

SPECIFICATIONS FOR ETO MACHINE

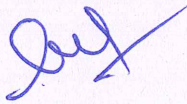


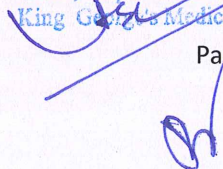
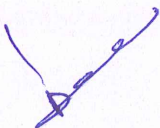
1. The Ethylene Oxide (ETO) Gas Sterilizer Should be Fully Automatic with software Controlled Operation System Suitable for Low-Temperature Sterilization of Heat and Moisture Sensitive Medical and Surgical Item
2. The Chamber Should be Preferably Rectangular with a Capacity of 200 to 250 L or 8 Cubic FT.
3. The Chamber Should be double walled and made of suitable material which is resistant to corrosion and gas.
4. The interior of the Chamber should be smoothly finished to minimize gas deposits.
5. The Sterilant Should be 100 % ETO Gas.
6. Sterilizer should have automatic gas puncturing system and work under NEGATIVE PRESSURE ensuring operator safety.
7. The Sterilizer Should Work on a single dose Cartridge of ETO with a 2 D Barcode for record keeping.
8. The ETO Cartridge should be EPA registered and should be of the same make as the sterilizer.
9. Sterilizer should have a System for Variable Parameter Settings of Time, Temperature, Relative humidity (RH), Gas Exposure, and Aeration Depending on Load and Composition of materials.
10. The Sterilizer should have a video Screen to display the Status of Program Cycle Parameters including Pressure temperature and RH.
11. The Sterilizer should have a Device of data storage for at least 100 cycles as well as a facility of Internet and USB Connection for Transfer of data of the Cycle.
12. The Sterilizer should operate for the following minimum essential program cycles.
 - i. Sterilization cycle for heat Sensitive objects that ensure Temperature from 33 to 55 degreesC with subsequent aeration for protection of the operating personnel.

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- ii. Aeration cycle to extract residual gas out of the sterilized objects after each sterilization cycle.
- iii. Automatic chamber evacuation cycle with subsequent venting before opening the door lock to avoid any gas exposure to operating personnel.
13. The Sterilizer should have a Single door with a suitable Safety interlocking arrangement so that the Sterilizer process does not start unless the door is properly locked in position.
14. The Equipment should work on Negative Pressure to avoid any leakage of ETO to the Surroundings and Exposure of Gas to the Operator.
15. Sterilizer should have inbuilt Alpha-numeric Graphical dot matrix / thermal Printer to Print date, Program type, and Program Parameters.
16. The manufacturer should also provide an ETO protection kit along with the equipment specifications
17. Consumables to carry out sterilization cycles (min 50 cycles) with packaging papers.
18. Incubatory should be provided free of cost for microbial testing of biological indicators.
19. There should be provision for safe disposal of toxic gases as per govt norms.
20. Should be provided with a heat-sealing machine along with its accessories (for sterilizing various equipment)
21. A box of class 5 sterilization indicators should be provided.

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.






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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.
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.

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- 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 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.

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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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