SPECIFICATION FOR DOUBLE DOOR STEAM STERILIZER

Sl.No.	Dismantling / Supply/ Fixing/ Installation/ Demonstration & Operation/ Comprehensive Maintenance (with spares + Labour + Consumable +Accessories) required for functionality of the Sterilizer during 05 years warranty + 05 years CAMC after certified successful installation.	
A.	Capacity: - Chamber volume double door (900 - 1000lts.)/ 32 - 36 cu. ft Double Door Steam Sterilizer: (Qty. – 01 No.)	
	Double Door Steam Sterilizer should be automatically PLC controlled and should be horizontal in size with pre and post-vacuum treatment having chamber capacity of approx. 900 – 1000ltrs (Approx 32 - 36 cu. ft). The sterilizer should have ergonomic and user-friendly design with in-built to use touch screen at ergonomic height for user & inbuilt electric Steam Generator and vacuum pump.	
B.	Door & Door Safety Systems: -	
	1	The sterilizer should have automatic double door with pneumatically operated vertical / horizontal sliding doors (Manual opening in case of automatic mechanism failure). Pneumatic door cylinder should be in stainless steel for eliminating the risk.
	2	Pressure monitoring system should be available in the chamber to monitor the chamber pressure before opening of the door. Chamber should be completely depressurized before the door seal is retracted by vacuum. Should have an essential safety feature that when the door seal is retracted the chamber is completely vented to atmosphere while the door is still retained in the fully closed and mechanically locked position.
	3	Door safety to prevent starting of process unless the door is closed and opening of door when the chamber is pressurized.
	4	The door seal should be made of silicon rubber gasket & on commencement of the process the door gasket is pressed against the rear face of the door by Air to ensure the door remains closed during the process
	5	A mechanical safety edge stops the door i.e. Emergency stop should be there for extra door safety mechanism to protect staff from force of the door.

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	6	IBR/ ISO approved pressure-reducing valves with gauges; the tenderer should provide traps in lines and safety valves for jacket and chamber for over pressure safety.
C.	Construction: - The chamber, doors and steam generator should be made of solid, high quality 316L Stainless Steel. Water level indicator should be made of Stainless Steel and jacket should be made of high graded SS – 316L/ 316 Ti with pressure gauge.	
	1	Mounting: The chamber should be jacketed to ensure the temperature uniformity in chamber. The chamber floor should be slightly sloped towards an internal drain to facilitate drainage. A stainless-steel mesh strainer protects the drain port from blockage by debris. The chamber should be mounted on a stainless-steel frame work with height adjustable feet.
	2	Insulation: The sterilizer jacket, doors & steam generator should be completely insulated with 50 to 80mm chloride free mineral wool thereby keeping the autoclave cool on the outside. The insulation should be completely encased in removable rigid aluminum/ SS 316 sheet housing.
	3	Steam Supply (Steam Generator):- The sterilizer should have an inbuilt steam generator of adequate capacity. It should be mounted under the sterilizer chamber & should be made of SS316L. The steam generator pressure vessel should be made of stainless steel. The sterilizer should be equipped with dual water connections for different water quality for cooling water and steam generator. All connecting pipes and valves shall be made of good quality stainless steel. Process valves should be pneumatic.
	4	It should have a built-in thermostat, pressure safety valve & water level glass gauge inspection device or water level indication on screen visible from service area.
	5	Firm to mention installation space required, loading system (floor or semi floor/trolley and loading rack) offered, power supply input and fuse protection & its consumption for control process & vacuum pump.
	6	Firm to confirm the size of steam supply line, steam consumption, size of water supply line, drain, exhaust and compressed air line required.

