

## Report Test

**M/C :** Henan Sanqiang Medical Equipment Liability Co. Ltd

**Model :** SQ-H220

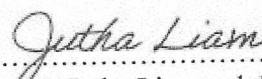
**Serial No :** HNSQ2020050063

**LOT No :** 00972

**Date :** 12 May 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	
<b>Humidification</b>			
Humidity	50.0-90.0%	20.2 %	
<b>Sterilization</b>			
Sterilization Temperature	40.0-55.5 °C	43.5 °C	
<b>Gas Injection</b>			
Final pressure	0-10 kPa	4 kPa	
Final temperature of vaporizer	40.0-55.5 °C	44.8 °C	
<b>Exposure</b>			
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	
<b>Exhaust</b>			
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	
<b>Storage</b>			
Storage Time	≥ 48 hour	≥ 48 hour	
<b>Chemical Test</b>			
EO sterilization temperature 40-55°C, Time Sterilization by EO 3hours	Blue	Red	Pass
<b>Biological Test</b>			
EZ Test Biological Indicator	Green	Green	Pass

  
 (.....)  
 Mr. Jutha Liamukda  
 Research and Development Engineer

ISO 9001 ISO 14001 ISO 45001 SEDEX CSR-DIW

Intertek Intertek Intertek Sedex CSR-DIW

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

FM-ISO0-009 Rev.02 (05/11/2020)



