RAJASTHAN MEDICAL SERVICES CORPORATION LTD.
D- Block, SwasthyaBhawan, TilakMarg, C-Scheme JAIPUR (Raj)
Ph. No. 0141-2223887, Fax No. 0141-2228065 CIN: U24232RJ2011SGC035067 E-Mail –edpmrmsc-rj@nic.in

No. F-8( ) RMSC/EPM/M-1/NIB-791/2023-24/ 508 Dated: 14/9/23

CLARIFICATION/CORRIGENDUM/ADDENDUM

Subject: Amended Technical Specification of bid document of item Contact Blast Freezer, under No. F-8() RMSC/EPM/M-1/NIB-791/2023-24/295 date: 27.07.2023

In reference to subject cited above NIB-791, various representation received from the firms and issues raised by the bidder are examined by the competent authorities and technical committee. The following clarification/corrigendum/addendum is issued for inclusion in bid document of items as below:-

Revised Technical Specification - Contact Shock/Blast Freezer/ snap freezer-

1. Purpose/ Objective of Equipment
   For rapid freezing to core temperature of plasma bag below -30 °C in just 45 minutes to prevent decay of plasma coagulation factor at(-70 to -80) °C storage of Plasma Bags as per Drug and Cosmetic Act 1940.

2. Compression type blast freezer that uses CFC free refrigerant gas.

3. Capacity:
   Up to 24 standard plasma bags (up to 250 ml) for Contact/Blast freezing/ Storage up to 100 bags, bag store should be horizontal/Vertical

4. Construction:
   a) Vertical upright type. But bag should be stored/ kept at flat portion.
   b) Construction of double wall CFC free PUF (Polyurethane foam min 125 mm) Insulated with efficient insulation to minimize temperature loss, outer surface temperature should not lower 10 deg from ambient temp. After 5 hrs at chamber temp (-70- to -80), Surface Temperature of blast freezer body at a distance of 200 mm from the gate. Inner chamber should be made for SS 304 grade non corrosive stainless steel & outer made of high quality corrosion resistance sheet with powder coated scratch less. Documents should be submitted, should be rtd calibration port to access external check to compare on calibrator.
   c) Should have Trouble free cleaning and disinfection facilities.
   d) Should have handle for opening the door life time comfortable and suitable to all men/women height, flush type.
   e) Should have at least 4 shelves. Arrangement for plasma bag should be flat position at plate.
   f) Should have high quality silicon gasket or equivalent gaskets not to hard at -80 deg c
   g) Should have triple silicon rubber gasket sealing for long life.
   h) Should have hot line around the gate of the cabinet which prevents condensate formation.

i) Separate refrigeration of the fixed cover plate and the electrically adjustable working surface of the upper and lower plates.
j) Should have rust free door hinge makes the door open up to an angle of 120^{O}.
k) Should have well located ventilator which helps in better condensation process.
l) Should be heavy duty refrigeration system, maintenance free, with hermetically sealed refrigeration compressors reliable refrigeration with minimum noise & vibration.
m) Inner doors with magnetic/mech latches ensure storage and less cold air loss during opening and closing of the door.

5. Refrigeration
   a) Refrigeration design should be as per minimum 60/40 % on/off cycle, precool temp time should within 90 minutes, Noise level should not more than 55 db at 2meter from machine
   b) Can perfectly maintain internal temperature as above at full load in an ambient temperature of $+10^{0}$ C to at least $+40^{0}$ C.
   c) A full load of blood packs at -35^{0} C ($\pm 5^{0}$ C) and chamber temp (-75) should take at least 6 hours to rise to above -20^{0} C, if power off.
   d) A full load of blood plasma packs at $+25^{0}$ C should take a maximum of one hours for all the packs to reach below -(-30^{0} C)
   e) Refrigeration cycle should be declared with dq documents

6. Internal Temperature Control & Recording
   a) Must have at least(7" to 12") inch, user friendly touch screen self explanatory LCD display, USB Support, weekly non editable electronic circular temperature chart recorder with range of -150^{0} C to $+10^{0}$ C, and accuracy should be $\pm 0.1^{0}$ C, for clear visual($\pm 1^{0}$ C)
   b) In weekly non editable electronic circular temperature chart recorder, to view previous two weeks and current week chart should be stored in the memory, validation port should available.
   c) Working temperature range -70° C to -80° C as per Drug and Cosmetic Act 1940.
   d) Microprocessor based electronic temperature control, Operating temperature reachable lowest up to -80^{0} C with setting accuracy of $\pm 1^{0}$ C (preferably ± 0.1° C). Calibration.
   e) Should have user friendly microprocessor controlled programmable digital temperature indicator & controller to ensure the usage.
   f) Should have a chart range of -150 degree Celsius to +10°C. with higher and lower uses marking.
   g) Freezing time depending on load and ambient temperature should be 30 to 60 minutes to core temperature of FFP of 250 ml.
   h) Energy consumption per freezing cycles should not be more than 0.8 kWh (unit).
   i) Should have battery back-up for monitoring of cabinet temperature for 12 hrs (for full charge) by sealed maintenance free battery.
   j) Should have microprocessor based temperature controller with integrated audio visual temperature and power failure alarm with digital monitoring display to comply Drug and Cosmetic Act 1940.

