

Technical Specifications For The Supply, Delivery & Installation of ETO Machine

S.N.	Proposed Specifications	Bidders Compliance Data			Remarks (if any)
			Yes/ No	Page no. in catalogue	
Brand:					
Type / Model:					
Country of Origin:					
1	Description of Function	Qty.			
1.1	Ethylene oxide (also known as EO or EtO) is a low temperature gaseous process widely used to sterilize a variety of healthcare products, such as single-use medical devices.	1			
2	Operational Requirements				
2.1	Sterilization: Ethylene Oxide Sterilization System. Sealed sterilization cabinet and variable speed exhaust extractor.				
3	System configuration				
3.1	Free standing sterilizer cabinet and extractor unit.				
4	Technical Specifications				
4.1	Free standing sterilizer cabinet and extractor unit				
4.2	Machine should be 100% Ethylene Oxide, no CFCs or HCFCs				
4.3	The system should use unit dose cartridges and plastic sterilization bags, no external EO tanks require.				
4.4	Machine should use Gas diffusion technology with advanced micro-processor control.				
4.5	The micro-processor keeps track of the bags in the sterilizer, and the operator may load new bags or unload finished bags while others are in process.				
4.6	It shall sterilize and aerates in the same cabinet.				
4.7	Digital display with load tracking functions. Displays temperature, pressure and load time.				
4.8	Power outage back-up protection with UPS unit				
4.9	Double wall , a set of heating elements keep temperature at 50°C				
4.1	Easy installation requires with no compressed air or water source, only a dedicated outside vent and a single-phase AC outlet.				
4.11	Separate chambers shall allow independent loading for added flexibility.				
4.12	Gas Exhaust removes gas residuals from chamber and exhausts the gas to the outside of the building.				
4.13	Label Printer with two labels, one for the sterilization bag and one for the record book.				
4.14	Flame sealed glass ampoule with outer plastic cartridge				
4.15	ETO Gas should be included with Cartridges Refill Dispenser Kit				

4.16	Capacity: Not less than 900 Liter.				
4.17	Cabinet Capacity: Not less than 10 x 60 L bags				
5 Accessories, spares and consumables					
5.1	Accessories:				
	ETO Refill Kit- 5 box				
	ETO paper- 5 roll				
5.2	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer. Bidders must specify the quantity of every item included in their offer (including items not specified above).				
6 Operating Environment					
6.1	The system offered shall be designed to be stored and to be operated normally under the conditions of the purchaser's country. The conditions include Power Supply, Climate, Temperature, Humidity, etc.				
6.2	Power supply: 220-240V/50 Hz AC fitted with appropriated plugs. The power cable must be minimum 3 meters length.				
7 Standards and Safety Requirements					
7.1	Must submit ISO 13485:2003/AC: 2007 for Medical Devices AND				
7.2	European CE (93/42 EEC Directives) or USFDA approved product certificate.				
8 User Training					
8.1	The supplier shall conduct user training for this equipment to enable operators to use the equipment properly. The training shall include the use of all operational functions of the equipment, as well as routine checks and maintenance expected by users.				
9 Warranty					
9.1	Comprehensive Warranty for 2 years, after Installation and acceptance.				
10 Maintenance Service during warranty period					
10.1	During warranty period supplier must ensure planned preventive maintenance (PPM) at least 4 times a year and corrective / breakdown maintenance whenever required.				
11 Installation and Commissioning					
11.1	The bidder must arrange for the equipment to be installed and commissioned by certified or qualified personnel; any prerequisites for installation to be communicated to the purchaser in advance, in detail.				
12 Documentation					
12.1	User (Operating) manual in English.				
	Service (Technical/maintenance) manual in English				
12.2	List of important spare parts and accessories with their part numbers and costing.				

12.3	Certificate of calibration and inspection from factory.				
	Authorization letter from the manufacturer should be provided.				
12.4	Bidders should provide original catalogue or e-copy that correlates with yes/no chart. Any manipulation in the brochure is not entertained and imprinting of published specification in the brochure will be disqualified without any observation.				
12.5	Bidder must completely fill the Technical Specification Form (TSF). Only Yes/No /all complies should not be written. Page number in the catalogue of all the required parameters must be clearly mentioned and highlighted. Failure in doing so may lead to rejection of bid from the technical committee.				