



Notice Inviting e-Tender

West Bengal Medical Services Corporation Limited
Swasthya Sathi
GN-29, Salt Lake, Sector-V
Kolkata-700091

Phone No (033) 40340308/319

E mail: procurement@wbmsc.gov.in / mp@wbmsc.gov.in

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- 76 /2018

Dated-25.04.2018

The following amendments have been made in the tender document,

Amendment-XIX **(Applicable for Schedule VI)**

Section I: Instructions to Tenderers

A. Important information at a glance

(The item suffixed by "E" in bracket indicates Eligibility Criteria for a bidder)

4. Annual Turnover requirements: (E)

The Tenderers should have annual sales turnover (i.e. total turnover of the company) of minimum on an average of last three financial years (2015-16, 2016-17, 2017-18) as per the Audited Accounts of the Organization as mentioned in the table below:

SCHEDULE	ITEM	Annual Turnover in Crore Rs.
Schedule-VI	Deep Freezer (-40°C)	3.0

Amendment-XX

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	i) For Schedule VI, VII, X, XVIII CE ("Conformite Europeene") Class II A certificate 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"
6	Average Annual Turnover of the Company in medical equipment division during the last 3 Financial Years (2015-16, 2016-17, 2017-18) (in INR) - to be certified by practicing Chartered Accountant as per format given in FORM 10

Amendment-XXI

Form 2: CHECK-LIST

BID - B				
Sl. No.	Activity	Yes/No/N A	Page No in the Bid	Remark
24	ii) For Schedule VI, VII, X, XVIII CE ("Conformite Europeene") Class II A certificate 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			
26	Average Annual Turnover of the Company in medical equipment division during the last 3 Financial Years (2015-16, 2016-17, 2017-18) (in INR) - to be certified by practicing Chartered Accountant as per format given in FORM 10			

Amendment-XXII

Form 10: TURNOVER CERTIFICATE

I certify that Average Annual Turnover of *(insert the name of the company)* in India in medical equipment division during the last 3 Financial Years **2015-16, 2016-17, 2017-18** is Rs. as per the Audited Accounts of the Organization.

Signature and seal of Chartered Accountant

Amendment-XXIII

TECHNICAL SPECIFICATION

Deep freezer -40 degree

1. TECHNICAL CHARACTERISTICS:

- Compression freezer with CFC free refrigerant.
- Internal: Stainless steel (min. 22g).
- Mounted on Lockable Castor wheels.
- External: Solid outer Corrosion Resistant (at least 1mm thickness).
- CFC free insulation.
- Design: Upright Type. **350**-400 Lit capacity.
- Door does not project at side when opened.
- Insulation and gasket should Polyurethane/ Silicon insulation should be minimum of 80mm.
- Internal Temperature Control: Electronic temperature control.
Operating temperature reachable lowest up to -40° C with setting accuracy of ± 1 deg C whatever the load.
- Manual defrost within safe temperature range.
- Casing & door should have insulation panel with silicon / polyurethane foam & **70 to** 100 mm thickness.
- Refrigerant CFC free/ green gas.

- **External Ambient temperature:** Performs in an ambient temperature of + 10 deg C to + 30 deg C.
- **Hold over time:** 2 hrs ambient temperature.
- **Cooling Down time:** A full load of plasma packs at + 25 deg C takes a maximum of 5 hrs for all the packs to reach below 5 deg C.
- **Temperature Monitoring:** Digital temperature (LED) display with 0.1 deg C graduation.
- **Capacity:** As required by the blood bank (e.g. atleast 400 plasma bags of 200 mL each)
- **Settings:** Manual
- **User's Interface:** Manual
- **Alarm:** Power failure, High Temperature, Low Temperature, Power Failure, Remote alarm facility (provision)

2. PHYSICAL CHARACTERISTICS:

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

3. ENERGY SOURCE (electricity, UPS solar, gas, water, CO2.....):

3.1. **Power requirement:** Input voltage 220/240V 50 Hz alongwith a line voltage corrector of appropriate rating

3.2. Battery operated display, chart recorder & thermograph.

4. ACCESSORIES, SPARE PARTS, CONSUMABLES:

4.1. **Accessories & spare parts:** Complete with comprehensive set of spare parts and a suitable capacity voltage stabilizer. The make, rating, model, description, specification, price, quantity or each item shall be furnished separately.

4.2. 100 pieces of thermograph paper should be supplied at the time of delivery with supportive ink of 12 marking ink pen (if inkless thermograph, pen is not required)

5. ENVIRONMENTAL & DEPARTMENTAL CONSIDERATIONS:

5.1. **Atmosphere / Ambiance (air conditioning, humidity, dust...):** Capable of operating continuously in ambient temperature of 10 to 30 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 30 deg C and relative humidity of 15 to 90 %.

5.2. **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.

