

C.A.M. Supply Inc.

ETO Sterilization Method

1. All items that are to be sterilized are moved to clean rooms where they are prepped for Sterilization. Every product that is sterilized is wiped clean with alcohol soaked cotton ball. (Step 1)
2. After being cleaned all products are packed in one of the following FDA Approved packing: (Step 2)
 - a. Blister packaging
 - b. Sterilization tubing
 - c. Sterilization pouches
3. After being sealed in their packages, all products are placed in labeled boxes and sealed. These boxes are placed into larger boxes and moved to the HDX Sterilization chamber. This is the chamber where all items are sterilized. (Step 3)
4. The door is then closed and sealed. This is to ensure that the ETO (Ethylene Oxide) gas is not leaked. (Step 4)
5. The temperature is set between 38 and 2 Celsius. This is done with steam. (Step 5)
6. When the steam temperature is lower than 30.0%Rh, the steam is released again until the desired temperature is heated to 50.00%Rh. The control limit is maintained between 30% and 80% Rh. (Step 6)
7. Form #WI-T-Date is completed verifying process is correct. (Step 7)
8. Steps 6 & 7 are repeated. (Step 8)
9. Air is vacuumed out of the room. (Step 9)
10. Pressure is set at 3.0 KPa-20.0 KP-a. (Step 10)
11. When the pressure reaches between 3.0KPa and 2.0KPa, the vacuuming stops. (Step 11)
12. Room is kept at current condition for 3-5 minutes. (Step 12)
13. Outer seals are checked again for leaks. (Step 13)
14. If when the air is vacuumed out, the moisture level is lower than 30.0% Rh, then the control limit must be brought back and maintained between 30% and 80% Rh. (Step 14)
15. ETO gas is then released into the chamber. (Step 15)
16. ETO stays in the chamber for approximately 8.5 hours. (Step 16)
17. Computers monitor reactions throughout process. (Step 17)
18. Alarm sounds when 8.5 hours is completed. (Step 18)
19. Air is vacuumed again from the chamber. (Step 19)
20. Pressure is set at 30.0 Kpa for 5 minutes. (Step 20)
21. Air is replaced in the chamber (Step 21)
22. Air is vacuumed again (Step 22)
23. Steps 21 & 22 are repeated 3 times. (Step 23)
24. Form # WI-T-Date is re-completed. (Step 24)
25. Operated prints computer printed WI-T-Date and signs his name. (Step 25)
26. Door is released and opened (Step 26)
27. Products are removed from chamber and indicators are individually checked. If item is not sterile, process must be re-completed. (Step 27)
28. Each box is labeled with the date the process is completed in the following form:
 - a. QP-date
29. All ETO sterilized items are guaranteed to stay sterile for 2 years or the length of time indicated on package.

Our medical device numbers

C.A.M. Supply FDA Registration#: 2085835

C.A.M. Supply FDA Operator#: 9026450

C.A.M. Supply 510K #: K964861

Yours Truly

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