Specification for Low Temperature Hydrogen Peroxide Gas Plasma Sterilizer 25-50 litres

1. The Sterilizer should use Low Temperature H_2O_2 Gas Plasma for sterilization with plasma energy generated inside the sterilization chamber using RF energy/DBD Plasma for better efficacy and avoid the residual hydrogen peroxide for the safety of user and instruments.
2. Shape of sterilization chamber should be Rectangular.
3. Type of Hydrogen Peroxide Gas Sterilization technology used should be plasma technology Generated inside the chamber.
4. Sterilizer should have chamber temperature of 50 - 56^0 C at all the time during the cycle.
5. Sterilizer should have usable volume 25 - 50 liters.
6. Shelf size should be of minimum 60 cm depth so that trays can be sterilized easily. It should be able to sterilize 2 Trays in one cycle. [Each Tray of size 20 - 23inch x 8 – 10 inch x 2 -3 inch]
7. Sterilizer should have process certificate ENISO 14937.
8. The quoted model should be certified for sterilization of metal and non-metal medical devices by USFDA/European CE/BIS and CDSCO certificate.
9. The sterilizer should have 15 minutes readout time biological indicator system and BI should be approved as PCD for highest level of resistance. Reader and biological indicator should be from same sterilizer company to assure proper validation if reader is from different company, it should come along with the traceability certificate from the authorized NABL labs.
10. Consumables should be supplied with each sterilization unit sufficient for running full load 100 sterilization cycles.
11. Sterilizer should have facility to completely monitor its operation with audiovisual alarms and alarm history.
12. Should have built in facility for recording and printing cycle details and smart information technology device for automatic collection, reconciliation & communication of sterilization records.
13. Sterilizer should have preprogrammed cycles without any room for human error due to manual programming. Fastest cycle time should be less than 30 minutes and longest cycle should be less than 40 min with automated moisture check cycle before the start of the

cycle to reduce cycle cancellation and wastage of sterilant and time. There should be separate cycle for non- lumen/lumened instruments.

14. Warranty should be 5 Years followed by CMC for 5 years.
15. The leading/reputed device manufacturers should clearly specify in their instruments IFU (Instructions for Use) that the sterilizer brand as a validated method for reprocessing/ sterilizing Telescopes, Camera head, Fiberoptic Cables, Laparoscope, rechargeable batteries, arthroscopes, orthopedic drills, power tools & shaver and other orthopedic instruments etc. present in the hospital. Validation Documents from at-least two of these companies mentioned above needs to be submitted. No third party/self-declaration will be valid.

16. The By-products of the sterilizer should be non-toxic and eco-friendly. The OEM should provide EPA certificate/or environment safety document for the safety of the user and environment.

17. Sterilant cassette should be storable at room temperature and should have multidose cassettes/ cartridges to release calibrated sterilant for every Sterilization cycle.

18. Sterilant (H_2O_2 concentration >= 55%) should be in cassette form with leak proof indicator to avoid exposure of concentrated H_2O_2. 1 cassette should run minimum 5 or more cycles.

19. Original Manufacturer or their subsidiary or authorized Dealer who is quoting should be present in India having Plasma Sterilizer selling experience of more than 5 years and installation.

20. The bidder/ OEM should have their service team based at the location of installation. With service center Help lines numbers.

21. The sterilizer should have a provision for connecting a smart information technology device to connect, correlate & communicate cycle data and BI result across multiple sterilizers on hospital information network through cloud, desktop & smartphone access. To have the live data access of the machine. User should be notified through email and message alerts It should do automatic reconciliation of data to track the sterilized instruments and provided with bar code scanner and printer.

22. Sterilizer should be supplied with dedicated online UPS with 5 Years warranty.

23. **Demonstration (physical) of the quoted model at the site is must at the stage of technical evaluation**