6. STANDARDS & SAFETY:

6.1. Product Certification: CE (“Conformite Europeene”) Class II A certificate 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>)

6.2. Quality Certification: ISO Certified

6.3. Supporting documents to be provided for protection of electrical safety.

7. WARRANTY & MAINTENANCE:

7.1. Warranty: 2 years

7.2. CMC: 5 years



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(Submission of Bid through *online*)

Bid Reference No.: WBMSCL/NIT- 76 /2018

Dated-25.04.2018

The following amendments have been made in the tender document,

Amendment-XIX **(Applicable for Schedule VII)**

Section I: Instructions to Tenderers

A. Important information at a glance

(The item suffixed by "E" in bracket indicates Eligibility Criteria for a bidder)

5. Annual Turnover requirements: (E)

The Tenderers should have annual sales turnover (i.e. total turnover of the company) of minimum on an average of last three financial years (2015-16, 2016-17, 2017-18) as per the Audited Accounts of the Organization as mentioned in the table below:

SCHEDULE	ITEM	Annual Turnover in Crore Rs.
Schedule-VII	Deep Freezer (-80°C)	3.0

Amendment-XX

E. Submission and Opening of Bids

36. The following are to be submitted:

(ii) Statutory Documents

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

4	<p>iii) For Schedule VI, VII, X, XVIII CE (“Conformite Europeene”) Class II A certificate from European Union notified body having 4 digit identification number</p> <p style="text-align: center;">OR</p> <p>The product must be enlisted under US FDA and the quoted model must have US FDA certification to market in US</p>
6	Average Annual Turnover of the Company in medical equipment division during the last 3 Financial Years (2015-16, 2016-17, 2017-18) (in INR) - to be certified by practicing Chartered Accountant as per format given in FORM 10

Amendment-XXI

Form 2: CHECK-LIST

BID - B				
Sl. No.	Activity	Yes/No/N A	Page No in the Bid	Remark
24	<p>iv) For Schedule VI, VII, X, XVIII CE (“Conformite Europeene”) Class II A certificate from European Union notified body having 4 digit identification number</p> <p style="text-align: center;">OR</p> <p>The product must be enlisted under US FDA and the quoted model must have US FDA certification to market in US</p>			
26	Average Annual Turnover of the Company in medical equipment division during the last 3 Financial Years (2015-16, 2016-17, 2017-18) (in INR) - to be certified by practicing Chartered Accountant as per format given in FORM 10			

Amendment-XXII

Form 10: TURNOVER CERTIFICATE

I certify that Average Annual Turnover of *(insert the name of the company)* in India in medical equipment division during the last 3 Financial Years **2015-16, 2016-17, 2017-18** is Rs. as per the Audited Accounts of the Organization.

Signature and seal of Chartered Accountant

Amendment-XXIII

TECHNICAL SPECIFICATION

Deep freezer -80 degree

1. TECHNICAL CHARACTERISTICS:

- Compression freezer with CFC free refrigerant.
- **Construction:** Internal: Stainless steel (min 22g).
- External: Solid outer Corrosion Resistant (at least 1mm thickness).
- CFC free insulation.
- Mounted on Lockable Castor wheels.
- **Design:** Upright Type, **350**-400 Lit capacity.
- Door does not project at side when opened.
- **Internal Temperature Control:** Electronic temperature control. Operating temperature reachable lowest up to -80° C with setting accuracy of $\pm 1^\circ$ C whatever the load.
- Manual defrost within safe temperature range.
- Casing & door should have insulation panel with silicon / polyurethane foam & **70 to** 100 mm thickness.

- **External Ambient temperature:** Performs in an ambient temperature of +10° C to +30° C.
- **Hold over time:** 2 hrs ambient temperature.
- **Cooling Down time:** A full load of plasma packs at +25° C takes a maximum of 5 hrs for all the packs to reach below 5° C.
- **Temperature Monitoring:** Digital temperature (LED) display with 0.1° C graduation.
- **Capacity:** As required by the blood bank (e.g. atleast 400 plasma bags of 200 mL each)
- **Settings:** Manual
- **User's Interface:** Manual
- **Alarm:** Power failure, High Temperature, Low Temperature, Power Failure, Remote alarm facility (provision)

2. PHYSICAL CHARACTERISTICS:

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

3. ENERGY SOURCE (electricity, UPS solar, gas, water, CO2.....):

3.1. **Power requirement:** Input voltage 220/240V 50 Hz along with a line voltage corrector of appropriate rating

3.2. Battery operated display, chart recorder & thermograph.

4. ACCESSORIES, SPARE PARTS, CONSUMABLES:

4.1. **Accessories & spare parts:** Complete with comprehensive set of spare parts and a suitable capacity voltage stabilizer. The make, rating, model, description, specification, price, quantity or each item shall be furnished separately.

4.2. 100 pieces of thermograph paper should be supplied at the time of delivery with supportive ink of 12 marking ink pen (if inkless thermograph, pen is not required)

5. ENVIRONMENTAL & DEPARTMENTAL CONSIDERATIONS:

5.1. **Atmosphere / Ambiance (air conditioning, humidity, dust...):** Capable of operating continuously in ambient temperature of 0 to 50° C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 30° C and relative humidity of 15 to 90 %.

5.2. **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.

