"OZONE & HYDROGEN PEROXIDE & HEAVY MOLECULE PLASMA STERILIZATİON DEVICE TECHNICAL SPECIFICATIONS"

1. SUBJECT:

This Technical Specification covers the technical features, control, and inspection methods related to the purchase of a Low-Temperature Ozone & Hydrogen Peroxide Plasma Hydronium Heavy Molecule Sterilization Device.

2. TECHNICAL SPECIFICATIONS

2.1. The device should be capable of sterilizing medical and electronic, electromechanical materials that are sensitive to high temperature and humidity, especially metals and non-metallic structures such as tubing with lumens and endoscopic materials of all lengths, which require low-temperature sterilization. The device should have multiple sterilization techniques and be of advanced high technology.

2.2. The device should operate both as a heavy molecule device and as a Hydrogen Peroxide Plasma device. It should utilize gas sterilization, plasma, and heavy molecule sterilization methods, where the powerful chemical agent Ozone gas is ionized and introduced into the sterilization environment, and liquid Hydrogen Peroxide is vaporized under vacuum and applied to the materials being sterilized. To create heavy molecules (hydronium) (H2O4, HO5, H3O, Hydroxyl, and radicals), Hydrogen Peroxide (H2O2) and Oxygen (O2) gases should be used

2.3. The sterilization chamber of the device should have a volume of 152 ±4 liters. The sterilization chamber must be made of 316L material.

2.4. Device should have a generator that produces effective Plasma (HRF Cold Plasma). Within the sterilization chamber, there should be an electrode sensor surrounding the inner walls of the chamber, which is activated when triggered by the HRF generator. The pressure inside the chamber should be electronically controllable via pressure vacuum gauge mounted on the top of the sterilization chamber.

2.5. Device should operate at low temperature. Device should sterilize materials at temperatures ranging from 37°C to 45°C in hydronium mode. During short program with full load, it should be able to sterilize materials in 70 minutes, and for long program with full luminal load, it should complete the sterilization in no more than 95 minutes.

2.6. Sterilization should be monitored with chemical and biological indicators developed for the H2O2 plasma system or H3O.

2.7. Device should have a USB connection for downloading past cycle information. Reports can be retrieved via USB from the device's memory. Device should be capable of connecting to a network system, and error codes should be displayed both in writing and visually.

2.8. Device should have a microcomputer system and software that continuously monitors and controls the vacuum, temperature, and other parameters, including the sterilization process phases such as vacuum, injection, diffusion, Ozone, Hydronium adsorption, dilution, plasma, and air intake.

2.9. Touch screen color operator panel on the front of the device should allow the user to graphically monitor the cycle stages, the number of past cycles, and the elapsed time. Screen menu should include a stage control diagram, allowing the user to track the processes the device is performing and which stage of sterilization it is in. The user should be notified through the same screen when the device's periodic maintenance is due. User should also be able to track how many more cycles the Hydrogen Peroxide Solution can be used for through the plasma sterilizer device's screen

2.10. The device should have a printer that provides information about all phases of the sterilization cycle and sterilization parameters (such as date, time, sterilization phase, etc.).

2.11. If any issues arise during sterilization, cycle should be automatically cancelled. Device should give visual and audible alarm and display the reason for the alarm on the screen. Error codes, problem description, and possible solutions should be provided via the front panel or printer. The device will operate fully automatically and will be equipped with appropriate security and warning systems.

2.12. In addition to the Plasma generator, device should also have an Ozone generator. After completing the sterilization phases, device should automatically perform air washing, and the user should be able to determine the number of air washing cycles.

2.13. Device should not require highly specialized trained personnel for operation. A sterilization technician who can use an H2O2 sterilization device should be able to operate this device as well. The device menus should guide the user in English and/or other installed language options.

2.14. The device must have a special sterilization lumen program that can sterilize any type of lumen and flexible endoscope, regardless of size and length, without causing damage. The sterilization process should be completed without the need for any additional apparatus (such as a booster kit etc). The device should fully sterilize medical materials such as endoscopes with a steel lumen with an internal diameter of 0.7 mm to 50 cm in length and multi-channel flexible lumens of at least 2 mm in diameter and 10 m in length. The device should have an accredited inspection report confirming sterilization testing for these lengths.

