

Report Test

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We erased their address from this document.

LOT No : 0284/2021
Date : 22 September 2021

Determination of Sterilization Operation Specification

Item Detail	Specification	Setting	Result
Chamber Setting Temperature	40.0-55.5 °C	45.0 °C	
Vacuum pressure	40-60 kPa	60 kPa	
Vacuum Time	50-60 min	60 min	
Humidification			
Humidity	50.0-90.0%	20.2 %	
Sterilization			
Sterilization Temperature	40.0-55.5 °C	43.5 °C	
Gas Injection			
Final pressure	0-10 kPa	4 kPa	
Final temperature of vaporizer	40.0-55.5 °C	44.8 °C	
Exposure			
Temperature at start point of Exposure time period	40.0-55.5 °C	43.3 °C	
Temperature at finish point of Exposure time period	40.0-55.5 °C	46.0 °C	
Exposure Time	120-240 min	180 min	
Exhaust			
Exhaust Time	60-80 min	75 min	
First Vacuum pressure	0-2 kPa	1.5 kPa	
Second Vacuum pressure	0-2 kPa	1.5 kPa	
Third Vacuum pressure	0-2 kPa	1.5 kPa	
Fourth Vacuum pressure	0-2 kPa	1.5 kPa	
Fifth Vacuum pressure	0-2 kPa	1.5 kPa	
Storage			
Storage Time	≥ 48 hour	≥ 48 hour	
Chemical Test			
EO sterilization temperature 40-55°C, Time Sterilization by EO 3hours	Blue	Red	Pass
Biological Test			
EZ Test Biological Indicator	Green	Green	Pass

(.....)
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Air replacement:
 Temperature: 45.5°C
 Humidity: 58.3RH
 Pressures: -1.5KPa
 Sterilization time: 0Hour
 Air replace rounds: 1
 round time: 0min(s)
 2021-8-26 16:10

Air replacement:
 Temperature: 46.2°C
 Humidity: 61.6RH
 Pressures: -1.5KPa
 Sterilization time: 0Hour
 Air replace rounds: 2
 round time: 0min(s)
 2021-8-26 17:50

Air replacement:
 Temperature: 45.6°C
 Humidity: 64.3RH
 Pressures: -1.5KPa
 Sterilization time: 0Hour
 Air replace rounds: 3
 round time: 0min(s)
 2021-8-26 17:30

Air replacement:
 Temperature: 46.1°C
 Humidity: 68.1RH
 Pressures: -1.5KPa
 Sterilization time: 0Hour
 Air replace rounds: 4
 round time: 0min(s)
 2021-8-26 17:9

Air replacement:
 Temperature: 45.3°C
 Humidity: 79.0RH
 Pressures: -1.5KPa
 Sterilization time: 0Hour
 Air replace rounds: 5
 round time: 15min(s)
 2021-8-26 16:49

Sterilization:
 Temperature: 45.8°C
 Humidity: 80.9RH
 Pressures: -0.0KPa
 Sterilization time: 0Hour
 Air replace rounds: 5
 round time: 15min(s)
 2021-8-26 16:44

Sterilization:
 Temperature: 43.4°C
 Humidity: 77.7RH
 Pressures: -4.7KPa
 Sterilization time: 3Hour
 Air replace rounds: 5
 round time: 15min(s)
 2021-8-26 13:45

Sterilization:
 Temperature: 43.5°C
 Humidity: 68.5RH
 Pressures: -4.1KPa
 Sterilization time: 3Hour
 Air replace rounds: 5
 round time: 15min(s)
 2021-8-26 13:43

Add E0 gas
 Temperature: 43.6°C
 Humidity: 70.3RH
 Pressures: -4.0KPa
 Sterilization time: 3Hour
 Air replace rounds: 5
 round time: 15min(s)
 2021-8-26 13:43

Evacuation
 Temperature: 44.5°C
 Humidity: 66.2RH
 Pressures: -0.0KPa
 Sterilization time: 3Hour
 Air replace rounds: 5
 round time: 15min(s)
 2021-8-26 13:36

Keeping Temp
 Temperature: 44.9°C
 Humidity: 20.2RH
 Pressures: -1.5KPa
 Sterilization time: 3Hour
 Air replace rounds: 5
 round time: 15min(s)
 2021-8-26 12:38

Keep pressure qualified
 Temperature: 44.1°C
 Humidity: 20.1RH
 Pressures: -59.2KPa
 Sterilization time: 3Hour
 Air replace rounds: 5
 round time: 15min(s)
 2021-8-26 12:36

Evacuation
 Temperature: 42.5°C
 Humidity: 20.1RH
 Pressures: -3.0KPa
 Sterilization time: 3Hour
 Air replace rounds: 5
 round time: 15min(s)
 2021-8-26 12:25

Heating-up:
 Temperature: 24.4°C
 Humidity: 20.1RH
 Pressures: -3.0KPa
 Sterilization time: 3Hour
 Air replace rounds: 5
 round time: 15min(s)
 2021-8-26 11:58

Setting:
 Temperature: 45.0°C
 Humidity: 55.0RH
 Pressures: -60.0KPa
 Sterilization time: 3Hour
 Air replace rounds: 5
 round time: 15min(s)