7. Feature of system
   a) Screen visual :
      Should view single graph, scroll all graph history ,high-low temperature, gate status, specific (equipment ID, equipment name, sr no),view of circular weekly graph of current and previous two weeks, can view in excel sheet also,
   b) Graph visual :
      Should be weekly circular chart with high, low and safe using range for specific product-fresh frozen plasma etc
      Must have automatic e-mailing facility to mail the weekly digital temperature chart recorder at every weekend & must also have a Manual e-mail option to send e-mail whenever wanted. Daily e-mail of all processes in excel sheet(i.e- deposit, withdrawal, balance etc), can view on any system, should not require any life time external software
   c) Data download: should have Barcode Reader: To scan and update the process data. by pen drive and auto mail
   d) Provision to connect with central (Temperature) monitoring system / facility of wireless data transfer facility & storage of temp. Data on cloud, with continuous accessibility of data on PC or laptop and on smart phones with internet facility.
   e) About instruments : Information sheet for installed date, calibration status, preventive maintenance planned and done date etc
   f) Maintenance: auto mailing system should be on events at three mails (i.e.- pre planned calibration due date, preventive maintenance, all data should show on screen about equipment details (i.e- date of installation, model, calibration plan and done, preventive maintenance plan and don. High voltage, low voltage control and visual information on screen should available. Electronic fuse should be available.

8. Electrical safety
   Equipment shall be supplied with external Servo Voltage Stabilizer with input voltage rating 90- 280V and 50Hz.

9. Quality Standard
   a) The quoted model should be compliant with European CE (Notified Body) as per LVD or MDD directive/USFDA /BIS (Valid Bid document should be submitted in technical bid.)
   b) The manufacturer should have ISO 13485.
   c) Quality certification: ISO 9001
   d) Electrical Safety: Equipment meets electrical safety specification such as that of IEC 61010-1
   e) CFR 21 CMPLAINCE
   f) IP-20 COMPLAINCE

10. TRAINING AND INSTALLATION
   a) Pre-installation : Pre-installation requirements should be declared
   b) Training of staff : Training of staff (medical paramedical, technicians) OPTIONAL (Depending upon scope of work order)
11. Guarantee: Three years on equipment from the date of installation.

12. CMC: CMC will be given @ 5 % of net rate - exclusive GST (as applicable) and yearly escalation of 5 % on last year's CMC price. The CMC may be awarded for five years (on yearly basis) after completion of Guarantee period of three years.

13. Additional Requirements

a) Validation and Calibration reports should have traceability to applicable national and international standards.
b) Complete with comprehensive set of spare parts and a suitable capacity voltage stabilizer should be supplied with the system free of cost with the system.
c) The make, rating, model, description, specifications, price quantity of each item should be furnished separately.
d) Necessary catalogues, technical write up in English, should be attached with the offer both in hard and electronic copies and should at least 4 installation similar products in INDIA with user satisfaction.
e) Demonstration and continued comprehensive training for lab staff and support services till familiarity with the system.
f) Should provide a set of equipments for calibration (eg Thermometer) and routine preventive Maintenance as per manufacturer documentation in service/technical manual.

Other terms and condition to be covered during guarantee period by the supplier:-

- Response time- < 48 Hours after logged the complain in complain portal.
- Service hours- As per health facility schedule.
- Preventive Maintenance Schedule (PM)-As per OEM (Mention PM Schedule)
- Calibration Schedule – As per OEM (Mention Schedule)
- Up time- 95% (346 Days)
- Technical & Application Support, Demonstrations & Trainings - As & when required
- Toll Free No-
- Life of the equipment- As per OEM

Note:- Please note that all above amendments/corrigendum in technical specifications/bid conditions is the integral part of (Section-VIII) and the bid document. This corrigendum/ addendum should be signed and annexed with bid document. All other terms & conditions remains the same.

Executive Director (EPM)
RMSCL, Jaipur