2.15. The device should have a program that can sterilize all items together, without the need for separate short, long, lumen, or endoscope programs. Additionally, the device should have a program for lumens longer than 7.5 meters.

2.16. The Hydronium Heavy Molecule Sterilization Device must also be capable of working as a Hydrogen Peroxide Sterilization Device. The device should have 5 programs, with 2 programs working under the Heavy Molecule sterilization feature for long lumen and load sterilization.

2.17. The other 3 programs should work with Hydrogen Peroxide Sterilization, with short, long, and lumen programs, so the device can operate solely with H2O2.

2.18. The device should automatically detect moist materials and dry them to ensure sterilization continues uninterrupted. This will prevent unnecessary cartridge consumption.

2.19. The device must have a single door. The front of the sterilization cabin where the materials to be sterilized are placed should have a secure door system with an electronic locking mechanism that can open vertically or horizontally. The system should have an electrical safety mechanism preventing the door from opening unexpectedly. A silicone O-ring seal should be present on the inside of the door to prevent leaks. A foot pedal should be available for opening and closing the door.

2.20. The device should be easily movable with its wheels, which should be lockable. The device should be easy to install and operate at any location. The device should also have an exhaust outlet for ozone gas waste.

2.21. Hydronium Heavy Molecule Sterilization Device should be able to operate with a 50% Hydrogen Peroxide solution as the sterilizing agent, a cartridge/cassette that can be used at least 5 times, and medical oxygen with a concentration exceeding 90%. The device should include a 13.6 MHz RFID (Radio Frequency Identification) cartridge recognition system. The cartridge/cassette must be compatible with the device.

2.22. The device’s waste material should be water and oxygen. Additionally, the system should include a sterilization counter in its menu to display the number of sterilizations performed. The device should also allow the user to monitor the amount of Hydrogen Peroxide solution remaining in the reservoir through its display. A waste container for unused H2O2 liquid should also be available.

2.23. The device should have 3 sterilization trays, and these trays should be provided with the device. Each tray should be capable of carrying up to 30 kg of load.

2.24. The device should have a HEPA filter that cleans the air taken from the environment. The vacuum pump should be a two-stage rotary pump with automatic one-way operation.

2.24. The device should have Sterilization Validation Testing software. The VH2O2 Device must have a validation program that complies with the EN ISO 14937 standard.

2.25. The device and the manufacturer should have CE, ISO 13485, and certifications and an Accredited Inspection Report according to international standards.

2.26. The device should have a 3-tiered user password system to restrict access and control device usage. At least 3 personnel should receive sufficient training and certification to operate the device.

2.27. The device should operate with 220 V / 50Hz / 25 Amp (± 10%) city mains electricity.

3. REQUIRED DOCUMENTS

3.1. The authorization certificate provided by the manufacturer or distributor to the selling company for the proposed device must be included in the offer.

4. TECHNICAL SERVICE WARRANTY AND SPARE PARTS

4.1. The selling company will document its technical service capabilities and infrastructure (number of technical staff, maintenance and repair facilities, etc.).

4.2. The device should be under a one (1) year warranty against any manufacturing defects, excluding user errors and consumables. This warranty will be valid provided that the necessary periodic maintenance is carried out on time, the product and consumables are used appropriately, and the spare parts used are original.

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

4.4. The bidding company will specify the technical specifications and names of the spare parts and consumables likely to be replaced under warranty and outside warranty in the device. They will also state the prices in foreign currency for a period of 5 years and include them in the offer.

5. ACCEPTANCE AND INSPECTION:

5.1. The acceptance and inspection of the devices will be carried out by a commission to be determined by the administration. During the inspection, the compliance with all specifications requested in the tender and stated in the offer will be checked. Additionally, the spare parts, accessories, and consumables will be inspected and counted.

6. INSTALLATION: The Selling Company/Representative/Distributor will install the devices free of charge and deliver them in working condition along with all materials and accessories. All materials and costs necessary for the installation will be borne by the company.

7. TRAINING: The awarded company will provide free training for 3 hours by its trained personnel to the number of staff designated by the administration on the usage, maintenance, and troubleshooting of the devices. Furthermore, free training will be provided to personnel at the installation sites regarding the use and maintenance of the devices. This condition will be committed by the company in the offer document