CRITICAL CARE UNIT (CCU) AND HIGH DEPENDENCY UNIT (HDU) IN THE HOSPITALS AND MEDICAL COLLEGES OF THE GOVERNMENT OF WEST BENGAL.

(Submission of Bid through *online*)

Bid Reference No.: WBMSCL/NIT-55/2016 **Dated-28.09.2016**

2nd call of tender no. WBMSCL/NIT-26/2016, dated: 23.05.2016 (Supply of Ventilator Standard - Schedule I)

Amendment – I (Revision of Technical Specification)

The revised technical specifications for the item is given below,

Ventilator - Standard

1. To serve adult & pediatric age group patients.
2. It should have integrated US FDA approved Compressor. The ventilator should be compressor driven.
3. Provision for running with compressed air supply with separate air inlet port. In absence or low pressure of air supply, ventilator should be run by compressor.
4. Hinged arm holder for holding.
5. Inbuilt Monitoring Screen (minimum 12 inches)
6. Automatic Compliance & Leakage compensation for circuit and artificial airway.
7. **Following settings for all age groups**
   a. Tidal volume – 50ml to 2000ml (and beyond both limits)
   b. Pressure (Insp) – 0 to 60cm H_2O
   c. Respiratory Rate – upto 60 breaths per minute or more.
   d. PEEP – 0 to 20 cm of H_2O (0 to upper limit of at list 20 cm of H_2O).
   e. FiO_2 21 to 100%.
   f. Pause time – 0-30% or equivalent time in seconds of breath cycle time.

g. Pressure & Flow Trigger – Pressure Trigger 0-20 cm H_2O below PEEP; Trigger Flow 0.5 – 6 LPM
h. Inspiratory rise time – 0-20% of breath cycle time or equivalent in second.
i. I:E ratio – Standard Range (1:1.5 – 1:3) with Provision for inverse ratio ventilation.
j. Ti – 10-80% or equivalent time in seconds of breath cycle time.
k. Peak Output Flow up to 140 LPM or more.

8. Monitoring of the following parameters
   a. Airway Pressure (Peak, Plateau & Mean)
   b. Tidal Volume (Mandatory:- Inspiratory & Expiratory, Desirable:- Spontaneous)
   c. Minute Volume (Inspiratory, Expiratory & Spontaneous)
   d. Total Frequency of breaths & I:E ration
   e. Alarms for all measured & monitored parameters

9. Modes of Ventilation
   a. Volume Cycled Ventilation
      i. Assist / Controlled / SIMV
   b. Pressure Controlled
      i. Assist / Controlled / SIMV
   c. CPAP/PSV
   d. Provision of future upgradation to the following modes: Pressure Regulated Volume Control (PRVC) / Proportional assist Ventilation / Volume assured pressure support / Volume support / Adaptive support ventilation / Airway Pressure Release Ventilation (APRV) / Bilevel / Noninvasive (or equivalents) - Bidder should quote the rates for available upgradation separately in **Form 10 (c).**

10. Apnea / Back-up ventilation: - Volume and/ or pressure controlled in user friendly manner
11. Audio – Visual Alarm for
    a. Airway Pressure
    b. High continuous Pressure
    c. FiO_2
    d. Expired minute volume
    e. Apnea
    f. End expiratory pressure
    g. Respiratory rate
    h. Gas Failure
    i. Battery
12. Preferably Automatic Patient Detection facility.
13. Battery Back-up for minimum 1 hour (including compressor).
14. System Configuration Accessories, Spares & Consumables
    a. ICU Ventilator – 1
    b. Adult & Pediatric reusable silicon breathing circuit – 02 each
    c. FDA approved Heated Humidifier – 01
    d. FDA approved Inbuilt / integrated nebulizer – 01.
15. Environmental Factor
    a. The Unit shall be capable of being stored continuously in ambient temperature of 0 – 50^0C & relative humidity of 15 – 90%

b. Shall Meet IEC – 60601 – 1 – 2:2001 (or Equivalent BIS) general requirements of safety for electromagnetic compatibility.
c. Shall be capable of operating continuously in ambient temperature of 10 – 40^{0}C and relative humidity of 15 – 90%.
d. All sensors and other non-consumable items (other than reusable silicon ventilator circuits) should be free of cost during warranty and CMC.

