

# Jiangsu Ruiben Medical Technology Co., Ltd

Customer 's Medical Equipment & Sanitary Goods

## Entrust Sterilization Examining Report

Manufacturer: JIANGSU HUIDA MEDICAL INSTRUMENTS CO.,LTD

Product Name : 18145,PETRI DISHES, Ø90MM X 15MM, 3 ROOMS.

Amount : 5000 Volume : 0.65596 m<sup>3</sup>

Lot Number : H20240701 Disinfection Date : 2024.08.01

Disinfection Equipment : HSX - 20 (20 m<sup>3</sup>) disinfection cabinet of ethylene - oxide by

Computer programme - controlled .

Disinfection Method : STERILE EO .

Standard : ISO11135-2014,GB18279-2008,GB15980-2009.

Technical Parameter : Ethylene oxide dosage : 700 mg / L ;

Temperature: 51.0--55.0 °C Humidity: 40-60 % Time: 8 h

### Detection method:

**Chemical indicator method (Nantong Pakion):** If the color of the indicator changes from yellow to red to blue after disinfection, it indicates that the product has been disinfected.

**Biological indicator method (3M, Attempt):** The 1264S model ethylene oxide sterilized biological culture indicator is placed and inspected according to the standard. If there is no positive reaction after cultivation, it indicates that the product is disinfected.

**Physical parameter value :** Measure and analyse the data which comes from disinfect process to confirm disinfect running in a tolerance as stated , it proved that the product has been disinfected .

**Ethylene Oxide Residues Amount :** Base on standard ISO 10993-7 to inspect and protract seasonal graph to evaluate after 10 days to use .

**Disinfection Validity Period :** Keep intact original package and pollution - free , the period of validity is 5 years .

**Conclusion :** It is qualified that this batch of 100000 pieces after disinfection.

**Explanation:** This report only covers the standards and technical data during the disinfection process of medical and sanitary supplies provided by the client. The sterilization indicators reported comply with ISO11135-2014, GB18279-2008, and GB15980-2009. After disinfection, no analysis or evaluation will be conducted on whether the product meets other indicators.

### Automatic record

#### of computer

24/08/01	16:26	1
54.8°C	+18kp	
54.2°C	+17kp	60%
54.7°C	+17kp	60%
55.0°C	+16kp	59%
55.0°C	+16kp	59%
55.0°C	+14kp	59%
54.9°C	+13kp	59%
54.9°C	+12kp	59%
54.0°C	+14kp	59%
53.2°C	+13kp	59%
53.3°C	+13kp	59%
51.0°C	+12kp	59%
51.0°C	+12kp	59%
51.5°C	+11kp	59%
51.8°C	+11kp	59%
51.8°C	+10kp	59%
52.9°C	+10kp	59%
52.0°C	+10kp	60%
54.0°C	+10kp	60%
54.4°C	+10kp	59%
55.0°C	+09kp	59%
55.0°C	+09kp	59%
54.4°C	+08kp	59%
53.5°C	+08kp	59%
55.0°C	+07kp	60%
54.2°C	+07kp	59%
55.0°C	+07kp	59%
55.5°C	+07kp	59%
54.2°C	+07kp	60%
51.8°C	+06kp	60%
55.0°C	+06kp	60%
55.0°C	+06kp	60%
55.0°C	+06kp	59%
55.0°C	+06kp	59%
24/08/01	08:25	三
55.0°C	+02kp	59%
55.0°C	-06kp	59%
55.0°C	-15kp	59%
24/08/01	07:55	二
55.0°C	-20kp	59%
24/08/01	07:40	一

Sigu : QI JINGJING

Date : AUG.1ST.2024