# Jiangsu Ruiben Medical Technology Co., Ltd

### Customer's Medical Equipment & Sanitary Goods

## **Entrust Sterilization Examining Report**

Manufacturer: JIANGSU HUIDA MEDICAL INSTRUMENTS CO.,LTD		Automatic record		
Product Name: 18249,PETRI DISHES, Ø 90MM X 15MM , 1 ROOM.		of computer		
Amout : 10000 Volume : 1.31192 m <sup>3</sup>	24/08/01	16:26	1	
Lot Number: H20240701 Disinfection Date: 2024.08.01	54.8°C	+18kp		
	54.2°C	+17kp	60%	
Disinfection Equipment: HSX – 20 (20 m³) disinfection cabinet of ethylene - oxide by	54.7°C	+17kp	60%	
Computer programme - controlled .	55.0°C	+16kp	59%	
	55.0°C	+16kp	59%	
Disinfection Method: STERILE EO.	55.0°C	+14kp	59%	
Standard: ISO11135-2014,GB18279-2008,GB15980-2009.	54.9°C	+13kp	59%	
	54.9°C	+12kp	59%	
Technical Parameter: Ethylene oxide dosage:700mg / L;	54.0°C	+14kp	59%	
Temperature: 51.055.0 °C Humidity: 40-60 % Time: 8 h	53.2°C	+13kp	59%	
	53.3°C	+13kp	59%	
	51.0°C	+12kp	59% 59%	
Detection method:	51.0°C	+12kp	59%	
Chemical indicator method (Nantong Pakion): If the color of the indicator changes from	51.5°C	+11kp +11kp	59%	
	51.8°C 51.8°C	+10kp	59%	
yellow to red to blue after disinfection, it indicates that the product has been disinfected.	52.9°C	+10kp	59%	
Biological indicator method (3M, Attempt): The 1264S model ethylene oxide sterilized	52.0°C	+10kp	60%	
hiological culture indicator is placed and inspected according to the standard. If there is no	54.0°C	+10kp	60%	
biological culture indicator is placed and inspected according to the standard. If there is no	54.4°C	+10kp	59%	
positive reaction after cultivation, it indicates that the product is disinfected.	55.0°C	+09kp	59%	
Physical parameter value : Measure and analyse the data which comes from disinfect	55.0°C	+09kp	59%	
	54.4°C	+08kp	59%	
process to confirm disinfect running in a tolerance as stated, it proved that the	53.5°C	+08kp	59% 60%	
product has been disinfected .	55.0°C	+07kp +07kp	59%	
	54.2°C 55.0°C	+07kp	59%	
Ethylene Oxide Residues Amount: Base on standard ISO 10993-7 to inspect and	55.5°C	+07kp	59%	
protract seasonal graph to evaluate after 10 days to use .	54.2°C	+07kp	60%	
Disinfection Validity Period : Keep intact original package and pollution - free , the	51.8°C	+06kp	60%	
	55.0°C	+06kp	60%	
period of validity is 5years .	55.0°C	+06kp	60%	
Conclusion: It is qualified that this batch of 100000 pieces after disinfection.	55.0°C	+06kp	59%	
-17	55.0°C	+06kp	59%	
Explanation: This report only covers the standards and technical data during the disinfection	0.	08:25	Ξ	
process of medical and sanitary supplies provided by the client. The sterilization indicators	17.55.0°C	+02kp	59% 59%	
(2) (1)	55.08	-06kp	59%	
reported comply with ISO11135-2014, GB18279-2008, and GB15980-2009. After 天前航	人章 55.0℃	-15kp	=	
disinfection, no analysis or evaluation will be conducted on whether the product meets	- FROM .	07.55 -20kp	59%	
	24/08/01	07:40		
other indicators.	- 400101	¥1.40		

Sigu: QI JINGJING Date: AUG.1ST.2024

#### CERTIFICATE OF EO STERILE

COMPANY OF STERILIZATION: HAIMEN XIN CHUANG STERILIZATION SERVICE

Exporter: ZHEJIANG RENON MEDICAL INSTRUMENT CO., LTD.

IMPORTER: Global Trade Technology - Comércio, Importação e Exportação Ltda - EPP.