16. Power Supply
a. Power input should be 220 – 240 V AC, 50Hz.
b. Resettable over current breaker shall be fitted for protection.
c. Suitable online UPS with commensurate capacity for all ventilators including compressor supplied in each CCU with maintenance free batteries for minimum one hour back-up should be supplied.

17. Standards, safety and training
a. Should be US FDA and CE approved.
b. Certified to be compliant with ISO-7767 (or equivalent) for Oxygen monitoring.
c. Demonstration of quoted equipment model is a must.
d. The successes bidder will have to setup its own service center in West Bengal and submit proper documents in support within 15 days of received of AOC (Award of Contract). The manufacture will also have to setup their regional office in West Bengal.
e. The service provider should have the necessary equipment recommended by the manufacturer to carry out preventive maintenance test as per guidelines provided in the service/maintenance manual.
f. Warranty for 2 years and CMC for 5 years

18. Documentation
a. Certificate of calibration and inspection from factory.
b. List of equipment available for providing calibration and routine maintenance support as per manufacturer documentation in service / technical manual.
c. User manual in English.
d. Service manual in English.
e. Log Book with instructions for daily, weekly, monthly and quarterly maintenance checklist. The job description of the hospital technician and company engineer should be clearly spelt out.
f. List of important spare parts and accessories with their part number and costing.
g. Compliance report to be submitted in a tabulated and point wise manner clearly mentioning the page/Para number of original catalogue/data sheet. Any point, if not substantiated with authenticated catalogue/manual, will not be considered.
h. The bidders should submit a declaration that the quoted model is not obsolete and availability of spare parts and accessories will be ensured for next 10 years.

NOTE:

1) Reusable consumables (other than reusable silicon ventilator circuits) should last during the warranty period.
2) In case any additional reusable consumables are required during the warranty period those will be supplied free of charge by the supplier.

3) The life expectancy of the reusable consumable is expected to be of at least one year from the date of purchase of the same. The reusable consumables will be procured at the prices accepted as per the contract.
4) Any reference to brand / product in case it occurs anywhere in the technical specification is purely for indicative/illustrative purposes and should be read as including its equivalent.
5) The product quality requirement in this ICB will be CE ("Conformité Européene") and US FDA.
6) Unless specified otherwise in the Technical Specifications, all offers should include UPS unit or battery backup of at least one hour, as the case may be, with each equipment.
7) Offered product catalogue to be attached in original (2 in nos.) with each bid.
8) Attach valid quality certification document(s); no self-certifications admissible.
9) Quality Management System in conformity with ISO 1901:2008 where specified.
10) Product quality standard (CE and US FDA) to be supported by authentic documents; Warranty, its scope and service facilities to be clearly indicated in the documents.
11) One CD/DVD of demonstration video must be supplied with the equipment for end users.
12) One CD/DVD of demonstration video must be submitted along with the bid.

Amendment – II

E. Submission and Opening of Bids

31. The following are to be submitted:

I) Non statutory documents to be submitted under My Document

(Each sub-category item should be in multiple page single PDF file)

Guidelines for uploading documents in My Document:

