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## <u>Corrigendum-I</u>

Bihar Medical Services and Infrastructure Corporation Limited (BMSICL) had invited E-Bids from the interested parties for Procurement, Rate contract, Supply, Installation of Medical Equipment vide Tender No.-BMSICL/2023-24/ME-334. During and after Pre-bid meeting various suggestions were received from different prospective bidders regarding amendment in technical specification of equipment which were discussed and deliberated on by the experts. On the basis of their recommendations certain amendments in the technical specification of the equipment have been made which are annexed as **Annexure-I** of this corrigendum.

SD/-GM (Procurement) BMSICL

## Annexure-1

	Name of Equipment :-Deep Freezer -40°C		
SI. No	Technical Specification as per tender	<b>Final Amendment</b>	
1	Purpose of Equipment: To Freeze or store Plasma.	No change	
2	Must be designed specifically for blood bank use. Commercial or modified commercial freezers for other purpose are not acceptable.	No change	
3	Type of Equipment	No change	
i	Approved standard electrical Blood Bank plasma freezer that uses a compressor circulating CFC-free refrigerant.	No change	
ii	Upright type	No change	
4	US FDA/ European CE (Issued by Notified Body) approved Model should be offered.	No change	
5	Equipment must meet electrical safety specifications of IEC 61010-1.	No change	
6	Capacity: 300 to 450 litters.	No change	
7	Construction	No change	
i	Outside Corrosion Resistant Sheet at least 1 mm thick	No change	
ii	Inside stainless steel of at least 22 G.	No change	
iii	Insulation polyurethane foam >80mm thick, foaming agent CFC free	No change	
iv	Double Outer Door with standard independent locking to prevent cold air from escaping.	No change	
V.	Should be mounted on lockable caster wheels	No change	
8	Drawers: At least four or more in number in both upper and lower chambers.	Drawers: At least four or more inside the chamber.	
9	Door	No change	
i	Automatic/Magnetic closing at angle up to 90°.	No change	
ii	Separate inner doors to prevent cold loss	No change	
iii	Heating device in front to avoid condensation	No change	
iv	Opening angle limited (e.g. <60-70%.)	No change	
10	Electrical characteristics	No change	
i	Compatible with Input 220 V +/- 10 %, 50 Hz Single phase AC	No change	
ii	Should have an integrated voltage stabilizer or external stabilizer of appropriate ratings meeting ISI Specifications (Input 160-260 V and output 220 V +/- 1 % or better, 50 Hz).	No change	
11	Internal Temperature	No change	
i	Should be able to maintain internal temperature minus 40°C or below.	No change	
ii	Whatever the load, setting accuracy less than or equal to 1°C.	No change	
12	External Ambient Temperature: Can perfectly maintain internal temperature as above at full load in an ambient temperature of +10 to at least +30 °C	No change	
13	Hold-Over Time	No change	
i	A full load of plasma packs at -36 °C takes at least 1 hr to rise to above -20 °C	No change	
ii	A full load of plasma packs at -36 °C takes at least 32 hrs to rise to above -5 °C	No change	
14	Cooling Down Time	No change	
i	A full load of plasma packs at $+25^{\circ}$ C takes a maximum of 5 hrs for all the packs to reach below -5 °C	No change	

ii	A full load of plasma packs at +25 °C takes a maximum of 30	No change
11	hrs for all the packs to reach below -20 °C	
15	Temperature monitoring, thermograph and related alarms	No change
i	Digital temperature (LED) display with 0.1 °C graduation.	No change
ii	Microprocessor controlled primary temperature control	No change
iii	Integrated Visual AND Audible Temperature alarm systems,	No change
iv	There should be a method to test the alarm system	No change
iv	Alarm history: temperature maximum and minimum, average	No change
IV	temperature during alarm period, time of duration of alarm	
V.	Provision to be connected to a remote monitoring system and	No change
	remote alarm.	
vi	The temperature record should be electronically logged (that can be retrieved e.g. by USB port) and also documented on a physical thermograph; preferably with a 7-day graphic chart recorder with supply of free charts for full period of warranty.	The temperature record should be electronically logged (that can be retrieved e.g. by USB port or any other port) and also documented on a physical thermograph; preferably with a 7-day graphic chart recorder with supply of free charts for full period of
vii	Must have Battery backup for temperature recordings which is especially needed during power failure/fluctuations.	No change
viii	Additional Battery backup for alarm so that alarm will not fail	No change
	in case of power failure, and should be able to sustain the alarm.	
16	Noise factor should not exceed 60 db	No change
17	At room temperature of 25°C should be able to maintain at ideal	No change
1/	compressor.	

	Name of Equipment :-Sterile connecting device		
SI. No	Technical Specification as per tender	<b>Final Amendment</b>	
	Product & Manufacturer Quality Standards:		
1	The quoted model should be either "USFDA approved (Device listed with registration under valid FEI number / having CFG)" or "European CE certified (where EU-CE certificate should be issued from Notified body having notified body number)" or "BIS certified conforming to the standard BIS specification/ guideline specifically for 'Sterile Connecting device'."	No change	
2	The quoted model should confirm to "IEC 60601-1" or "IEC 61010" or "IS/ ISO / IEC 80601 (Part 2)" or "IS 13450 (Part 1)".	No change	
3	The quoted medical device must be registered under CDSCO and submit the licence to manufacture for sale or for distribution of the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid.	No change	
4The manufacturer of the quoted product should have EN ISO 13485 certificate issued from a notified body or ICMED 13485 (with or without plus) certificate issued from certification bodies accredited by NABCB or ISO 13485 certificate issued from certification bodies accredited by NABCB / Nationally Recognized Accreditation Board under IAF MLA. Operational Requirement: Sterile connecting devices produce sterile welds between two pieces of compatible tubings.No change		No change	
	Technical Specification:	No change	
1	Should able to accommodate & weld all types of blood bag PVC tubes used.	No change	

