



浙江苏嘉医疗器械股份有限公司

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## Validation of the Sterilization

Product(s): Reinforce tracheal tube, Tracheal tube, Tracheotomy tube, 3-way stopcock, Mucus Extractor (Suction Tube), Umbilical Cord Clamp, Epidural Anaesthesia Kits, Epidural Needle, Spinal Needle, Extension Tube, Dressing Kits, Analgesia Infusion Pumps.

We hereby certify that Products above mentioned are sterilized with Ethylene Oxide and found to conform with the sterility requirements of EN550:1994 & EN1616:1997

The details and the process of sterilization are as follows:

1- Type of sterilization cycle

2- Gas mixture

3- Maximum level of gas residue

4- Sterilization process:

a. Load the Products in the sterilization chamber.

b. Load and locate 20 bio-indicators in the sterilization chamber for proving and check the sterility.

c. Precondition at 55 +/-1 °C temperature and 49-70% humidity for 30 minutes.

d. Initial vacuum 50+/-1 Kpa.

e. Inject the 20% Ethylene Oxide into the sterilization chamber and operate the sterilization cycle at temperature 55+/-1 °C and 40-70% humidity with exposure pressure 135 Kpa for 8 hours.

f. Evacuate the gas to 70+/-2 Kpa, and then turn off the vacuum valve.

g. Inject the fresh air into the sterilization chamber, when the pressure of the chamber is atmospheric, turn off the air valve.

h. Repeat the process of f and g for 3 times.

5- Expiry period: 5 years

Signature:

Stamp:

