SINGLE-DOOR LOW-TEMPERATURE HYDROGEN PEROXIDE PLASMA 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 metal and non-metal materials, particularly sensitive medical and electronic items that are not resistant to high temperatures and humidity, using the Hydrogen Peroxide (H_2O_2) plasma method, especially at low temperatures.

2.2. The sterilization chamber volume shall be 113 ±2 liters.

2.3. The device shall include 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 is activated when stimulated by an HRF generator of at least 500 Watts. The chamber pressure shall be electronically controlled via a vacuum/pressure gauge mounted on top of the sterilization chamber.

2.5. The device shall employ a gas plasma sterilization method, in which liquid Hydrogen Peroxide, a strong chemical agent, is vaporized under vacuum, sprayed onto the materials to be sterilized, ionized by the HRF generator, and mixed with air. The device shall include a controlled separator system. Hydrogen Peroxide sterilizers that only use vapor without plasma shall not be preferred.

2.6. The device shall sterilize materials at 37°C–55°C, with short program exposure of 30 minutes, long program 47 minutes, and lumen program 63 minutes, without exceeding the specified sterilization exposure time. The plasma process shall occur inside the sterilization chamber.

2.7. In each cycle, the amount of hydrogen peroxide injected by the device shall be fixed and defined, and shall not increase depending on the type or quantity of the load or the selected program on the device. The system, together with consumables, shall be validated and fully documented.

2.8. The device shall have a dedicated lumen program to sterilize flexible endoscopes without causing damage. No additional equipment shall be required. It shall fully sterilize medical devices with non-metallic lumens (polyethylene or Teflon), with lumen diameters of 1 mm and lengths up to 1 meter.

2.9. Sterilization shall be monitored using chemical and biological indicators developed for the plasma system. Materials to be sterilized shall be exposed to H_2O_2 gas (dose) and plasma at least twice during long and lumen cycles.

2.10. The device shall have a USB port to download past cycle information. At least 100 past reports shall be retrievable via USB. The device shall be capable of network connection, and error

codes shall be displayed both visually and in writing.

2.11. The device shall include a PLC microprocessor and software system that controls the sterilization process phases (vacuum, injection, diffusion, plasma, and aeration), continuously monitors vacuum, temperature, and other parameters, makes necessary adjustments, and takes precautions in case of problems.

2.12. The front panel shall include a touchscreen operator panel of at least 7 inches, displaying cycle stages, number of past cycles, and elapsed time graphically. The menu shall include a stage control diagram, allowing the user to see on the colored screen which processes are running and the current sterilization stage. The user shall be warned of periodic maintenance requirements via this screen.

2.13. The front panel printer shall provide information on all stages of the sterilization cycle and sterilization parameters (e.g., date, time, sterilization stage).

2.14. In case of any problem during sterilization, the cycle shall automatically stop, and the device shall issue audible and visual alarms indicating the cause. The front panel screen shall provide guidance on the problem and its solution.

2.15. The device shall be fully automatic. A foot pedal shall be provided for opening the door.

2.16. Operation shall not require specially trained personnel; the user shall be guided through Turkish menus on the device.

2.17. The chamber front (for non-sterile material loading) shall have a safe door system that opens up and down with an electronic locking mechanism. A pneumatic safety mechanism shall prevent door opening unless the cycle is stopped by the user. Safety systems shall protect against material or hand collisions. The inner side of the door shall have a silicone O-ring seal to prevent leaks. The door shall be electronic and vertically sliding.

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

2.19. The device shall not require external water, drainage, ventilation, or installation. It shall be mobile, easily movable with its wheels, allowing installation and operation anywhere. The sterilization chamber shall be 316 stainless steel, and the outer frame shall be stainless steel/DKP ESC powder-coated and antibacterial DKP sheet, resistant to oxidation and chemical cleaning.

2.20. The device shall have 3 shelf positions. Three original sterilization baskets compatible with the device shall be provided. The user shall be able to monitor the remaining hydrogen peroxide amount on the device screen or cycle report.

2.21. The device shall include a HEPA filter for incoming air and an Ag. (HEPA) filter at the outlet. The vacuum pump shall be an automatic, single-direction, two-stage rotary pump capable of at least 10-2 Torr.

2.22. The device shall operate with at least 50% Hydrogen Peroxide solution and at least 5-use cartridges/cassettes. It shall include a 13.6 MHz RFID cartridge recognition system, and the cartridges/cassettes must be compatible with the device. The system shall produce no waste. The menu shall include a sterilization counter, and the H2O2 solution level in the reservoir shall

be visible on the device screen. Cartridge/cassette information shall be declared.

2.23. The device shall have EN 14937 sterilization validation.

2.24. At least 3 personnel shall be provided sufficient operational training and certification for using the device.

2.25. The device shall have a two (2) year warranty against all manufacturing and assembly defects. After the warranty period, the supplier shall provide paid spare parts and technical service support for ten (10) years.

3. REQUIRED DOCUMENTS

3.1. The supplier company shall provide, together with the offer, the device's original promotional documents (sufficient to answer every item in the technical specifications).

3.2. For the offered device, the authorization certificate issued by the manufacturer or distributor to the supplier company shall be attached to the offer.

4. TECHNICAL SERVICE, WARRANTY, AND SPARE PARTS

4.1. Devices shall have a 2-year warranty, which shall be provided separately in the offer by the supplier, representative, and manufacturer. During the warranty period, except for consumables and maintenance kits, no fees shall be charged for maintenance, repair, or spare parts. Faults shall be addressed within 72 hours after notification, and the device shall be fully operational within 5 days. If parts need to be sourced from abroad, they shall be procured and serviced within 30 days.

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

4.3. After the warranty period, the manufacturer and representative company shall commit to providing spare parts for at least 10 years for a fee.

4.4. The bidder shall specify the technical specifications and names of spare parts and consumables that may require replacement during or after the warranty, provide their prices in foreign currency valid for 5 years, and include this information in the offer.

5. ACCEPTANCE AND INSPECTION

5.1. Acceptance and inspection of the devices shall be conducted by a commission determined by the administration. During inspection, compliance with all features specified in the technical specifications and the offer shall be verified. Additionally, spare parts, accessories, and consumables shall be checked and counted.

5.2. If testing of the device's technical features and performance is requested during acceptance and inspection, the supplier shall provide the necessary personnel and setup free of charge. The supplier shall be responsible for any accidents or damage occurring during inspection.

5.3. Factory Acceptance Test (FAT) and Site Acceptance Test (SAT) reports, as well as quality control certificates, 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 fully operational with all materials and accessories. All materials and costs required for installation shall be covered by the supplier.

7. TRAINING

The winning company shall provide 3 hours of free training to a number of personnel determined by the administration on the use, maintenance, and troubleshooting of the devices, conducted by its trained staff. In addition, free training on usage and maintenance shall be provided to personnel at the sites where the devices will be installed. This condition shall be guaranteed in the offer.