SINGLE-DOOR LOW-TEMPERATURE PLASMA HYDROGEN PEROXIDE STERILIZATION DEVICE – TECHNICAL SPECIFICATIONS

1. SUBJECT

1.1. This Technical Specification covers the technical features, control, and inspection methods of the Low-Temperature Hydrogen Peroxide Plasma Sterilization Device to be procured domestically for …….

2. TECHNICAL SPECIFICATIONS

2.1. The device shall be capable of sterilizing all types of materials, both metallic and non-metallic, that are sensitive to high temperature and humidity, including delicate medical and electronic materials, using the Hydrogen Peroxide (H2O2) plasma method, particularly for low-temperature sterilization.

2.2. The sterilization chamber of the device shall have a volume of 152 ± 2 liters.

2.3. The device shall be equipped with an HRF plasma generator that produces effective Cold Plasma waves.

2.4. Inside the sterilization chamber, there shall be an electrode sensor surrounding the inner walls of the chamber, which activates when stimulated by the HRF generator with a minimum output of 700 Watts. The pressure inside the chamber shall be electronically controlled via a pressure vacuum gauge mounted on top of the sterilization chamber.

2.5. The device shall use the gas plasma sterilization method, in which liquid Hydrogen Peroxide, a strong chemical agent, is vaporized under vacuum and sprayed onto the items to be sterilized, then ionized with the HRF generator and mixed into the air. The device shall include a controlled separator mechanism. Hydrogen Peroxide sterilization devices that operate only with vapor and do not generate plasma shall not be accepted.

2.6. The device shall sterilize materials at a temperature range of 37°C to 55°C, with cycle durations not exceeding: 30 minutes for the short program, 47 minutes for the long program, and 63 minutes for the lumen program. The plasma process shall be performed inside the sterilization chamber.

2.7. In each cycle, the amount of Hydrogen Peroxide injected by the device shall be constant and defined. The amount shall not increase based on the type or quantity of the load or the program selected on the device. The system, along with consumables, shall be fully validated and documented.

2.8. The device shall have a special lumen program capable of sterilizing flexible endoscopes without causing damage. No additional accessories shall be required. The device shall fully sterilize non-metallic medical items (e.g., polyethylene or Teflon lumens) with a lumen diameter of 1 mm and a length of up to 1 meter.

2.9. Sterilization shall be monitored using chemical and biological indicators developed for plasma systems. Functionally, materials to be sterilized, especially during long and lumen cycles, shall be exposed to H2O2 gas (dose) and plasma at least twice.

2.10. The device shall have a USB port to download previous cycle information. At least 100 past cycle reports shall be retrievable from the device memory via USB. The device shall be network-capable, and error codes shall be displayed both in writing and visually.

2.11. The device shall be equipped with a printer on the front panel to provide all information related to the sterilization cycle and parameters (e.g., date, time, sterilization stage).

2.12. In the event of any problem during sterilization, the cycle shall be automatically canceled, and the device shall issue audible and visual alarms, indicating the cause. The front panel screen shall provide information on the problem and instructions for resolution.

2.13. The device shall operate fully automatically. An additional foot pedal shall be provided for door opening.

2.14. The device shall be user-friendly and operable without specialized personnel, with the user guided through Turkish menus preferred.

2.15. The chamber where materials are loaded shall have a safe front door (non-sterile material loading) that opens up and down, equipped with an electronic locking system. A pneumatic safety mechanism shall prevent door opening unless the cycle is stopped by the user. The door shall include safety measures to prevent contact with materials and hands. A silicone O-ring seal shall be provided on the inside of the door to prevent leaks. The door shall be electronic and vertically sliding.

2.16. The device shall operate on 220 V / 50 Hz / 25 A (+/-10%) mains electricity.

2.17. The device shall not require external water, drainage, ventilation, or installation connections. It shall be mobile, easily moved using existing wheels, and capable of being installed and operated anywhere. The sterilization chamber shall be 316 stainless steel, and the external frame shall be stainless steel / DKP ESC powder-coated and antibacterial DKP sheet to resist oxidation and chemical cleaning agents.

2.18. The device shall have 3 shelf positions. It shall be supplied with 3 original sterilization baskets, and the user shall be able to monitor the remaining Hydrogen Peroxide through the device screen or cycle report.

2.19. The device shall be equipped with a HEPA filter for incoming air and a HEPA/Ag. filter for exhaust. The vacuum pump shall consist of at least a two-stage, single-direction rotary vacuum pump, capable of achieving 10^-2 Torr automatically.

2.20. The device shall operate with at least 50% Hydrogen Peroxide solution and a minimum of 5-use cartridges/cassettes. It shall include a 13.6 MHz RFID cartridge recognition system. Cartridges/cassettes shall be fully compatible with the device. The system shall produce no waste. The menu shall include a sterilization counter displaying the number of cycles. The H2O2 solution level in the reservoir shall be visible on the device screen. Cartridge/cassette details shall be declared.

2.21. The device shall have EN 14937 sterilization validation testing.

2.22. The device and manufacturer shall possess international standards and service competency certifications, including CE, ISO 13485 (design), ISO 9001, TUR, TSE Service Qualification, UBB/UTS registration, and the device shall have its own barcode number.

2.23. The supplier company shall submit a Domestic Product (Local Goods) Certificate for the supplied products/materials.

2.24. A minimum of three (3) personnel who will operate the device shall receive adequate training and be issued training certificates.

2.25. The device shall have a two (2) year warranty against all manufacturing and assembly defects. Following the warranty period, the supplier company shall guarantee spare parts and technical service for ten (10) years for a fee.

3. REQUIRED DOCUMENTS

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

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

4. TECHNICAL SERVICE, WARRANTY, AND SPARE PARTS

4.1. The devices shall have a two (2) year warranty, which shall be separately provided in the bid by the supplier, the authorized representative, and the manufacturer. During the warranty period, no fees shall be charged for maintenance, repair, or spare parts, excluding consumables and maintenance kits. Following a fault notification, intervention shall occur within 72 hours, and the device shall be fully operational with all functions restored within a maximum of 5 days. If parts are required from abroad, they shall be supplied and intervention completed within 30 days.

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

4.3. After the warranty period, the manufacturer and authorized representative shall commit to providing 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 during or after the warranty period, quoting their prices in foreign currency, valid for five (5) years, and include this information in the bid.

4.5. The manufacturing company of the device shall possess a TSE Service Qualification Certificate.

5. ACCEPTANCE AND INSPECTION

5.1. Acceptance and inspection of the devices shall be conducted by a commission appointed by the administration. During the inspection, 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 company shall provide the necessary personnel and equipment free of charge. The supplier company shall be responsible for any accidents or damages occurring during acceptance and inspection.

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

6. INSTALLATION

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

7. TRAINING

The company awarded the tender shall provide free training of 3 hours on device operation, maintenance, and troubleshooting of possible malfunctions, conducted by its own trained personnel, to the number of staff determined by the administration. In addition, free training on operation and maintenance shall be provided to personnel at the locations where the devices will be installed. This condition shall be formally committed by the company in the bid dossier.