		2535447			
20	THD-Z-TINEL-1.6-0.4	STERILE TITANIUM INTERNALLY THREADED BARBELL	2536774	LOT NO 00972	490
7	THD-Z-INLSCB1-1.6-5	STERILE SURGICAL STEEL ATTACHMENT FOR 1.6MM INTERNALLY THREADED PINS	2536774	LOT NO 00972	390
10	THD-Z-INSCPA13-1.2	STERILE SURGICAL STEEL MICRO ATTACHMENT FOR 1.2MM INTERNALLY THREADED PINS	2536774	LOT NO 00972	390
		2538088			
3	TDI-Z-TINO-CP-1.6-0.5-2.35-CR	STERILIZE CZECH CRYSTAL CURVED NOSE STUD FOR TDI		LOT NO 00972	390
12	TDI-Z-TIGM-TM-1.6-2.8-0.3-CR	STERILE GOLD PVD COATED TITANIUM MICRO LABRET WITH OPTIMA CRYSTAL BALL		SET/30	390
19	TDI-Z-TIGM-TM-1.6-12.0-0.3-CR	STERILE GOLD PVD COATED TITANIUM DOUBLE OPTIMA CRYSTAL JEWEL NAVEL BANANA		SET/20	290
		2538841			
1	Z-CPSC-ES558	STERILE GOLD PVD COATED SURGICAL STEEL EAR STUDS PAIR		LOT NO 00972	10
		2539090			
1	Z4DBLSCC2-1.9-36-9-5	STERILE SURGICAL STEEL INDUSTRIAL BARBELL - ARROW		LOT NO 00972	20
		2539357			
1	PT-Z-GPTBL-1.6-16-0-6	STERILE GOLD PVD COATED TITANIUM BARBELL		LOT NO 00972	190
2	PT-Z-GPTBL-1.6-10-0-5-8-CR	STERILE GOLD PVD COATED TITANIUM PREMIUM CRYSTAL JEWEL NAVEL BANANA		LOT NO 00972	190
3	PT-Z-GPTBL-1.6-12-0-5-8-CR	STERILE GOLD PVD COATED TITANIUM PREMIUM CRYSTAL JEWEL NAVEL BANANA		LOT NO 00972	190
24	PT-Z-TBL-1.6-12-2-28-CR	STERILE TITANIUM JEWEL NAVEL BANANA FOR PTIT ROC		SET/50	590
		2539606			
1	TDI-Z-TBL-CP-1.6-10-0-5-8-CR	STERILE TITANIUM JEWEL NAVEL BANANA FOR TDI		LOT NO 00972	390
		2539785			
5	PT-Z-TBL-CP-1.6-10-0-5-8-CR	STERILE TITANIUM JEWEL NAVEL BANANA FOR PTIT ROC		LOT NO 00972	190
		2538406			
8	PT-Z-GPTBL-1.2-8-0-3-CR	STERILE GOLD PVD COATED TITANIUM PREMIUM CRYSTAL JEWEL MICRO LABRET		LOT NO 00972	50
		2540575			
4	TDI-Z-TBL-CP-1.6-12-0-5-8-CR	STERILE TITANIUM JEWEL NAVEL BANANA FOR TDI		LOT NO 00972	390
		2540650			
1	Z-NEEDLES-0.8-48.0	STERILIZED STAINLESS STEEL NEEDLE		LOT NO 00972	850
2	Z-NEEDLES-1.0-48.0	STERILIZED STAINLESS STEEL NEEDLE		LOT NO 00972	1300
3	Z-TIPINUS-1.2-8.0-3-HP-CR	STERILE TITANIUM JEWEL THREADED LABRET		LOT NO 00972	2
		2541028			
1	TDI-Z-TBL-CP-1.2-8.0-3-CR	STERILE SURGICAL STERIL CZECH CRYSTAL JEWEL MICRO LABRET FOR TDI		LOT NO 00972	390
2	TDI-Z-TBL-CP-1.5-10-0-5-8-CR	STERILE TITANIUM JEWEL NAVEL BANANA FOR TDI		LOT NO 00972	390
		2541186			
4	PT-Z-GPTBL-1.2-8-0-3	STERILE GOLD PVD COATED TITANIUM MICRO BARBELL		LOT NO 00972	450
5	PT-Z-GPTBL-1.2-8-0-3	STERILE GOLD PVD COATED TITANIUM MICRO CIRCULAR BARBELL		LOT NO 00972	100
9	PT-Z-GPTBL-0.8-6-2	STERILE GOLD PVD COATED TITANIUM CURVED BALL NOSE STUD		LOT NO 00972	100
10	PT-Z-TBCSH-0.8-8-0-HP	STERILE TITANIUM HINGED SEGMENT RING FOR PTIT ROC		LOT NO 00972	100
11	PT-Z-TBCSH-1.6-12-0-HP	STERILE TITANIUM HINGED SEGMENT RING FOR PTIT ROC		LOT NO 00972	30
12	PT-Z-TBL-1.6-12-0-4	STERILE TITANIUM TITANIUM CURVED BARBELL FOR PTIT ROC		LOT NO 00972	200
13	PT-Z-TBL-1.6-12-0-4	STERILE TITANIUM TITANIUM CURVED BARBELL FOR PTIT ROC		LOT NO 00972	50
14	PT-Z-TBL-CP-1.6-12-0-5-8-CR	STERILE TITANIUM DOUBLE JEWEL NAVEL BANANA FOR PTIT ROC		LOT NO 00972	100
15	PT-Z-TINEL-1.6-16-0-5-HP	STERILE TITANIUM INTERNALLY THREADED BARBELL		LOT NO 00972	50
16	PT-Z-TINEL-1.2-10-0-3-HP	STERILE TITANIUM INTERNALLY THREADED CURVED MICRO BARBELL FOR PTIT ROC		LOT NO 00972	50
17	PT-Z-TINO-CP-0.8-6-2-35-CR	STERILE TITANIUM JEWEL CURVED NOSE STUD FOR PTIT ROC		LOT NO 00972	100
18	PT-Z-TINEL-1.2-14-0-3	STERILE TITANIUM MICRO CURVED BARBELL FOR PTIT ROC		LOT NO 00972	50
19	PT-Z-TINEL-1.2-7-0-3	STERILE TITANIUM MICRO LABRET FOR PTIT ROC		LOT NO 00972	150
20	PT-Z-TINEL-1.2-10-0-3-48-CL	STERILE BIOFLEX MICRO LABRET WITH STEEL BALL FOR PTIT ROC		LOT NO 00972	50
21	PT-Z-TINEL-1.2-12-0-3-48-CL	STERILE BIOFLEX MICRO LABRET WITH STEEL BALL FOR PTIT ROC		LOT NO 00972	100