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D	Vacuum Pump, Pipes, Valves &Components: - The sterilizers should have a high-capacity efficient liquid ring vacuum pump. It should be mounted on vibration isolator for quiet operation. It should be connected to condensers to assist air removal. It should also have low water level alarm to protect it from dry run.	
	1	The piping system should be made of Stainless Steel/ Brass/ Copper/ AISI 316L.
	2	All the process valves should be stainless steel or Copper Valves or Red Brass Valves or AISI 316L & should be pneumatically/ electrically operated piston valves for loner trouble free operations.
	3	All the non-standard components should be non-proprietary & should be easily sourced.
	4	All the hot pipes should be properly insulated. Safety valves should be made of brass/ copper/ stainless steel.
	5	Primary piping & fitting should be stainless steel
	6	Primary components: 316 quality triclamps or threaded fitting components like-manual valve, non-return valve, pressure regular, pneumatic valves etc.
	7	Electrical Components: the terminals & contacts should be housed in a water tight cabinet while the other electrical component should be directly mounted on sterilizer.
	8	Air Filter: Air filter should be provided for filtering the atmospheric air before entering inside the chamber. The filter separation efficiency should be higher than 99.9988% for particle size less than 0.3µm. Air filter should be covered under warranty and CMC period.
	9	Should pass a hollow load (A) test (Batch monitoring system)
	10	Steam Sterilizer should have provision for connecting a ¾" line terminating in the shutoff valve, none turn valve, Pressure relief valve, steam riser, condensate drain and other essential accessories (for future steam connection from the central boiler).
	11	In case tenderer offering standalone steam generator they should provide alternatives for ensuring clean steam (as per International Standards)
	12	High vacuum compressor with recycling facility.
E	Control System & Operating Panel: -	

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	1	The sterilizer should be equipped with Microprocessor PLC control system which is dedicated to control the sterilizer including Digital Input Output for Sterilizer control Analog measuring Inputs COM ports for printer & PC communications. The Control System is operated via access code.
	2	8 to 10" Colour touch screen to provide well-arranged simple service controls on loading side. As a default the operator should have access to select cycle, start cycle & to close door. Digital display of chamber pressure, temperature, cycle no., Batch no., Time & date, Alarm Indicator, Low water indicator. Remaining cycle time also should be visible. Also, on de- loading side in double door sterilizer, there should be touch screen of 5"– 7" for operator's ease.
	3	Access to other functions such as setting parameters, calibration servicing and maintenance is controlled using pre-defined access level which prevents unauthorized access.
	4	The control system should have built in Linearization to correct the individual characteristics of each type of sensors.
	5	Control system should have built in battery backup so that it can support the controller and operator panel in case of power loss.
F	Automatic Operation with thermal/ laser Printer:	
	1	The sterilizer shall be fitted with suitable PLC (Microprocessor) for fully automatic cycle operation instead of manual operation.
	2	Cycle documentation- The sterilizer should be equipped with an alpha-numeric Laser/ thermalprinter which prints each cycle parameter performed by the sterilizer. The measured values of temperature and pressure are printed at fixed time intervals, according to various phases of the sterilization process such as 4 minutes time interval for vacuum, 1 minute time interval for sterilization, and the start and end time of the drying phase.
	3	All these time intervals should be user defined. Vendor should supplycustomized time intervals as desired by the user prior to order delivery.
G	Alarms should be Audio &Visual: -	
	1	The Control System should have comprehensive alarm/ alert systems which

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		automatically trigger pre-programmed information alerts (preventive maintenance schedule etc).
	2	In the event of any deviation in the type tested cycle, the control system should register an alarm
	3	The range of alarms should include ➢ Temperature & Pressure sensor failure ➢ Phase time-outs ➢ Door(s) not properly closed ➢ Power failure (less than 10 seconds will be ignored) ➢ Continuous self-checking of all safety devices ➢ Low water level (seal water to vacuum pump)
	4	The sterilizer should be equipped with following Pre-programmed cycles Programs should include: ➢ Wrapped solid and hollow instruments, textiles, porous load (134^0C). Type tested program for sterilization of medical devices, e.g. textiles, utensils. ➢ Wrapped, heat sensitive solid and hollow goods, rubber, plastic, porous load (121^0C). ➢ Bowie & Dick Test ➢ Automatic Leak rate test ➢ Heavy load (134^0C). ➢ Specific goods (134^0C).
H	Temperature and Pressure Sensors: -	
	1	The sterilizer should have at least 2 temperature & pressure sensors one at chamber drain & one in Jacket. It should also have temperature & pressure sensor in chamber.
	2	The sensors should be PT100 sensors to confirm class A of the IEC 751 standard, with accuracy of $\pm 0.0^0$C while the pressure sensor should have the accuracy of 1% pressure & pressure sensor in chamber.
	3	Each sensor circuit should be calibrated with individual constants to correct the deviation in manufacturing and aging.
I	Loading/ Unloading System: -	

