



EP Division

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No: KMSCL/EP/17261/2023

Dated: 25.01.2024

NOTICE

Sub:- Tender No.T510)/ 2023 - Cancellation Notice - Decontamination Autoclave - reg.

- Ref:-**
1. Tender Inviting Notice published dated 04.10.2023
 2. Technical bid opening held on 06.11.2023 @ 11.00 A M
 3. Eligible list published on 28.11.2023
 4. Reports of demonstration/ document evaluation of Decontamination Autoclave received on 22.01.2024

I. The reports of technical document evaluation/ demonstration of Decontamination Autoclave as per reference no. 4th cited above were submitted by the technical committee appointed for the purpose. The details of the tenderers participated in the technical evaluation are tabulated as follows:

A. M/s Genist Technocracy Pvt Ltd

Rejected model:GTA-004A/ GENIST

Reason for rejection:

Clause no	Technical Specification	Compliance of the model
2	Doors and jackets shall be constructed of stainless steel sheet of 304 grade. Doors must be provided with automatic safety locking and unlocking devices. All doors must be gasketed to ensure a high temperature seal.	Doors doesn't have a automatic safety locking and unlocking devices.
6	Key locked main power switches should be provided for additional safety and security.	Not mentioned
5.2.d	Cycle parameters should be adjustable with the help of codes to prevent adjustments by non-authorized persons.	No
XI	Canopy hood shall be provided above the loading and unloading doors of the Autoclave to capture steam vapour and heat generated by the equipment. The canopy hood on the containment side shall be ducted and connected to the HEPA filtered laboratory exhaust and on the non-containment side shall be ducted and connected to normal exhaust. The Canopy hood exhaust air capture velocity shall be minimum 50 fpm.	Not mentioned in technical brochure
XIX 2	The sterilizer should have European CE with MDD 93/42 EEC or US FDA Certificate.	No valid certificate
XIX 3	Pressure equipment directives: PED 97/23 EC.	Not mentioned
	A detailed technical brochure of the	

XX	equipment and necessary certificates should be attached in technical bid which is mandatory for selection. Site should be visited before participating in the tender for exact measurements	No
2	If CDSCO (Central Drugs Standard Control Organization) certification is required for the import and marketing of the equipment, then the same shall be submitted along with the technical bid.	Not submitted

B. M/s Kerala Surgical Equipment Co

Rejected Model: Medipharm

Clause No	Technical specification	Compliance of the model
III	Capacity of the autoclave:200-600L	185 L only
IV	The chamber shall be constructed of heavy duty solid high quality SS of 316L or equivalent with full argon welding. The chamber material and construction shall meet ASME standards for unfired vessels. The chamber shall be duly reinforced with the help of carbon steel.	Not mentioned as per ASME in technical data sheet
2	Doors and jackets shall be constructed of stainless steel sheet of 304 grade. Doors must be provided with automatic safety locking and unlocking devices. All doors must be gasketed to ensure a high temperature seal.2	Doors doesn't have a automatic safety locking and unlocking devices.
4	The autoclave shall be insulated with 80 mm chloride free mineral wool or any latest alternative technology with industrial standards to minimize heat loss and restrict the skin temperature within reasonable limits so as not to cause burn due to accidental touch.	No
8	The autoclave shall be complete with a steam generator compatible with the autoclave and with adequate capacity. The steam generator shall be fabricated from SS316L with industrial immersion heater of reputed make. Steam generator should have an insulation of up to 50mm thick chloride free mineral wool with rigid aluminium housing. Should have a low water alarm. All service panels and vacuum pump arrangements should be outside the containment area.	Not mentioned in the technical data sheet
15	The temperature sensor should be PT100 type sensors which conform to Class A of IEC 571 standard with an accuracy of 0.1°C. The pressure should have an accuracy 1% over the range 0-6 bar. 0-0.2µ internal HEPA filter & external HEPA filter is required.	Class not mentioned in technical brochure
V.b	The autoclave should be equipped with a printer to record and print relevant information concerning operation during the cycle such as temperature, pressure, cycle time etc.	Not mentioned

c	The control system should be self diagnostic and must provide a fault message to the operator.	Not mentioned
d	Cycle parameters should be adjustable with the help of codes to prevent adjustments by non-authorized persons.	This feature is not available
2	The control system continuously cross checks the sterilizer safety system and limits set as per EN285 standards	No
X.2	Hydraulic Test: The autoclave chamber shall be tested to 1.5 times of the working pressure, sterilization jacket to twice the working pressure. The test pressure will be maintained for a minimum of 2 hours.	Not mentioned
XI	Canopy hood shall be provided above the loading and unloading doors of the Autoclave to capture steam vapour and heat generated by the equipment. The canopy hood on the containment side shall be ducted and connected to the HEPA filtered laboratory exhaust and on the non-containment side shall be ducted and connected to normal exhaust. The Canopy hood exhaust air capture velocity shall be minimum 50 fpm.	Not mentioned in technical brochure
XIX.1	The product should meet the following provisions and standards:Europe EN285 for large autoclave	No
XIX.2	The sterilizer should have European CE with MDD 93/42 EEC or US FDA Certificate.	No valid certificate
XIX.3	Pressure equipment directives: PED 97/23 EC.	Not mentioned
XX	A detailed technical brochure of the equipment and necessary certificates should be attached in technical bid which is mandatory for selection. Site should be visited before participating in the tender for exact measurements	This feature is not available
2	If CDSCO (Central Drugs Standard Control Organization) certification is required for the import and marketing of the equipment, then the same shall be submitted along with the technical bid	Not submitted

C. M/s Zenotrex Medico Pvt.Ltd

Rejected model;ZPL-AH02F/ Zenotrex Medico

Reason for rejection:

Clause No	Technical specification	Deviations noted
2	Doors and jackets shall be constructed of stainless steel sheet of 304 grade. Doors must be provided with automatic safety locking and unlocking devices. All doors must be gasketed to ensure a high temperature seal.2	Doors doesn't have a automatic safety locking and unlocking devices.
4	The autoclave shall be insulated with 80 mm chloride free mineral wool or any latest alternative technology with industrial standards to minimize heat loss and	No (50

	restrict the skin temperature within reasonable limits so as not to cause burn due to accidental touch.	mm)
8	The autoclave shall be complete with a steam generator compatible with the autoclave and with adequate capacity. The steam generator shall be fabricated from SS316L with industrial immersion heater of reputed make. Steam generator should have an insulation of up to 50mm thick chloride free mineral wool with rigid aluminium housing. Should have a low water alarm. All service panels and vacuum pump arrangements should be outside the containment area.	Alarm feature not in technical data sheet
10	The steam generators should have automatic pressure control and other safety features like low water cut off to safeguard heaters etc. The steam generator should be complete with all accessories, inlet, outlet, drain connections etc. Shall be electrical operated, shell and tube type and should be compatible with the autoclave.	Not mentioned
15	The temperature sensor should be PT100 type sensors which conform to Class A of IEC 571 standard with an accuracy of 0.1°C. The pressure should have an accuracy 1% over the range 0-6 bar. 0-0.2µ internal HEPA filter & external HEPA filter is required.	not mentioned
VIII	The control system continuously cross checks the sterilizer safety system and limits set as per EN 285 standards.	This feature is not available
3	The sterilizer should have either RS232 or Ethernet port to facilitate connectivity for network applications.	Not mentioned
7	Vacuum cycle for garment decontamination is required. Cycle should start only when both doors are closed. The non-containment door is locked until the cycle completes.	Not mentioned
IX.1	The vacuum autoclave shall give a minimum of three vacuum cycles to purge the autoclave of all the air.	No
IX.3	The autoclave should completely kill the approved biological indicator at the maximum design capacity. Biological indicators shall be Bacillusstearotherophilusspores using vials or spore strips, with at least 1X10 ⁶ spore/ml. The steam condensate shall meet EUWFI Specifications.	Not mentioned
X.2	Hydraulic Test: The autoclave chamber shall be tested to 1.5 times of the working pressure, sterilization jacket to twice the working pressure. The test pressure will be maintained for a minimum of 2 hours.	Not mentioned
XI	Canopy hood shall be provided above the loading and unloading doors of the Autoclave to capture steam vapour and heat generated by the equipment. The canopy hood on the containment side shall be ducted and connected to the HEPA filtered laboratory exhaust and on the non-containment side shall be ducted and connected to normal exhaust. The Canopy hood exhaust air capture velocity shall be minimum 50 fpm.	Not mentioned in technical brochure

XIX.2	The sterilizer should have European CE with MDD 93/42 EEC or US FDA Certificate.	No valid certificate
XIX.3	Pressure equipment directives: PED 97/23 EC.	Not mentioned
XX	A detailed technical brochure of the equipment and necessary certificates should be attached in technical bid which is mandatory for selection. Site should be visited before participating in the tender for exact measurements	No
XXI	The details of the installed locations should be submitted during the technical bid.	No
2	If CDSCO (Central Drugs Standard Control Organization) certification is required for the import and marketing of the equipment, then the same shall be submitted along with the technical bid	Not submitted

II. Due to administrative reason the tender for **KMSCL/EP/T510/8G/2023 Decontamination Autoclave** is cancelled.

Dr. Shibulal A
General Manager