22	PT-Z-TINEL-1.2-14-0-3-48-CL	STERILE BIOFLEX MICRO LABRET WITH STEEL BALL FOR PTIT ROC		LOT NO 00972	50
23	PT-Z-TBL-CP-1.6-12-0-5-8-CR	STERILE TITANIUM DOUBLE JEWEL NAVEL BANANA FOR PTIT ROC		LOT NO 00972	500
24	PT-Z-TBL-CP-1.2-10-0-3	STERILE TITANIUM MICRO LABRET FOR PTIT ROC		SET/50	500
25	PT-Z-TBL-CP-1.2-10-0-3	STERILE TITANIUM MICRO LABRET FOR PTIT ROC		SET/120	500
26	PT-Z-TBL-CP-1.2-10-0-3-5-8-CR	STERILE TITANIUM MICRO LABRET WITH JEWEL BALL FOR PTIT ROC		SET/120	500
27	PT-Z-TBL-CP-1.2-8-0-3-5-8-CR	STERILE TITANIUM MICRO LABRET WITH JEWEL BALL FOR PTIT ROC		SET/15	150
28	PT-Z-TBL-CP-1.2-8-0-3-4-CR	STERILE TITANIUM MICRO LABRET WITH JEWEL BALL FOR PTIT ROC		SET/15	150
		2541951		SET/20	200
1	TDI-Z-TBL-CP-1.2-10-0-3	STERILE TITANIUM MICRO LABRET FOR TDI		LOT NO 00972	200
		2541517			
1	TDI-Z-TBL-CP-1.2-8-0-3	STERILE TITANIUM MICRO LABRET FOR TDI		LOT NO 00972	300
3	TDI-Z-TBL-CP-1.2-8-0-3	STERILE TITANIUM MICRO CIRCULAR BARBELL		LOT NO 00972	500
4	TDI-Z-TBL-CP-1.2-10-0-3	STERILE SURGICAL STEEL MICRO BARBELL FOR TDI		LOT NO 00972	100
		2541853			
1	TDI-Z-TBL-CP-1.6-10-0-5-8	STERILE TITANIUM NAVEL BANANA FOR TDI		LOT NO 00972	150
		2542044			
1	TDI-Z-TBL-CP-1.5-14-0-5	STERILE TITANIUM BARBELL FOR TDI		LOT NO 00972	300
		2542238			
2	Z-NEEDLES-1.5-48.0	STERILIZED STAINLESS STEEL NEEDLE		LOT NO 00972	3050
		2542383			
1	THD-Z-ENBL-1.5-12-0-4	STERILE BLACK PVD COATED SURGICAL STEEL BARBELL FOR THENIRO		LOT NO 00972	100
3	THD-Z-ENBL-1.5-12-0-4	STERILE BLACK PVD COATED SURGICAL STEEL CURVED MICRO BARBELL FOR THENIRO		LOT NO 00972	150
6	THD-Z-CPBL-1.6-16-0-6	STERILE GOLD PVD COATED SURGICAL STEEL BARBELL FOR THENIRO		LOT NO 00972	100
12	THD-Z-UL-1.5-2-0-3	STERILIZED SURGICAL STEEL MICRO LABRET FOR THENIRO		LOT NO 00972	100
13	THD-Z-ENBL-1.5-10-0-4-6-CR	STERILE SURGICAL STEEL DOUBLE JEWEL MINI NAVEL BANANA FOR THENIRO		LOT NO 00972	250
15	THD-Z-TINEL-1.6-28-0-5	STERILE TITANIUM INTERNALLY THREADED BARBELL		LOT NO 00972	60
24	THD-Z-TINEL-1.2-3-HP	TITANIUM MICRO CONE FOR 1.2MM INTERNALLY THREADED PINS		LOT NO 00972	300
27	THD-Z-TINEL-1.2-5-0-3	STERILE TITANIUM INTERNALLY THREADED MICRO LABRET		LOT NO 00972	300
28	THD-Z-TBL-1.6-10-0-4	STERILE TITANIUM LABRET FOR THENIRO		LOT NO 00972	250
30	THD-Z-TBL-1.6-6-0-4	STERILE TITANIUM LABRET FOR THENIRO		LOT NO 00972	100
31	THD-Z-TBL-1.2-6-0-3	STERILE TITANIUM MICRO BARBELL FOR THENIRO		LOT NO 00972	100
32	THD-Z-TBL-CP-1.2-6-0-3	STERILE TITANIUM MICRO CURVED BARBELL FOR THENIRO		LOT NO 00972	100
		2542423			
11	PT-Z-HP-1.2-50-0	STERILE SURGICAL STEEL INTERNALLY THREADED INSERTION PINS FOR PTIT ROC		LOT NO 00972	50
12	PT-Z-TBCSH-1.2-8-0-HP	STERILE TITANIUM HINGED SEGMENT RING FOR PTIT ROC		LOT NO 00972	100
15	PT-Z-TBL-1.6-10-0-4-6-CR	STERILE TITANIUM JEWEL NAVEL BANANA FOR PTIT ROC		LOT NO 00972	100
16	PT-Z-TBL-1.2-8-0-3-HP	STERILE TITANIUM INTERNALLY THREADED MICRO LABRET FOR PTIT ROC		LOT NO 00972	200
17	PT-Z-TINO-CP-0.8-6-2-35-CR	STERILE TITANIUM JEWEL CURVED NOSE STUD FOR PTIT ROC		LOT NO 00972	400
19	PT-Z-TINO-CP-0.8-6-2-35-CR	STERILE TITANIUM LARGE CURVE JEWEL NOSE STUD FOR PTIT ROC		LOT NO 00972	200
23	PT-Z-TBL-CP-1.2-12-0-3	STERILE TITANIUM MICRO LABRET FOR PTIT ROC		LOT NO 00972	100
		2542543			
1	Z-TBCSH-0.8-6-0-HP	STERILE TITANIUM HINGED SEGMENT RING		LOT NO 00972	20
2	Z-TBCSH-0.8-6-0-HP	STERILE TITANIUM HINGED SEGMENT RING		LOT NO 00972	20
		2538029			
4	SV-STERILIZE	SERVICE STERILE		LOT NO 00972	20
		2540165			
1	SV-STERILIZE	SERVICE STERILE		LOT NO 00972	30
		2533138			
1	SV-STERILIZE	SERVICE STERILE		LOT NO 00972	1
		2540091			
3	SV-STERILIZE	SERVICE STERILE		LOT NO 00972	20
		2540991			
2	SV-STERILIZE	SERVICE STERILE		LOT NO 00972	10
		2542845			
2	SV-STERILIZE	SERVICE STERILE		LOT NO 00972	4
					31913

