LOW-TEMPERATURE HYDROGEN PEROXIDE & HYDRONIUM HEAVY MOLECULE PLASMA STERILIZATION DEVICE – TECHNICAL SPECIFICATIONS

1. SUBJECT

1.1. This Technical Specification covers the technical features, control, and inspection methods for the Low-Temperature OZONE & Hydrogen Peroxide Plasma Sterilization Device operating with Hydronium heavy molecules, to be procured domestically for ……

2. TECHNICAL SPECIFICATIONS

2.1. The device must be suitable for sterilizing medical, electronic, and electromechanical materials that are sensitive to high temperatures and moisture, including tubing, lumens, and flexible endoscopes of various lengths, especially items requiring low-temperature sterilization. The sterilization method should utilize Ozone (O_3), Hydrogen Peroxide (H_2O_2), and heavy molecules (Hydronium H_3O). The device must be an advanced high-tech product.

2.2. The device should function both as a heavy molecule sterilizer and a Hydrogen Peroxide plasma sterilizer. Sterilization must involve ionized Ozone gas and vaporized liquid Hydrogen Peroxide under vacuum, achieving gas, plasma, and heavy-molecule sterilization. Hydronium heavy molecules (H_2O_4, HO_5, H_3O, hydroxyl radicals) should be generated using Hydrogen Peroxide (H_2O_2) and Oxygen (O_2) gas.

2.3. The device must have a microcomputer system and software to manage all sterilization stages, including vacuum, injection, diffusion, Ozone, Hydronium adsorption, dilution, cold plasma, and aeration, continuously monitoring vacuum, temperature, and other parameters.

2.4. The sterilization chamber must have a capacity of 152 ±4 liters and be made of 316L stainless steel.

2.5. The device must have a single door with a secure electronically locked sliding mechanism that opens vertically. The door should include electric and pneumatic safety interlocks, a silicone O-ring to prevent leakage, and a foot pedal for opening and closing.

2.6. The device must sterilize all types of lumens and flexible endoscopes without damage, even at full load, using a special heavy-molecule lumen sterilization program. No additional accessories (e.g., booster kits) should be required. It must fully sterilize multi-channel medical instruments (endoscopes, etc.) with inner diameters 0.7 mm to 2 mm, lengths up to 50 cm or at least 10 m, at full load. Accredited Inspection Reports must document sterility testing for such long products.

2.7. The device must be capable of sterilizing mixed loads in a single chamber without differentiation for short, long, lumen, or endoscope programs. A long-lumen program must exist for lumens longer than 7.5 meters.

2.8. The heavy-molecule sterilizer must also function independently as a Hydrogen Peroxide sterilizer. The device must have five programs: two programs for long lumen and load sterilization using the Heavy Molecule feature, and three programs operating as a Hydrogen Peroxide sterilizer.

2.9. The Hydrogen Peroxide programs must include short, long, and lumen cycles, operating solely with H_2O_2.

2.10. The device must operate with at least 50% Hydrogen Peroxide solution, a cartridge/cassette with at least 5 uses, and medical-grade oxygen >90%. It must feature a 13.6 MHz RFID cartridge recognition system, fully compatible with the cartridges/cassettes.

2.11. Waste must be limited to water and oxygen. The system must include a sterilization counter and display the remaining H_2O_2 solution in the reservoir. An unused H_2O_2 collection container must be included. Cartridge/cassette information must be documented.

2.12. The device must automatically detect moist instruments, dry them without interrupting sterilization, and prevent unnecessary cartridge consumption.

2.13. The device must include a Cold Plasma generator. Inside the sterilization chamber, an electrode sensor must activate when triggered by a high-voltage RF generator. Chamber pressure must be electronically controlled via a mounted vacuum gauge.

2.14. In Hydronium mode, the device must sterilize materials at 37°C–45°C, achieving full sterilization within 70 minutes for full load and up to 95 minutes for full-lumen complex loads.

