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: 18140A,PETRI DISHES, PS MATERIAL, ⊘150MM X 15MM		of computer		
Amout : 3000 Volume : 0.127673 m³	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 :mg / L ;	54.0°C	+14kp	59%	
Temperature: 51.055.0 °C Humidity: 40-60 % Time: 8 h	53.2°C	+13kp	59% 59%	
	53.3°C	+13kp	59%	
	51.0°C	+12kp	59%	
Detection method:	51.0°C 51.5°C	+12kp +11kp	59%	
Chemical indicator method (Nantong Pakion): If the color of the indicator changes from	51.8°C	+11kp	59%	
mallamata and as laborate and as district and as the state of the stat	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%	
biological culture indicator is placed and inspected according to the standard. If there is no	54.0°C	+10kp	60%	
	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% 59%	
process to confirm disinfect running in a tolerance as stated , it proved that the	53.5°C	+08kp +07kp	60%	
product has been disinfected .	55.0°C 54.2°C	+07kp	59%	
Ethylene Oxide Residues Amount : Base on standard ISO 10993-7 to inspect and	55.0°C	+07kp	59%	
Ethylene Oxide Residues Amount : base on standard 150 10555-7 to hispect 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 is5years .	55.0°C	+06kp	60%	
Conclusion: It is qualified that this batch of 100000 pieces after disinfection.	55.0°C	+06kp	59%	
5. I have been a superior of the standards and the being laber during the standards and the standards and the standards and the standards and the standards are standards and the standards and the standards are	55.0°C	+06kp	59%	
Explanation: This report only covers the standards and technical data during the disinfection	0.	08:25	三 59%	
process of medical and sanitary supplies provided by the client. The sterilization indicators	17.55.0°C	+02kp	59%	
reported comply with ISO11135-2014, GB18279-2008, and GB15980-2009. After	55.0°C	-06kp -15kp	59%	
reported comply with 15011135-2014, GB182/9-2008, and GB15980-2009. After 文前确认	24人08/01	07.55	=	
disinfection, no analysis or evaluation will be conducted on whether the product meets 💥	58.0°C	-20kp	59%	
other indicators.	24/08/01	07:40		

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

Jiangsu Ruiben Medical Technology Co., Ltd

Customer's Medical Equipment & Sanitary Goods

Entrust Sterilization Examining Report

JIANGSU HUIDA MEDICAL INSTRUMENTS CO.,LTD	Automoti		
Manufactureri	Automatic record		
Product Name: 18140A,PETRI DISHES, PS MATERIAL, ⊘150MM X 15MM	of con	nputer	
Amout : 3000 Volume : 1.27673 m³	24/10/30	16:26	1
Lot Number: H20241001 Disinfection Date: 2024.10.30	54.8°C	+18kp	
This first Francisco New 20/20 and Miles of the first of	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%
	52.9°C	+10kp	59% 60%
Biological indicator method (3M, Attempt): The 1264S model ethylene oxide sterilized	52.0°C	+10kp	60%
biological culture indicator is placed and inspected according to the standard. If there is no	54.0°C 54.4°C	+10kp +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%
product has been disinfected.	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	609
	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 3000 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	C/24/10/30	08:25	Ξ
process of medical and sanitary supplies provided by the client. The sterilization indicators	1755.0°C	+02kp	599
TT (1.2)	1 55.0%	-06kp	599
reported comply with ISO11135-2014, GB18279-2008, and GB15980-2009. After 火山原	人章 55.0°C	-15kp	599 =
disinfection, no analysis or evaluation will be conducted on whether the product meets 💥	-50.000	07.55	599
other indicators.	24/10/30	-20kp 07:40	

Sigu: QI JINGJING Date: 2024.10.30