Sterilization:  
Temperature: 44.8°C  
Humidity: 20.184  
Pressures: -1.70kPa  
Sterilization time: 3Hour  
Air replace rounds: 5  
round time: 15min(s)  
2025-5-12 11:1

Add EO gas  
Temperature: 44.8°C  
Humidity: 20.264  
Pressures: -4.0kPa  
Sterilization time: 3Hour  
Air replace rounds: 5  
round time: 15min(s)  
2025-5-12 11:0

Evacuation  
Temperature: 44.3°C  
Humidity: 20.264  
Pressures: -0.0kPa  
Sterilization time: 3Hour  
Air replace rounds: 5  
round time: 15min(s)  
2025-5-12 10:50

Keeping Temp  
Temperature: 42.4°C  
Humidity: 20.184  
Pressures: -1.6kPa  
Sterilization time: 3Hour  
Air replace rounds: 5  
round time: 15min(s)  
2025-5-12 9:50

Keep pressure qualified  
Temperature: 42.3°C  
Humidity: 20.184  
Pressures: -38.6kPa  
Sterilization time: 3Hour  
Air replace rounds: 5  
round time: 15min(s)  
2025-5-12 9:48

Evacuation  
Temperature: 41.0°C  
Humidity: 20.184  
Pressures: -3.0kPa  
Sterilization time: 3Hour  
Air replace rounds: 5  
round time: 15min(s)  
2025-5-12 8:37

Heating up:  
Temperature: 23.6°C  
Humidity: 20.184  
Pressures: -0.0kPa  
Sterilization time: 3Hour  
Air replace rounds: 5  
round time: 15min(s)  
2025-5-12 9:0

Setting:  
Temperature: 45.0°C  
Humidity: 55.0RH  
Pressures: -0.0kPa  
Sterilization time: 3Hour  
Air replace rounds: 5  
round time: 15min(s)  
2025-5-12 9:8

12/5/25

Lot 972

END

Air replacement:  
Temperature: 45.0°C  
Humidity: 20.264  
Pressures: -1.6kPa  
Sterilization time: 3Hour  
Air replace rounds: 1  
round time: 3min(s)  
2025-5-12 15:29

Air replacement:  
Temperature: 45.3°C  
Humidity: 20.184  
Pressures: -1.6kPa  
Sterilization time: 3Hour  
Air replace rounds: 2  
round time: 3min(s)  
2025-5-12 15:8

Air replacement:  
Temperature: 45.1°C  
Humidity: 20.184  
Pressures: -1.6kPa  
Sterilization time: 3Hour  
Air replace rounds: 3  
round time: 3min(s)  
2025-5-12 14:48

Air replacement:  
Temperature: 45.0°C  
Humidity: 20.264  
Pressures: -1.6kPa  
Sterilization time: 3Hour  
Air replace rounds: 4  
round time: 3min(s)  
2025-5-12 14:28

Air replacement:  
Temperature: 45.3°C  
Humidity: 20.184  
Pressures: -1.6kPa  
Sterilization time: 3Hour  
Air replace rounds: 5  
round time: 3min(s)  
2025-5-12 14:7

Sterilization:  
Temperature: 45.4°C  
Humidity: 20.184  
Pressures: -0.0kPa  
Sterilization time: 3Hour  
Air replace rounds: 5  
round time: 15min(s)  
2025-5-12 14:1

Sterilization:  
Temperature: 45.3°C  
Humidity: 20.184  
Pressures: -0.0kPa  
Sterilization time: 3Hour  
Air replace rounds: 5  
round time: 15min(s)  
2025-5-12 11:3



FM-ISO0-009 Rev.02 (05/11/2020)