

AMENDMENT-04

TENDER REF: HLL/PCD/PMSSY-II/NAGPUR/08/15-16

ETO Sterilizer

1. Existing specifications

Para 4: The chamber shall be insulated against heat emission and jacket shall be connected to warm water circulation arrangement

Read as:

Para 4: The chamber shall be insulated against heat emission and **specify the mechanism of heat insulation.**

2. Existing specifications

Para 7: The sterilizer shall be provided with suitable vacuum pump and gas trap to separate and evacuate the gas

Read as:

Para 7: The sterilizer should be provided with suitable **mechanism to separate and evacuate the gas and specify the mechanism**

3. Existing specifications

Para 10.b: EO gas cartridges: 50 No.

Read as:

Para 10.b: DELETED

4. Existing specifications

Para 8a: Sterilization cycle for heat sensitive objects that ensure **temperature from 33-55degreeC** with subsequent aeration for protection of the operating personnel.

Read as:

Para 8a: Sterilization cycle for heat sensitive objects that ensure **temperature from 37-55degreeC** with subsequent aeration for protection of the operating personnel.

5. Existing specifications

Para 9: Capacity: Should have capacity of 200litre or more. Conversion from cu.ft to litres is as per standard conversion. For information, 1 cu.ft is 28.317 litres approximately

Read as:

Para 9: Capacity: Should have capacity of 200litre or more. Conversion from cu.ft to litres is as per standard conversion. For information, 1 cu.ft is 28.317 litres approximately. **Specify the standard cycles available with offered equipment and total time for completion for each cycle including aeration**

6. Existing specifications

Para 10C: Packaging material with chemical indicator of all sizes, 1 roll each.

Read as:

Para 10C: DELETED

7. Existing specifications

Para 13: The ETO sterilizer should have compliance to **BS EN ISO 9001:2000**. Certificate to be provided by equipment manufacturer

Read as:

Para 13: The ETO sterilizer should have compliance to BS EN ISO 9001Certificate to be provided by equipment manufacturer

8. Existing specifications

Para 14: The ETO sterilizer should have compliance to **ISO13485:1996**.Certificate to be provided by equipment manufacturer.

Read as:

Para 14: The ETO sterilizer should have compliance to **ISO13485 Certificate** to be provided by equipment manufacturer.

9. Existing specifications

Para 15: The ETO sterilizer should have compliance to **OSHA/ NIOSH** exposure monitoring. Certificate to be provided by equipment manufacturer

Read as:

Para 15: The ETO sterilizer should have compliance to **OSHA/ NIOSH/OHSAS** exposure monitoring. Certificate to be provided by equipment manufacturer.

10. Existing specifications

Para 16: The required safety & clearance certificate from the concerned department should be the responsibility of the supplier.

Read as:

Para 16: The required safety & clearance certificate from the concerned department **if any** should be the responsibility of the supplier.

11. Existing specifications

Para 17: The consumables including packing material required for 1000 cycles to be provided.

Read as:

Para 17: The consumables to be quoted as follows:ETO gas cartridges required for 1000 cycles of full load, Sterilization basket - 2 Nos, Packing material- 5 different sizes - 5 rolls each, Chemical indicators -4000, Biological indicators -200, Unit price &seperate price of each item to be provided so that user will place order for these items based on requirement during warranty & CMC period(consumables for 200 cycles will have to supplied along with main equipment. The order for remaining consumables will be given by user on requirement basis during warranty & CMC period). **In addition the rate of consumables and disposables to be fixed for five years.**

12. **Added Para1:** If any machine requires compressed air plant for running the machine it should be supplied as standard.

13. **Added Para2:** All listed accessories and parts (eg.Vent hoods and exhaust hoods) as per manufacturer's guidelines required for running ETO should be supplied as standard.

14. **Added Para3:** Appropriate pollution control device for safe disposal of E.O like catalytic converter or equivalent technology / gas disposal management -to be as per local pollution control norms, if any.