C	Tubing sizes: 3.9 to 4.5 mm (Outer diameter) and 2.9 to 3.1 mm	No change
2	(Inner diameter)	
3	Mechanism and heat transfer: Two straight tubes and using a	No change
	disposable wafer.	
4	Sterility: Wafer heated up to 300 degree Celsius to maintain	No change
	sterility during cutting and welding.	
5	Welding time: less than 30 seconds	No change
6	Should have seamless wielding.	No change
7	Should able to join wet-wet, dry-wet, dry-dry tubes.	No change
Q	Welding should not cause any alteration in physical or chemical	No change
0	properties of the tube and should not cause hemolysis of blood.	
0	Should have indication ongoing welding process & audio-visual	No change
9	alarm for any functional irregularities.	
10	The welding accessories should be available with the supplier	No change
	Throughout the functioning of the machine.	
11	The welding wafers of 100 nos. should be supplied with the	No change
	machine free of cost for trial.	
12	Accessories: AC power cable, Bag supports, Cassette of Wafer,	No change
12	Replacement Air Filter	

	Name of Equipment :-Refrigerated Water Bath		
SI. No	Technical Specification as per tender	<b>Final Amendment</b>	
	• Features: It should include timer of 2 hours fixed and variable temperature control, over temperature safety limit with audio visual alarm, power switch and digital temperature display, number of digit and resolution shall be included in the offer.	No change	
	Capacity: 65 liters	No change	
	• Storage Capacity: Holds up to minimum 5 stainless steel racks.	No change	
	• Overall interior dimension: It should be indicated by the bidder.	No change	
	• Operating temperature: +40C control sensitivity plus minus 0.20C.	No change	
	• Uniformity plus minus 0.20C.	No change	
	• ambient temperature may be as high as 450C.	No change	
	• The equipment should be able to thaw 15 plasma units in about 90 minutes.	No change	
	The equipment should have:	No change	
a	Stainless steel filter screen for protecting pump intake from debris such as levels etc.	No change	
b	Stainless steel tank of 22 gauge designed with curved corners for easy cleaning.	No change	
с	Stainless steel lid at least 20 gauge.	No change	
d	Outside mild steel sheet of 18 gauge.	No change	
	• The following accessories should be part of	No change	
	configuration		
i	Compression rack holder.	No change	
ii	Frozen Plasma rack holder.	No change	
iii	Thermometer for visual verification of water temperature.	No change	
	USFDA/European CE (Issued by Notified body) approved model should be offered.	No change	

Name of Equipment :-Hydrometer		
SI. No	Technical Specification as per tender	<b>Final Amendment</b>
1	It should be Glass & intended to measure the specific gravity of urine samples.	No change
2	Hydrometer with scale graduations corresponding to the range of specific gravity for urine.	No change
3	Manufacturer should have ISO Certificated (accredited by NABCB)	No change

	Name of Equipment :-Deep freezer (-80 degree)		
SI. No	Technical Specification as per tender	<b>Final Amendment</b>	
1	Should have galvanized steel body with epoxy paint/HDGI sheet-Power coated and vacuumed polyurethane foam panels, outer double/single door with locking facility.	No change	
2	Should have alarm for audible and visual fault acknowledgement, high and low temperature audio visual alarms, open door alarm, and power failure alarm.	No change	
3	Castor wheels should be provided with lock	No change	
4	Capacity:	No change	
i	Total storage capacity of 300 bags of 200ml plasma bags or more.	No change	
5	Refrigerant:	No change	
i	AFC free or HCFC free refrigerants with Biodegradable oil Compressor	No change	
6	Cooling System:	No change	
i	Cascade Cooling system	No change	
ii	It should have 2 stage compressors with standard refrigerants.	No change	
iii	Should have two compressors sealed with high grade seal.	No change	
7	Doors:	No change	
i	Single outer door foaming insulated with patent technology, left hinged, main door with CAM lock	Outer door foaming insulated with patent technology, left hinged, main door with locking system	
8	Inner Compartment:	No change	
i	Minimum 3 compartments with independent doors (304 SS)	No change	
9	Temperature:	No change	
i	LED Display, temperature sensor probe (PT100)	No change	
ii	Programmable temperature range at least minimum -80 degree Celsius in increment of 0.1 degree celsius	No change	
iii	Range -55 to -80 degree celsius, uniformity $\pm 3^{\circ}$ celcius	No change	
10	Additional accessories:	No change	
i	SS Racks and SS cassates to be provided.	No change	

	System monitoring and reporting technology systems built-in for diagnosis or set point variants	System monitoring and reporting technology:- Built-in system for monitoring of temperature.
iii	System should have provision for software to control and monitor upto 30 freezers simultaneously. (It is Optional)	No change
iv	iv. Noise level <70DB	No change
v	v. Servo Stabilizer of Suitable Capacity to be provided.	No change
vi	Continuous temperature monitoring facility and temperature chart that can be replaced weekly.	No change
vii	Temperature chart paper with pen should be provided.	No change
11	Power Supply	No change
i	230 volt/50-60HZ	No change
12	Power Consumption:	No change
i	Power consumption as required.	No change
ii	Voltage stabilizer 120-240V, 50-60 HZ	No change
13	Offered model equipment should be certified by US FDA/European CE (notified body)	No change

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