	1	The sterilizer should come with standard accessories like sterilization basket, basic insert, guiding rail for rack, grid tray, startup kit, transport and loading trolley etc. The sterilizer should be complete with side and top panels.
	2	Sterilizer should have the two rails for easy loading, shelf rack with shelves (carriage) with 1 set of loading and unloading trolley from the manufacturer.
J	Water Consumption: Specify water consumption levels.	
	1	The sterilizer should be supplied with Compatible water softener/ RO based water purification system to feed autoclave. Water purification system should be supplied with the sterilizer to feed dematerialized water to the sterilizer boiler with 5 years warranty and 5 years CMC to be included with main equipment Steam Sterilizer.
	2	R.O. System of 500ltrs. /hrs. should be quoted with pressure.
K	The Sterilizer should meet following Directive and standards: -	
	The manufacturer should have ISO 13485/ EN-285 FOR Large Autoclaves (Europe) EN ISO 17665-1 ISO 13485/ EN ISO 14001:2015/ EN 61326-1/ IEC 61326-1/ EN/ IEC 61010-2-040 & Part 2-040/ 93/ 42/ EEC.	
L	Authorization, warranty, CMC & uptime clause Authorization letter and Compliance to above specification from the manufacturer must be submitted along with following points in the bid document: -	
	1	The Steam Sterilizer model to be offered with above Technical generic specifications should be one of the latest models with minimum 10 years of guaranteed service backup and spares availability. Also, OEM firm has to ensure to keep Steam Sterilizer maintenance beyond 10 years (warranty + CMC) period till an alternative functional arrangement is made by the Institute.
	2	The comprehensive warranty will be 5 years (including all spares and labour) from the date of satisfactory installation of equipment. Also quote rates for comprehensive CMC (including all spares and labour) for 6^{th} to 10^{th} year, after expiry of warranty period. CMC offered for the quoted equipment must be on OEM letter head, (CMC offered on distributors/ Vendor letter head will not be considered).
	3	List of accessories and consumables should be mentioned in the bid with cost to be

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		fixed for warranty + CMC period, of proprietary and non-proprietary items separately.
	4	95% uptime of the machine. Facility for good after sales and services with trained engineers posted in Lucknow. IN case of down time exceeds 5% in a calendar year, the comprehensive warranty will be extended beyond 5 years for double the number of days for which the unit is nonfunctioning. Similar clause will apply each year of CMC period.
	5	The manufacturers should have at least 10 installations of steam sterilizer in India with reputed govt. hospitals. Performance/ Satisfactory installation reports should be enclosed with the bid.
	6	After Sales Service: After-Sales-Service/ Maintenance shall be provided by the manufacturer/ authorized firm through Service engineer based at Lucknow.

	Following accessories are also required for CSSD functionality to be supplied with sterilizer: -	Qty.
	A. Heavy duty Closed Transport Trolley from three sides with 3shelves for distribution of sterile packing made of S.S. Sheet 304 (Size:45" H x 25.5" D x 42" W)	04 Nos.
	B. Heavy duty Revolving Stool with Cushion Top & back	06 Nos.
	C. Sterilization Containers having USFDA EN-CE/ EN - ISO 13485/ ISO 9001:2015/ ISO 17665/ ISO 11607 to be Supplied should be with hinge- less opening button, Thermoloc Bottom with condensate drain (valve), Lid made of high-performance plastic – PPSU or anodized aluminum, lid should have silicon lip gasket with reusable microbial barrier filter. The sterilization container handle should have	

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	low heat conductivity and heat storage properties and also have indicator to show completion of sterilization cycle, the indicator turns to green, & as soon as the opening button is pushed the indicator turns to red and also	
	Approx Size of sterilization Container to be supplied: 60cm x 30cm x 30cm	05 Nos.
	30cm x 30cm x 30cm	10 Nos.
	30cm x 30cm x 07cm	05 Nos.

