Notice Inviting e-Tender

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SUPPLY AND COMMISSIONING OF MEDICAL EQUIPMENTS FOR BLOOD COMPONENT SEPARATION UNIT FOR THE HOSPITALS AND MEDICAL COLLEGES OF THE GOVT. OF WEST BENGAL.

(Submission of Bid through *online*)

Bid Reference No.: WBMSCL /NIT- 13 /2017	**Dated – 24.03.2017**

2nd call of Bid Reference No. WBMSCL/NIT-08/2017, Dated - 03.03.2017

AMENDMENT - III:

Section I: Instructions to Tenderers

E. Submission and Opening of Bids

35. The following are to be submitted:

(ii) Statutory Documents

(b) BID – B (Should be in multiple page single PDF file)

4	CE ("Conformite Europeene") Class II A from European Union notified body having 4 digit identification number OR The product must be enlisted under US FDA and the quoted model must have US FDA certification to market in US & export to other countries. The manufacturer must operate in substantial compliance with Good Manufacturing Practice (GMP) (vide U.S. FOOD & DRUG ADMINISTRATION- https://www.accessdata.fda.gov)

AMENDMENT - IV:

TECHNICAL SPECIFICATIONS

Refrigerated Centrifuge (Cryo Centrifuge)

Purpose: For separation of blood components like packed cells, platelet rich plasma, platelet concentrate, Plasma, Cryoprecipitate etc.

1. TECHNICAL CHARACTERISTICS:

1.1. **Refrigerant Centrifuge with CFC free refrigerant.**

1.1.1. **Construction:**

- Microprocessor controlled system to make operation automatic, Programmable memory: Memory with tamper proof facility.
- Stainless steel chamber : Easy to clean, corrosion resistant with provision of both drain and condensed water collection container, Removable plastic cups (2 sets of 12 plastic cups) to hold single/double/triple/quadruple/quintuple (soft filter) blood bags with partition in every bucket.
- Insert with hook adapter to spin buffy coat or small volume of blood and balancing weights for inserts. Must be equipped with automatic lid lock system which means the lid cannot be opened manually and / or by any internal force during operation to prevent accidental incident.
- Speed variation: Microprocessor controlled rotor speed to within 10 rpm of set value.
- Adjustable acceleration and deceleration profiles & digital display must be available.
- Microprocessor controlled rotor temperature within ±1 deg C of set temperature regardless of the centrifuge speed.
- Programmable time: 0-99 minutes or more with minimum resolution of 1 minute.
- Digital display of temperature, speed and time with full resolution.
- There should be Motor imbalance detection system and the Centrifuge should immediately shut down if such imbalance is detected. Should incorporate alarms for imbalance detection, lid interlock, over temperature, rotor over speed.
- Temperature should reach 4 deg C with full load (accuracy ±0.5 deg C)

1.2. **Capacity:** Swing bucket blood bank rotor: With metal buckets, 6 x 2000mL, wind shielded, Suitable adaptors for 12 blood bags of 350mL & 450mL with soft filter, atleast 4 set of volume and weight compensate for maintenance of quality of the components.

1.3. **Settings:** Manual

1.4. **User's Interface:** Manual

1.5. **Software and/or standard of communication:** required for the documentation purposes

PHYSICAL CHARACTERISTICS:

1.6. **Noise (in dBA):** Noise factor should not exceed 60 decibels

2. ENERGY SOURCE (electricity, UPS, solar gas, water, CO_2....):

2.1. **Power Requirements:** Input voltage single phase along with a servo voltage stabilizer of appropriate rating with input voltage of 110 to 280 V 50 Hz and output voltage 220 V ±10 and high low voltage auto cut.

3. ACCESSORIES, SPARE PARTS, CONSUMABLES:

3.1. **Accessories & spare parts:** Complete with comprehensive set of spare parts. Volume & weight compensate accessories should be provided in adequate quantity to run full capacity.

4. ENVIRONMENTAL & DEPARTMENTAL CONSIDERATIONS):

4.1. **Atmosphere / Ambiance (air conditioning, humidity, dust…):** Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%

4.2. Additional requirement: All equipments should specify design qualifications, installation qualifications, operational qualification and performance qualifications; validation and calibration reports should have traceability towards applicable national/ international standards. Performance, efficiency, other factors such as distortions etc as applicable be also furnished. Complete construction details in respect of manual specification, thickness, finish etc are to be furnished.

4.3. Facility to remove the blood bags during power failure / emergency.

4.4. Provision for calibration window during intra-operative phase.

5. STANDARDS & SAFETY:

5.1. **Product Certification:**

CE ("Conformite Europeene") Class II A from European Union notified body having 4 digit identification number

OR

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5.2. Quality Certification: ISO Certified

5.3. Supporting documents to be provided for protection of electrical safety that of IEC (Class I).

6. WARRANTY & MAINTENANCE:

6.1. **Warranty:** 2 years

6.2. **CMC:** 5 years

AMENDMENT - V:

Section V. Bidding Forms

Form 2: CHECK-LIST

[Please fill in and include with your Bid]

Non statutory documents to be submitted under My Document				
Sl. No.	Activity	Yes/No/NA	Page No in the Bid	Remark
23	CE ("Conformite Europeene") Class II A from European Union notified body having 4 digit identification number OR The product must be enlisted under US FDA and the quoted model must have US FDA certification to market in US & export to other countries. The manufacturer must operate in substantial compliance with Good Manufacturing Practice (GMP) (vide U.S. FOOD & DRUG ADMINISTRATION-https://www.accessdata.fda.gov)			