Technical Specifications of an Ethylene Oxide Low-Temperature Gas Sterilizer

1. SUBJECT

1.1 This Technical Specification covers the technical characteristics, inspection, and testing methods of the Ethylene Oxide Low-Temperature Gas Sterilization Device / Sterilizer to be procured domesticall

2. TECHNICAL SPECIFICATIONS

2.1 The device shall be suitable for the sterilization, using ethylene oxide gas, of all types of plastic and metal medical devices, whether heat- and moisture-resistant or not, including electromechanical medical devices, synthetic materials, fiber optic devices, PVC-based medical devices, surgical instruments, and laboratory equipment, and shall operate automatically.

2.2 The device shall be capable of sterilizing cardiovascular (KVC) materials, catheters, laparoscopic and endoscopic instruments, and similar disposable materials in the shortest possible time.

2.3 The internal volume of the sterilization chamber shall be 134 L ±2%, of a prismatic type. All processes shall be carried out within a single cabinet. The chamber shall be made of 316 stainless steel.

2.4 The sterilizer shall consist of a single complete cabinet and shall operate using ethylene oxide gas. A cartridge chamber shall be located inside the cabinet, and original cartridges containing 100 g of 100% ethylene oxide, or equivalent cartridges declared acceptable by the manufacturer, shall be used. The device shall be equipped with a 13.6 MHz RFID (Radio Frequency Identification) Cartridge Recognition System.

2.5 During the ethylene oxide exposure period of the sterilization cycle, the gas concentration inside the sterilization chamber shall comply with TS EN 11135-1 Standard, within the range of 300–1200 mg/L. The device shall generate an error for all factors that may alter gas concentration during sterilization (such as missing or incomplete cartridge installation, air ingress, vacuum system failure, etc.). The device shall operate at an ethylene oxide dose of 746 ±2% ppm EO.

2.6 No additional materials such as dosimeters, humidification packs, or similar items shall be required other than the cartridge used for device operation.

2.7 After the sterilization chamber door is closed and the required pressure, temperature, and humidity conditioning is automatically completed, the cartridge shall be automatically punctured and the gas released into the sterilization chamber. The device shall prevent any possible premature puncturing through its integrated electronic safety system.

2.8 The device shall use PLC and HMI software technology and shall not have a keypad. Control shall be provided via a color touchscreen panel, from which all functions shall be controlled automatically and, when necessary, manually.

2.9 The device shall operate based on the principles of vacuum, heating, humidification, sterilization, and air washing, all of which shall be performed automatically without user intervention. The screen shall alert the user with error codes in the event of errors, alarms, or nonconformities. In alarm conditions, the device shall provide both visual alerts on the screen

and audible alerts, and these shall be simultaneously traceable via the printer. The pre-conditioning, sterilization, and aeration stages shall be viewable on the screen. Time, temperature, and vacuum values shall be continuously monitored via the display. Process completion and phase transitions shall be identifiable on the operator panel both graphically and audibly.

2.10 The device shall be equipped with a thermal printer, and sterilization data shall be saved in PDF format to a USB flash drive upon completion of the process. Post-process values shall be printable in alphanumeric format. Functional parameters shall be digitally monitored. The operator touchscreen interface shall display user and technical modes in Turkish, and the software shall also support the English language. Setup and validation settings shall be configurable directly via the device. An easy-to-use operating manual shall be integrated into the device software and shall be easily accessible via the touchscreen. The printed records shall display sterilization parameters (humidity, temperature, pressure, duration, date) as well as any errors occurring during sterilization and their corresponding codes.

2.11 The sterilization process shall be carried out under continuous negative pressure. Accordingly, during gas exposure and aeration phases, the pressure inside the sterilization chamber shall remain lower than ambient pressure. The device shall be equipped with safety measures in compliance with international standards.

2.12 The device shall utilize an oil-sealed vacuum pump with a minimum capacity of 500 mmHg. The sterilizer shall operate using compressed air in the range of +6 to +8 bar. The device shall contain a minimal number of mechanical components that could cause service issues; components such as circulation pumps, water heaters, and steam generators shall not be present. The device shall have an external air connection.

2.13 Operating temperature data shall be adjustable between 37–55 °C according to different time and pressure settings. The device shall have at least two fixed programs for sterilizing heat-sensitive materials (5 hours at 37–38°C and 3 hours at 54–55°C with printouts available via the printer for verification).

2.14 The humidification process shall operate using a cold dry steam vacuum technique, independent of the municipal water supply. No drainage connection shall be required. With its integrated humidification tank, the device shall be capable of performing at least 30 sterilization cycles. The water level in the humidification tank (full/empty status) shall be electronically monitored and visually indicated on the screen. Through its relative humidity monitoring capability, the device shall continuously monitor the sterilization chamber during the pre-conditioning phase.

2.15 The device door and gasket shall be resistant to ethylene oxide and fully leak-tight. The gasket shall be of single-piece construction, and chamber thermal insulation shall be made using isopolymer material.