Sl. No.	Category Name	Sub - Category Name	Document Name
1	CERTIFICATES	CERTIFICATES	a) PAN Card b) Service Tax registration Certificate c) VAT Registration Certificate d) CST registration Certificate
2	COMPANY DETAILS	COMPANY DETAILS 1	a) License from Government/ Statutory Authority as applicable. OR b) Registration with the Registrar Of Companies, if applicable.
		COMPANY DETAILS 2	Manufacturing Licence (National/International). (In case, manufacturing licence is not required / applicable for production of the quoted item, notarized declaration from the manufacturer is to be submitted)
3	CREDENTIAL	CREDENTIAL 1	Performance Statement Form (For the period of last three calendar years ending December 2015) - Form 7 of Section V
		CREDENTIAL 2	ISO certificate
4	DECLARATION	DECLARATION1	Income Tax returns for Assessment Year 2013-14, 2014-15 & 2015-16
		DECLARATION2	Acknowledgement of VAT Returns / VAT Clearance Certificate for 2015-16.
		DECLARATION3	Acknowledgement of CST Returns / CST Clearance Certificate for 2015-16.
		DECLARATION4	Tender Form as per Form 1
		DECLARATION5	
5	EQUIPMENT	MACHINERIES 1	Manufacturer's Authorization (If applicable) as per Form 5 of Section V
		MACHINERIES 2	List of installations & commissioning in India of offered model. (self declaration)
		MACHINERIES 3	Satisfactory Performance Certificate from at least 3 (three) users of the quoted model in support of the satisfactory operation in India.
6	FINANCIAL INFO	P/L & BALANCE SHEET 2014-2015	P/L & Balance sheet 2014-2015
		P/L & BALANCE SHEET 2015-2016	P/L & Balance sheet 2015-2016

Amendment – III

Form 2: Check-List

[Please fill in and include with your Bid]

Note 1: It is essential that all documents in hard copy are to be placed before the Committee and arranged in the same sequence as given in the Check List. All the documents should be appropriately flagged.

Note 2: If any document is written in any language other than English, an English translation of the document duly authenticated is to be submitted.

Note 3: All the documents mentioned below are essential for qualifying in the technical evaluation.

Note 4: After opening of the technical bids, if it is found that any of the documents required to be submitted with the bids is wanting, WBMSCL shall reserve the right to allow late submission of such document at its discretion within a specified time limit.

Non statutory documents to be submitted under My Document				
Sl. No.	Activity	Yes/No/ NA	Page No in the Bid	Remark
1	PAN Card			
2	Service Tax registration Certificate			
3	VAT Registration Certificate			
4	CST registration Certificate			
5	License from Government/ Statutory Authority as applicable OR Registration with the Registrar Of Companies, if applicable.			
6	Manufacturing Licence (National/International). (In case, manufacturing licence is not required / applicable for production of the quoted item, notarized declaration from the manufacturer is to be submitted)			
7	Performance Statement Form (For the period of last three calendar years ending December 2015) - Form 7 of Section V			
8	ISO certificate			
9	Income Tax returns for Assessment Year 2013-14, 2014-15 & 2015-16			
10	Acknowledgement of VAT Returns /VAT Clearance Certificate for 2015-16.			
11	Acknowledgement of CST Returns /CST Clearance Certificate for 2015-16.			
12	Tender Form as per Form 1			
13	Manufacturer's Authorization (If applicable) as per Form no. 6			

	of Section V			
14	Satisfactory Performance Certificate from at least 3 (three) different types of medical equipments/instruments to any Govt. Organisation.			
15	Satisfactory Performance Certificate from at least 3 (three) users of the quoted model in support of the satisfactory operation in India.			
16	P/L & Balance sheet 2014-2015			
17	P/L & Balance sheet 2015-2016			

BID - A

Sl. No.	Activity	Yes/No /NA	Page No in the Bid	Remark
18	Earnest Money Deposit (EMD)/ Bid Security in the form of Bank Guarantee (BG)			
19	Declaration of the bidder on letter head that "We agree to submit a copy of the Tender Documents and its Amendments and Addendums thereto duly initialled by us in all pages with our seal/ rubber stamp affixed thereto, in token of acceptance thereof."			

BID - B

Sl. No.	Activity	Yes/No/NA	Page No in the Bid	Remark
20	Model of the equipment offered for **(Self Declaration)** with Technical Data Sheet			
21	Comparative Data Table of the Technical Specifications (Form No. 3 of Section V)			
22	2 sets of Brochure of the offered product / model.			
23	CE ("Conformité Européene") and US FDA approval as applicable			
24	Pre-requisites of installation [Power (KVA, Phase, Hz) and any other requirement, if any].			
25	Average Annual Turnover of the Company in India in medical equipment division during the last 3 Financial Years 2013-14, 2014-15 & 2015-16 (Rs in Crore) - to be certified by practicing Chartered Accountant as per format given in **FORM 10**			
26	**Form 11:** Declaration of Quality Certification of Equipment (as applicable)			