

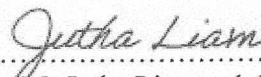
Report Test

M/C : Henan Sanqiang Medical Equipment Liability Co. Ltd
Model : SQ-H220
Serial No : HNSQ2020050063

LOT No : 001034
Date : 15 August 2025

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


 (.....)
 Mr. Jutha Liam mukda
 Research and Development Engineer

			LOT	Color	BOX	TOTAL / PCS
		212851				
1	Z-XBMNJ-1-1.6-12.0-5/8-CL-CR	BIOFLEX JEWEL NAVE BANANA WITH SURGICAL STEEL BALL	LOT No 01034			100
2	Z-XBMNJ-1-1.6-12.0-5/8-CL-AB	BIOFLEX JEWEL NAVE BANANA WITH SURGICAL STEEL BALL	LOT No 01034			24
		212954				
4	Z-TINMJD-1-2-3-HP-AB	STERILE TITANIUM PREMIUM CRYSTAL JEWEL DISC FOR 1.2MM INTERNALLY THREADED PINS	LOT No 01034			15
5	Z-TINMJD-1-2-3-HP-CR	STERILE TITANIUM PREMIUM CRYSTAL JEWEL DISC FOR 1.2MM INTERNALLY THREADED PINS	LOT No 01034			5
6	Z-TINMLB-PIN-1-2-10.0-4B-HP	STERILE TITANIUM INTERNALLY THREADED MICRO LABRET PIN	LOT No 01034			20
7	Z-TINMLB-PIN-1-2-8.0-4B-HP	STERILE TITANIUM INTERNALLY THREADED MICRO LABRET PIN	LOT No 01034			20
8	Z-TINMSJ1-1-2-3-HP-CR	STERILE TITANIUM PRONG SET JEWEL FOR 1.2MM INTERNALLY THREADED PINS - ROUND	LOT No 01034			10
		212970				
2	Z-XLBR-1-6-28.0-4-CL	STERILE BIOFLEX LABRET RETAINER WITH PUSH FIT DISC	LOT No 01034			6
		212986				
1	ZSINHP-1-2-50.0	STERILE SURGICAL STEEL INTERNALLY THREADED INSERTION PINS	LOT No 01034			50
2	ZSSTT-C-0.9-1.2	STERILE SURGICAL STEEL INTERNALLY THREADED CURVED TAPER	LOT No 01034			13
		212992				
1	Z-BN-1-6-12.0-4	STERILE SURGICAL STEEL CURVED BARBELL	LOT No 01034			100
2	Z-TMCB-1-2-10.0-3-HP	STERILE TITANIUM MICRO CIRCULAR BARBELL	LOT No 01034			50
		2551120				
40	THD-Z-TINMBN-1-2-10.0-3	STERILE TITANIUM INTERNALLY THREADED CURVED BARBELL FOR THENDRO	LOT No 01034			400
41	THD-Z-TINMBN-1-2-8.0-3	STERILE TITANIUM INTERNALLY THREADED CURVED BARBELL FOR THENDRO	LOT No 01034			200
		2551699				
15	PT-Z-GPTNO-0.8-6.5-2	STERILE GOLD PVD COATED TITANIUM CURVED BALL NOSE STUD	LOT No 01034			150
		2552612				
1	ZSNEEDLES-1-2-48.0	STERILIZED STAINLESS STEEL NEEDLE	LOT No 01034			2658
		2553049				
11	TDI-Z10TNO-1.0-6.5-2	STERILE TITANIUM CURVED BALL NOSE STUD	LOT No 01034		SET/30	300
		2552161				
1	SV-STERILIZE	SERVICE STERILE	LOT No 01034			10
						431

Sterilization:
Temperature: 44.9°C
Humidity: 20.1RH
Pressures: -2.3KPa
Sterilization time: 3Hour
Air replace rounds: 5
round time: 15min(s)
2025-8-15 13:41

Add EO gas
Temperature: 44.8°C
Humidity: 20.1RH
Pressures: -4.0KPa
Sterilization time: 3Hour
Air replace rounds: 5
round time: 15min(s)
2025-8-15 13:41

Evacuation
Temperature: 44.4°C
Humidity: 20.1RH
Pressures: -0.0KPa
Sterilization time: 3Hour
Air replace rounds: 5
round time: 15min(s)
2025-8-15 13:36

Keeping Temp
Temperature: 43.2°C
Humidity: 20.1RH
Pressures: -1.6KPa
Sterilization time: 3Hour
Air replace rounds: 5
round time: 15min(s)
2025-8-15 12:30

Keep pressure qualified
Temperature: 41.9°C
Humidity: 20.1RH
Pressures: -58.8KPa
Sterilization time: 3Hour
Air replace rounds: 5
round time: 15min(s)
2025-8-15 12:34

Evacuation
Temperature: 41.7°C
Humidity: 20.2RH
Pressures: -3.0KPa
Sterilization time: 3Hour
Air replace rounds: 5
round time: 15min(s)
2025-8-15 12:22

Heating-up:
Temperature: 23.8°C
Humidity: 29.1RH
Pressures: -3.0KPa
Sterilization time: 3Hour
Air replace rounds: 5
round time: 15min(s)
2025-8-15 11:46

Setting:
Temperature: 45.0°C
Humidity: 55.0RH
Pressures: -60.0KPa
Sterilization time: 3Hour
Air replace rounds: 5
round time: 15min(s)
2025-8-15 11:45

15/08/25

END LOT 1004

Air replacement:
Temperature: 45.1°C
Humidity: 20.1RH
Pressures: -1.6KPa
Sterilization time: 0Hour
Air replace rounds: 1
round time: 0min(s)
2025-8-15 18:8

Air replacement:
Temperature: 45.6°C
Humidity: 20.1RH
Pressures: -1.6KPa
Sterilization time: 0Hour
Air replace rounds: 2
round time: 0min(s)
2025-8-15 17:48

Air replacement:
Temperature: 45.3°C
Humidity: 20.1RH
Pressures: -1.6KPa
Sterilization time: 0Hour
Air replace rounds: 3
round time: 0min(s)
2025-8-15 17:28

Air replacement:
Temperature: 45.7°C
Humidity: 20.1RH
Pressures: -1.6KPa
Sterilization time: 0Hour
Air replace rounds: 4
round time: 0min(s)
2025-8-15 17:8

Air replacement:
Temperature: 45.7°C
Humidity: 20.2RH
Pressures: -1.6KPa
Sterilization time: 0Hour
Air replace rounds: 5
round time: 15min(s)
2025-8-15 16:47

Sterilization:
Temperature: 45.0°C
Humidity: 20.1RH
Pressures: -0.0KPa
Sterilization time: 0Hour
Air replace rounds: 5
round time: 15min(s)
2025-8-15 16:41

Sterilization:
Temperature: 44.7°C
Humidity: 20.2RH
Pressures: -0.0KPa
Sterilization time: 3Hour
Air replace rounds: 5
round time: 15min(s)
2025-8-15 13:43



FM-ISO-009 Rev.02 (05/11/2020)