2.16 The door locking system shall be electrically operated and electronically controlled via a microcomputer. For safety reasons, the door shall not open during power failures or while sterilization is in progress and gas is present inside the chamber. A lock protection system shall be provided to prevent door opening in the event of air leakage or power interruption. The door lock status shall be displayed on the screen. The door shall include a locking latch that allows safe opening and closing with a single motion. The process shall not start unless the door is fully closed. The door lock shall be an automatic electronic locking system and shall include electrical and pneumatic safety mechanisms to prevent door opening.

2.17 The device shall be supplied with two stainless steel loading trays.

2.18 The device shall optionally be supplied with a dedicated stand/table on which it can be placed.

2.19 The sterilization process shall be capable of being stopped in emergency situations. In such cases, the vacuum and aeration systems shall be automatically activated to remove and neutralize the gas inside the chamber.

2.20 In order to prevent the user from being exposed to Ethylene Oxide gas, the sterilization and aeration processes must be carried out in the same chamber. The aeration process shall be operable either automatically or manually, and the system shall include a special ventilation unit with a fume hood. After ventilation, the sterilized materials must be ready for immediate use without requiring additional aeration. Additionally, the device shall allow the user to select and apply the desired amount of aeration.

2.21 The external components shall be made of stainless steel and antibacterial DKP sheet metal. The device door and sterilization chamber shall be made of AISI 316 grade stainless steel or aluminum.

2.22 For safety purposes, the device shall be equipped with a hermetic exhaust fan that can be connected to a flue.

2.23 The heating system shall be dry, maintenance-free, and consist of homogeneous film heaters or silicone heaters.

2.24 The device shall operate on a 220V, 50 Hz mains power supply. To prevent gas and time loss, the device shall be resistant to ±10% voltage fluctuations. In the event of a power failure, the device shall retain all data in memory and switch to standby mode. When power is restored, depending on the stage of the process, the device shall either restart the sterilization cycle or continue from where it left off based on the current measurement values.

2.25 The device shall be supplied with standard accessories. These accessories shall be specified by the supplier company.

2.26 The sterilizer air inlet shall be connectable to the existing central air line of the central sterilization unit. The device's flue connection and gas exhaust shall be routed to the outside of the building or to a location higher than nearby buildings, in a manner that does not pose a risk to human health.

2.27 Usage training shall be provided to at least three (3) personnel who will operate the device, and training certificates shall be issued.

2.28 The device shall be covered by a two (2) year warranty against all manufacturing and assembly defects. The supplier company shall guarantee the availability of spare parts and paid technical service for a period of ten (10) years following the expiration of the warranty period.

3. REQUIRED DOCUMENTS

3.1 The supplier company shall submit, together with the bid, the original product brochures/manuals of the device, of sufficient detail to include responses to every item specified in the technical specifications.

3.2 An authorization certificate issued to the supplier company by the manufacturer or authorized distributor for the offered device shall be attached to the bid.

4. TECHNICAL SERVICE, WARRANTY, AND SPARE PARTS

4.1 The devices shall be covered by a two (2) year warranty. This warranty shall be separately provided in the bid file by the seller, the authorized representative, and the manufacturer. During the warranty period, no fees shall be charged for maintenance, repairs, or spare parts, excluding consumables and maintenance kits. Following a fault notification, intervention shall take place within 72 hours, and the device shall be fully operational with all functions restored within a maximum of five (5) days. If spare parts must be sourced from abroad, they shall be supplied and intervention completed within thirty (30) days.

4.2 The supplier company shall document its technical service capabilities and infrastructure (such as the number of technical personnel, maintenance and repair facilities, etc.).

4.3 After the expiration of the warranty period, the manufacturer and the authorized representative shall commit to supplying spare parts for a minimum period of ten (10) years, subject to payment.

4.4 The bidding company shall specify the technical specifications and names of spare parts and consumables that may require replacement both within and outside the warranty period. Prices for these items shall be quoted in foreign currency, valid for five (5) years, and included in the bid.

5. ACCEPTANCE AND INSPECTION

5.1 Acceptance and inspection of the devices shall be carried out by a commission appointed by the administration. During inspection and examination, compliance with all specifications requested in the technical specifications and stated in the bid shall be verified. In addition, spare parts, accessories, and consumables shall be inspected and counted.

5.2 During acceptance and inspection, if testing of the device’s technical specifications and performance is requested, the supplier companies shall provide the necessary personnel and equipment free of charge. The supplier company shall be responsible for any accidents or damages that may occur during acceptance and inspection.

5.3 Factory Acceptance Test (FAT) and Site Acceptance Test (SAT) reports, the quality control certificate, shall be provided by the Manufacturer together with the device.

6. INSTALLATION

6.1 The supplier company shall install the devices free of charge and deliver them in fully operational condition together with all materials and accessories. All materials and expenses required for installation shall be borne by the supplier company.

7. TRAINING

7.1 The company awarded the tender shall provide free user and maintenance training, after installation, to the number of personnel determined by the administration. The training shall be conducted by the company's own trained staff and shall cover device operation, maintenance, and troubleshooting of possible malfunctions. This condition shall be formally committed by the company in the bid dossier.