Av. José Antonio Miziara n 221 - Distrito Ind. José Aparecido Tomé -

Jaboticabal - SP. - 14.874-002

Fone/Fax: (16) 4042-4000

CPNJ: 07.610.601/0001-65 INSCRIÇÃO ESTADUAL: 391.173.147.116

DATE OF STERILIZATION: 11TH JUN 2024

GOODS	QTY	LOT	MFG date	Exp date
18249 PETRI DISHES, PS MATERIAL . Ø90MM X 15MM , 1 ROOM . 10PCS/POLYBAG, E.O.STERILE	1000packs	202406	06/2024	06/2026

EO DOZE:18KG

INVOICE NO: RN2024-094

We hereby certificate that the above goods have been sterilized by EO, with the lowest temperature of  $45^{\circ}$ C, highest temperature of  $60^{\circ}$ C sterilization duration

of 12 hours

2024-6-11

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## **Entrust Sterilization Examining Report**

JIANGSU HUIDA MEDICAL INSTRUMENTS CO.,LTD	Automoti		
Manufactureri		Automatic record	
Product Name: 18249,PETRI DISHES, Ø 90MM X 15MM , 1 ROOM.	of con	nputer	
Amout : 40000 Volume : 5.24768 m³	24/10/30	16:26	1
Lot Number: H20241001 Disinfection Date: 2024.10.30	54.8°C	+18kp	
	54.2°C	+17kp	60%
Disinfection Equipment: HSX – 20 (20 m³) disinfection cabinet of ethylene - oxide by	54.7°C	+17kp	60%
Computer programme - controlled .	55.0°C	+16kp	59%
Disinfection Method: STERILE EO.	55.0°C	+16kp	59%
Distriction Metriod: STERILE CO.	55.0°C	+14kp	59%
Standard: ISO11135-2014,GB18279-2008,GB15980-2009.	54.9°C	+13kp	59% 59%
Technical Parameter : Ethylene oxide dosage : 700 mg / L;	54.9°C	+12kp +14kp	59%
	54.0°C 53.2°C	+13kp	59%
Temperature: 51.055.0 °C Humidity: 40-60 % Time: 8 h	53.3°C	+13kp	59%
	51.0°C	+12kp	59%
Detection method:	51.0°C	+12kp	59%
	51.5°C	+11kp	59%
Chemical indicator method (Nantong Pakion): If the color of the indicator changes from	51.8°C	+11kp	59%
yellow to red to blue after disinfection, it indicates that the product has been disinfected.	51.8°C	+10kp	59%
Biological indicator method (3M, Attempt): The 1264S model ethylene oxide sterilized	52.9°C	+10kp	59% 60%
biological indicator method (SM, Attempt): The 12043 model ethylene oxide sternized	52.0°C	+10kp +10kp	60%
biological culture indicator is placed and inspected according to the standard. If there is no	54.0°C 54.4°C	+10kp	59%
positive reaction after cultivation, it indicates that the product is disinfected.	55.0°C	+09kp	59%
	55.0°C	+09kp	59%
Physical parameter value: Measure and analyse the data which comes from disinfect	54.4°C	+08kp	59%
process to confirm disinfect running in a tolerance as stated, it proved that the	53.5°C	+08kp	59%
product has been disinfected .	55.0°C	+07kp	60%
	54.2°C	+07kp	59%
Ethylene Oxide Residues Amount: Base on standard ISO 10993-7 to inspect and	55.0°C	+07kp	59% 59%
protract seasonal graph to evaluate after 10 days to use .	55.5°C 54.2°C	+07kp +07kp	60%
Distribution Validity Borlad - Koon intest original posture and call story from the	51.8°C	+06kp	60%
Disinfection Validity Period : Keep intact original package and pollution - free , the	55.0°C	+06kp	60%
period of validity is 5years .	55.0°C	+06kp	60%
Conclusion: It is qualified that this batch of 40000 pieces after disinfection.	55.0°C	+06kp	599
-17	55.0°C	+06kp	599
Explanation: This report only covers the standards and technical data during the disinfection	0.0	08:25	Ξ
process of medical and sanitary supplies provided by the client. The sterilization indicators	17,55.0°C	+02kp	599
IT 1.25	1 55.0%	-06kp	599 599
reported comply with ISO11135-2014, GB18279-2008, and GB15980-2009. After 火山南	55.0°C	-15kp	=
disinfection, no analysis or evaluation will be conducted on whether the product meets	2000	07.55 -20kp	599
other indicators.	24/10/30	07:40	

Sigu: QI JINGJING Date: 2024.10.30