

Report Test

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We erased their address from this document.

LOT No : 0341/2022
Date : 17 January 2022

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

(.....*Jutha Liam.*.....)
Mr. Jutha Liammukda
Research and Development Engineer
Salamander Jewelry Co., Ltd.

Sterilization:
Temperature: 44.7°C
Humidity: 20.2RH
Pressures: -4.1KPa
Sterilization time: 3Hour
Air replace rounds: 5
round time: 15min(s)
2021-11-12 15:20

Add E0 gas
Temperature: 44.6°C
Humidity: 20.2RH
Pressures: -4.0KPa
Sterilization time: 3Hour
Air replace rounds: 5
round time: 15min(s)
2021-11-12 15:20

Evacuation
Temperature: 44.7°C
Humidity: 20.1RH
Pressures: -0.0KPa
Sterilization time: 3Hour
Air replace rounds: 5
round time: 15min(s)
2021-11-12 15:10

Keeping Temp
Temperature: 44.9°C
Humidity: 20.1RH
Pressures: -1.5KPa
Sterilization time: 3Hour
Air replace rounds: 5
round time: 15min(s)
2021-11-12 14:10

Keep pressure qualified
Temperature: 43.8°C
Humidity: 20.1RH
Pressures: -58.8KPa
Sterilization time: 3Hour
Air replace rounds: 5
round time: 15min(s)
2021-11-12 14:8

Evacuation
Temperature: 42.5°C
Humidity: 20.1RH
Pressures: -3.0KPa
Sterilization time: 3Hour
Air replace rounds: 5
round time: 15min(s)
2021-11-12 13:56

Heating-up:
Temperature: 22.8°C
Humidity: 20.1RH
Pressures: -3.0KPa
Sterilization time: 3Hour
Air replace rounds: 5
round time: 15min(s)
2021-11-12 13:29

Setting:
Temperature: 45.0°C
Humidity: 55.0RH
Pressures: -60.0KPa
Sterilization time: 3Hour
Air replace rounds: 5
round time: 15min(s)
2021-11-12 13:26

END

Air replacement:
Temperature: 45.5°C
Humidity: 20.2RH
Pressures: -1.5KPa
Sterilization time: 0Hour
Air replace rounds: 1
round time: 0min(s)
2021-11-12 19:46

Air replacement:
Temperature: 45.9°C
Humidity: 20.2RH
Pressures: -1.5KPa
Sterilization time: 0Hour
Air replace rounds: 2
round time: 0min(s)
2021-11-12 19:26

Air replacement:
Temperature: 45.6°C
Humidity: 20.2RH
Pressures: -1.5KPa
Sterilization time: 0Hour
Air replace rounds: 3
round time: 0min(s)
2021-11-12 19:6

Air replacement:
Temperature: 46.0°C
Humidity: 20.2RH
Pressures: -1.5KPa
Sterilization time: 0Hour
Air replace rounds: 4
round time: 0min(s)
2021-11-12 18:46

Air replacement:
Temperature: 44.9°C
Humidity: 20.2RH
Pressures: -1.5KPa
Sterilization time: 0Hour
Air replace rounds: 5
round time: 15min(s)
2021-11-12 18:26

Sterilization:
Temperature: 44.9°C
Humidity: 20.2RH
Pressures: -0.0KPa
Sterilization time: 0Hour
Air replace rounds: 5
round time: 15min(s)
2021-11-12 18:21

Sterilization:
Temperature: 45.3°C
Humidity: 20.2RH
Pressures: -3.9KPa
Sterilization time: 3Hour
Air replace rounds: 5
round time: 15min(s)
2021-11-12 15:22

LINE	Code	Description	LOT	Color	BOX	TOTAL
		2375622				
1	PT-Z-TBCH-1.2-10.0-4	STERILE TITANIUM BALL CLOSURE RING WITH HEMATITE BALL FOR PTIT ROC	LOT-0341			143
2	PT-Z-TBCH-1.2-8.0-4	STERILE TITANIUM BALL CLOSURE RING WITH HEMATITE BALL FOR PTIT ROC	LOT-0341			151
		2359599				
3	TDI-Z-TINBN-1.6-10.0-4	STERILE TITANIUM INTERNALLY THREADED CURVED BARBELL FOR TDI	LOT-0341			200
		2366128				
2	TDI-Z-BKCNO-0.8-6.5-2	STERILE BLACK PVD COATED SURGICAL STEEL CURVED BALL NOSE STU DG FOR TDI	LOT-0341			50
		2376821				
3	PT-Z-TBCH-1.6-10.0-4	STERILE TITANIUM BALL CLOSURE RING WITH HEMATITE BALL FOR PTIT ROC	LOT-0341			53
		2384837				
18	PT-Z-TMLB-1.2-10.0-3	STERILE TITANIUM MICRO LABRET FOR PTIT ROC	LOT-0341			305
		160963				
44	Z-TMBL-1.2-9.0-3-HP	STERILE TITANIUM MICRO BARBELL	LOT-0341			50
		161007				
49	Z-PEB-1.6-5-WH	STERILE SYNTHETIC PEARL BALL	LOT-0341			10
		160963				
30	Z-TNO-0.8-6.5-2-HP	STERILE TITANIUM CURVED BALL NOSE STUD	LOT-0341			100
48	Z-TNOD-0.8-6.5-2-HP	STERILE TITANIUM CURVED DISC NOSE STUD	LOT-0341			15
		161090				
2	Z-COBC-1.2-10.0	STERILE SURGICAL STEEL SEAMLESS RING	LOT-0341			10
		161092				
18	Z-COBC-0.8-10.0	STERILE SURGICAL STEEL SEAMLESS RING	LOT-0341			10
19	Z-COBC-1.0-10.0	STERILE SURGICAL STEEL SEAMLESS RING	LOT-0341			10
		160767				
3	Z-NSS-1.6-12.0-5	STERILE SURGICAL STEEL NIPPLE STIRRUP WITH HOOP	LOT-0341			17
4	Z-NSS-1.6-10.0-5	STERILE SURGICAL STEEL NIPPLE STIRRUP WITH HOOP	LOT-0341			7
		161114				
11	Z-B-1.6-3	STERILE SURGICAL STEEL BALL	LOT-0341			2
12	Z-B-1.6-4	STERILE SURGICAL STEEL BALL	LOT-0341			2
13	Z-B-1.6-5	STERILE SURGICAL STEEL BALL	LOT-0341			2
14	Z-CNOJ2-0.6-6.5-1.7-AB	STERILE SURGICAL STEEL FLAT HIGH END CRYSTAL JEWEL ED CURVED NOSE STUD	LOT-0341			1
15	Z-CNOJ2-0.6-6.5-1.7-AQ	STERILE SURGICAL STEEL FLAT HIGH END CRYSTAL JEWEL ED CURVED NOSE STUD	LOT-0341			1
16	Z-CNOJ2-0.6-6.5-1.7-CR	STERILE SURGICAL STEEL FLAT HIGH END CRYSTAL JEWEL ED CURVED NOSE STUD	LOT-0341			1
		TOTAL				1140