

Sterilization of products

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The single package acupuncture needles are sterilized by EO to reach SAL=10⁻⁶, and the products are valid for more than three years from the time of sterilization. Allowable limits for <24

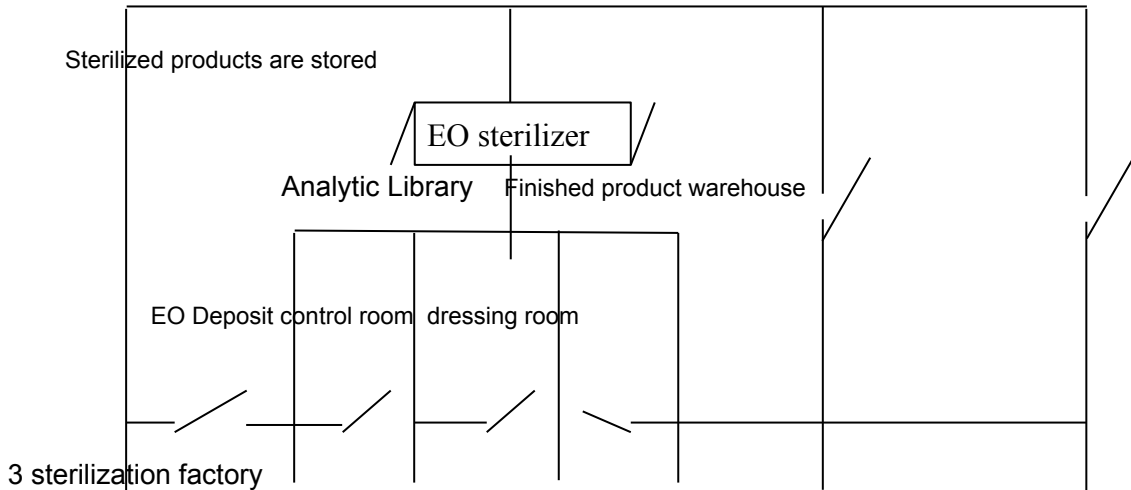
hour products for short term contact devices:

Average daily dose of EOG patients < 4mg/Day

Average daily dose of ECH patients < 9mg/Day

1 acupuncture needle sterilization basis: ISO11135-2014 standard.

2 the process layout of the sterilization workshop shall be shown as shown below to prevent the batch of sterilized and sterilized products.



The acupuncture needle products commissioned by the Wuxi Zhushi Acupuncture and Moxibustion Supplies Factory. The unit has been ISO 13485 certificate and ISO11135-1.

4 sterilization process

The product to be sterilized, according to figure in the sterilizer in stacking (with each box on the wall of the dose of EO color film, each sterilization cloth ATCC9372 indicator sheet) to close the front door, heating, vacuum, humidification, and EO, to keep the replacement (2-3) to open the discharging door, removed the sterilization the acupuncture needle, and finished products inspection and analysis

5 sterilization technical parameters temperature: $50^{\circ}\text{C}\pm 3^{\circ}\text{C}$, humidity: $60\%RH\pm 15\%RH$
 pressure: $-23\text{Kpa}-27\text{Kpa}$, EO concentration : $650\text{mg/L}\pm 50\text{mg/L}$ 。

The product is in EO gas, stay $6\pm 3\text{Kpa}$, keep 6h。

After 6h, Vacuum to $-20\pm 2\text{Kpa}$, Get in the fresh air, Repeat 3 times

Open the door of the sterilizing cabinet, remove the sterilized product, and change the color of the EO dose chameleon.

Take out the ATCC9372 instructions and send them to sterility test。

6 sterilization effect

Sterilization validation report