Conditions for tenderer:

1. All accessories should be from the same Original Equipment Manufacturer for the main unit.
2. Instruments must be ISO certified and a copy should be enclosed. (The ISO Certificate must be issued by any organization accredited by the Bureau of Indian Standard or accredited by the international accrediting forum "IAF" (Certificate to be attached).
3. Should be USA FDA and/ or European CE be approved by 4 digits notified body.
4. Other necessary certifications if any required will be provided by the bidder for the smooth functioning of the machine.
5. Installation process should be performed by O.E.M trained service engineers/ service representatives on OEM letterhead or Service Report within 15 days of supply, with the mandatory provision of providing preventive services visit of OEM trained Service Engineer/ Service Representative quarterly per year till the completion of warranty period .(i.e., 20 visits for the first 05 years) & further quarterly visits (04 visits/year) year till the completion of CMC period.
6. The equipment should have a Brand name/ Model Number embossed/etched on the equipment.

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7. All the technical specifications in the compliance statement must be supported by Original Literature from the firm/ O.E.M with highlighting Numbering & flagging of all technical certificates.
8. Offered Equipment should have a strong Government Installation base.
9. Offered Equipment should have a Regional Sales Service Centre of the Original Equipment Manufacturer in the region for a 95 % uptime guarantee.
10. For the offered main unit, the essential, optional required consumables'/accessories' shelf life should be declared on the Original Equipment Manufacturer's letterhead.
11. In case of technical snag/failure/breakdown the response time for the inspection should be within 24 hours and repair within 05 days otherwise provide a service machine/ alternate arrangement to be made till the period of recovery of the breakdown of the unit, failing which attracts penal action as per the decision of institute/ hospital.
12. For offered equipment the Training of technical staff and users should be performed by Original Equipment Manufacturer trained Service Engineers at the proper designated place- at bidders' cost.
13. Company should quote their latest model and need to provide an affidavit for the same.
14. As a tendering process the Demonstration of the offered Equipment is Mandatory at hospital/institute premises or other designated places at the bidder's cost.
15. The bidder must comply with the General Financial Rules and their modifications if any issued by the Government of India- 2017.
16. Any bidder from a country that shares a land border with India will be eligible to bid in the tender only if the bidder is registered with the Competent Authority (i.e., Registration certificate issued by the Ministry of Commerce and Industry (Department for Promotion of Industry and Internal Trade- DPIIT after October 2020). If any such bidder is not registered with DPIIT they will be liable for technical disqualification.
17. Principal (OEM) must authorize only one agent to be quoted in the bid otherwise multiple quotes through different agents in the same bid will be canceled.
18. The Bidder and its OEM both have to submit a notarized affidavit on the Indian Non-Judicial Stamp Paper of Rs.100/- that the bidder has not quoted the price higher than the current financial year and last financial year supplied to any government Institute/ Organization/ reputed Private Organization. OEM also has to submit that the price quoted by the bidder in the bid is on its behalf and the lowest in the current and last

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financial year in the country. Therefore, if at any stage it has been found that the supplier and its OEM have quoted lower rates than those quoted in this bid; the Institute (the purchaser) would be given the benefit of lower rates by the Supplier and any excess payment if any, will become immediately payable to the Institute (the purchaser). If such an affidavit is not submitted, the bid will be outrightly rejected. (Part of technical bid).

19. Guarantee / Warranty Period: Separate offers of Comprehensive Maintenance Contract (CMC on main equipment) and Annual Maintenance Contract (AMC on main equipment) for further 5 years after expiry of 5 years of warranty (i.e., 6th, 7th, 8th, 9th and 10th years) in rupees only (and on basis of percentage of price) should be included in a financial bid in the absence of which the offer is liable to be rejected. Payment for CMC/AMC shall be made only after the expiry of the warranty of 5 years, in case the Institute (the purchaser) decides for availing of CMC/AMC services. Contract for CMC/AMC shall be decided on expiry of warranty but rates (not more than 5% inclusive of all taxes for 6th to 10th year) will be frozen at the price of an issued purchase order before the release of payment by the Institute (the purchaser). However, the Institute (the purchaser) may decide not to enter into any CMC/AMC contract without assigning any reason for the same, which shall be binding upon the bid.
20. Should provide 5-year CMC. CMC cannot be more than 5% of the contract value.
21. System configured application-specific educational video tutorials shall be provided as standard with the system.
22. Details of service outlet in India to render services during 5 years warranty period.
23. The principals must give a certificate if the supplier/vendor is changed during the course of the guarantee/warranty period, the principals would be responsible for the upkeep/maintenance of the quote/supplied equipment, besides honouring all the terms and conditions of CMC/AMC in letter and spirit.

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