6. STANDARDS & SAFETY:

6.1. **Product Certification:** CE (“Conformite Europeene”) Class II A certificate 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>)

6.2. **Quality Certification:** ISO Certified

6.3. Supporting documents to be provided for protection of electrical safety.

7. WARRANTY & MAINTENANCE:

7.1. **Warranty:** 2 years

7.2. **CMC:** 5 years



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(Submission of Bid through *online*)

Bid Reference No.: WBMSCL/NIT- 76 /2018

Dated-25.04.2018

The following amendments have been made in the tender document,

Amendment-XIX **(Applicable for Schedule X)**

Section I: Instructions to Tenderers

A. Important information at a glance

(The item suffixed by "E" in bracket indicates Eligibility Criteria for a bidder)

6. Annual Turnover requirements: (E)

The Tenderers should have annual sales turnover (i.e. total turnover of the company) of minimum on an average of last three financial years (2015-16, 2016-17, 2017-18) as per the Audited Accounts of the Organization as mentioned in the table below:

SCHEDULE	ITEM	Annual Turnover in Crore Rs.
Schedule-X	Blood Bank Refrigerator (600 Ltr.)	2.0

Amendment-XX

E. Submission and Opening of Bids

37. The following are to be submitted:

(ii) Statutory Documents

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

4	v) For Schedule VI, VII, X, XVIII CE ("Conformite Europeene") Class II A certificate 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"
6	Average Annual Turnover of the Company in medical equipment division during the last 3 Financial Years (2015-16, 2016-17, 2017-18) (in INR) - to be certified by practicing Chartered Accountant as per format given in FORM 10

Amendment-XXI

Form 2: CHECK-LIST

BID - B				
Sl. No.	Activity	Yes/No/N A	Page No in the Bid	Remark
24	i) For Schedule VI, VII, X, XVIII CE ("Conformite Europeene") Class II A certificate 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			
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Amendment-XXII

Form 10: TURNOVER CERTIFICATE

I certify that Average Annual Turnover of *(insert the name of the company)* in India in medical equipment division during the last 3 Financial Years **2015-16, 2016-17, 2017-18** is Rs. as per the Audited Accounts of the Organization.

Signature and seal of Chartered Accountant



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(Submission of Bid through *online*)

Bid Reference No.: WBMSCL/NIT- 76 /2018

Dated-25.04.2018

The following amendments have been made in the tender document,

Amendment-XIX **(Applicable for Schedule XVIII)**

Section I: Instructions to Tenderers

A. Important information at a glance

(The item suffixed by "E" in bracket indicates Eligibility Criteria for a bidder)

7. Annual Turnover requirements: (E)

The Tenderers should have annual sales turnover (i.e. total turnover of the company) of minimum on an average of last three financial years (2015-16, 2016-17, 2017-18) as per the Audited Accounts of the Organization as mentioned in the table below:

SCHEDULE	ITEM	Annual Turnover in Crore Rs.
Schedule-XVIII	Refrigerated Centrifuge (Cryo Centrifuge)	2.0

Amendment-XX

E. Submission and Opening of Bids

38. The following are to be submitted:

(ii) Statutory Documents

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

4	vi) For Schedule VI, VII, X, XVIII CE (“Conformite Europeene”) Class II A certificate 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”
6	Average Annual Turnover of the Company in medical equipment division during the last 3 Financial Years (2015-16, 2016-17, 2017-18) (in INR) - to be certified by practicing Chartered Accountant as per format given in FORM 10

Amendment-XXI

Form 2: CHECK-LIST

BID - B				
Sl. No.	Activity	Yes/No/N A	Page No in the Bid	Remark
24	i) For Schedule VI, VII, X, XVIII CE (“Conformite Europeene”) Class II A certificate 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			
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Amendment-XXII

Form 10: TURNOVER CERTIFICATE

I certify that Average Annual Turnover of *(insert the name of the company)* in India in medical equipment division during the last 3 Financial Years **2015-16, 2016-17, 2017-18** is Rs. as per the Audited Accounts of the Organization.

Signature and seal of Chartered Accountant

Amendment-XXIII

TECHNICAL SPECIFICATION

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 {displaying RPM and RCF (at least 700-5000g) and acceleration & deceleration & temperature}.
- **Programmable memory:** Memory with tamper proof facility.
- **Stainless steel chamber:** Should be of easy to clean, corrosion resistant type. The chamber preferably should come with provision of both drain and condensed water collection container. The chamber should be supplied with 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 chamber 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, with or without 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, CO₂...):
 - 2.1. **Power Requirements:** Input voltage single phase / three phase along with a servo voltage stabilizer of appropriate rating with input voltage of 110 to 280 V / 200 to 400 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 certification 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>)

5.2. Quality Certification: ISO Certified

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

5.4. All the bidders or vendors to submit a validation / QC / process control data related to the components prepared on the quoted model at the time of bid submission.

i) FFP: PT, APTT, Fibrinogen

ii) Platelet concentrates: Platelet count / yield, WBC count, RBC count, Hct. (Both in PRP / PC & Buffy coat)

iii) Conc. RBC: Hct, Hb, Product volume, WBC count.

6. WARRANTY & MAINTENANCE:

6.1. **Warranty:** 2 years

6.2. **CMC:** 5 years