2.15. Sterilization must be monitored using chemical and biological indicators designed for H_2O_2 plasma. Wet or moist loads must trigger automatic drying and continue sterilization without canceling the cycle, ensuring safe sterilization.

2.16. The device must include a USB port for downloading past cycle information. Reports must be retrievable via USB. The device must support network connection, and errors must be displayed visually and in writing.

2.17. The device must have a color touch-screen operator panel showing cycle stages, past cycles, and elapsed time graphically. The screen must display the process status, including real-time progress and maintenance reminders. Remaining H_2O_2 solution usage must be visible on the screen.

2.18. Operation must be fully automatic. Safety systems must provide visual and audible alarms in case of errors, indicating the cause. Information must also be printable, including error codes and troubleshooting instructions.

2.19. The device must include a printer documenting all sterilization stages and parameters (date, time, cycle stage, etc.).

2.20. The device must include both a Plasma generator and an Ozone generator. It must automatically ventilate after sterilization.

2.21. The device must not require specially trained personnel; user guidance via Turkish menus is preferred.

2.22. The device must have 3 shelves, each portable and capable of holding 30 kg. Three original sterilization baskets must be provided.

2.23. The device must have a HEPA filter to clean incoming air. The vacuum pump must be an automatic, single-direction, two-stage rotary pump.

2.24. The device must be mobile, easily moved with wheels, and include infrastructure for an Ozone exhaust connection.

2.25. The device must operate on 220 V / 50 Hz / 25 A (±10%) mains power.

2.26. The device must include sterilization validation software compliant with EN ISO 14937.

2.27. The device and manufacturer must hold international standard certifications and service competence certificates, including CE, ISO 13485 (Design), ISO 9001, TSE Service Competence, UBB/ÜTS registration, and device barcode.

2.28. The supplier must provide a Local Product Certificate for delivered products/materials.

2.29. The device must include three user-level passwords to prevent unauthorized access. At least three personnel must receive training and certification for device operation.

2.30. The device must have a 2-year warranty against manufacturing and assembly defects. After this period, the supplier must guarantee paid spare parts and technical service for 10 years.

3. REQUIRED DOCUMENTS

3.1. The supplier must provide original promotional and technical documents capable of answering all items in the technical specifications along with the bid.

3.2. The manufacturer or distributor's authorization certificate must be included with the bid.

4. TECHNICAL SERVICE, WARRANTY, AND SPARE PARTS

4.1. Devices must have a 2-year warranty, provided separately by the supplier, representative, and manufacturer. Maintenance and spare parts (except consumables and maintenance kits) must be free of charge. Faults must be addressed within 72 hours and fully functional within 5 days. If foreign parts are required, they must be supplied within 30 days.

4.2. The supplier must document technical service capabilities, including personnel numbers and maintenance facilities.

After warranty, the manufacturer and representative must provide spare parts for at least 10 years against payment.

4.3. The bidder must list technical specifications and prices of spare parts and consumables that may require replacement during and after warranty, valid for 5 years, in foreign currency.

4.4. 4The manufacturer must have a TSE Service Competence Certificate.

5. ACCEPTANCE AND INSPECTION

5.1. Device acceptance and inspection will be performed by a commission appointed by the administration. Compliance with all specified and bid features will be checked, including spare parts, accessories, and consumables.

5.2. Vendors must provide staff and equipment free of charge for performance and technical tests during acceptance. The supplier is responsible for any accidents or damages during inspection.

5.3. Factory Acceptance Test (FAT) and Site Acceptance Test (SAT) reports, along with quality control documents, must be provided by the manufacturer with the device.

6. INSTALLATION

The supplier must install the device free of charge and deliver it fully operational with all accessories. All installation materials and costs are the supplier's responsibility.

7. TRAINING

The winning bidder must provide 3-hour free training to the number of personnel determined by the administration on device operation, maintenance, and troubleshooting. Training must also be provided at the installation site. This commitment must be included in the bid.