

To protect the privacy of customers or suppliers of Salamander Jewelry. We erased their address from this document.

TEST REPORT

CUSTOMER : Salamander Jewelry Co.,Ltd.

M/C : SHINVA

MODEL : XG 1 SERIES

SERIAL No. : 070997

Document No. : TR-EO-013280420

Date : 28/4/2020

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PRODUCT : ORDER NO. 2301717

Determination of Sterilization Specification

Item Detail	Specification	Setting	Result
Chamber Setting Temperature	55.0 - 59.0 (°C)	59 (°C)	-
Vacuum Level	5-12 kPa	9 kPa	-
Vacuum Time (min)	50-60 min	60 min	-
Humidification			
Humidity (%)	50%-90%	87%	-
Sterilization			
Steri Temp	55.0 - 59.0 (°C)	55.0 (°C)	-
Jacket Temp	60.0 - 65.0 (°C)	65.0 (°C)	-
Gas Injection			
Final pressure (kpa(abs))	0.21-0.23 kPa	0.21 kPa	-
Final temperature of vaporizer,Temp 10 (°C)	55.0 - 59.0 (°C)	55 (°C)	-
Exposure			
Temperature at start point of Exposure time period Temp. 1 (°C)	55.0 - 59.0 (°C)	60 (°C)	-
Temperature at finish point of Exposure time period Temp. 1 (°C)	55.0 - 59.0 (°C)	55 (°C)	-
Exposure Time (min)	390-420 min	420 min	-
Exhaust			
Exhaust Time (hour)	≥ 4 hour	4 hour	-
First Vacuum Level (kPa)	5-12 kPa	9 kPa	-
Second Vacuum Level (kPa)	5-12 kPa	9 kPa	-
Third Vacuum Level (kPa)	5-12 kPa	9 kPa	-
Storage			
Storage Time	≥ 48 hour	≥ 48 hour	-
Chemical tested, Sterile Strip			
EO sterilization temperatures 55-60 C° Time sterile by EO 7 hours .	Brown	Brown	Pass
Biological Test			
EZ Test Biological Indicator	Brown	Brown	Pass
24 hour results for EO	Red	Red	Pass

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SAMPLE SLIP PARAMETER

EXHAUST:04H ODMIN TOTAL :11H 56MIN			
PRETT :00H 55MIN STERI :07H 00MIN			
ACTUAL TIME			
04:57:02	STERILIZATION SUCCESS		
END	04:56:51	052,20	-002kPa
	04:56:51	052,20	-002kPa
	00:57:30	054,00	-015kPa
EXHAUST	00:54:51	054,10	001kPa
	00:50:21	054,20	001kPa
	00:40:21	054,10	001kPa
	00:30:21	054,20	001kPa
	00:20:21	054,30	001kPa
	00:10:21	054,30	002kPa
	00:00:21	054,30	002kPa
	23:50:21	054,50	001kPa
	23:40:21	054,70	002kPa
	23:30:21	054,60	001kPa
	23:20:21	054,70	002kPa
	23:10:21	054,60	002kPa
	23:00:21	054,60	001kPa
	22:50:21	054,90	002kPa
	22:40:21	054,80	002kPa
	22:30:21	054,80	002kPa
	22:20:21	054,80	002kPa
	22:10:21	054,60	002kPa
	22:00:21	054,70	002kPa
	21:50:21	054,70	002kPa
	21:40:21	054,80	002kPa
	21:30:21	054,80	002kPa
	21:20:21	054,80	002kPa
	21:10:21	054,90	002kPa
	21:00:20	054,80	002kPa

	20:50:20	054,50	002kPa
	20:40:20	054,70	001kPa
	20:30:20	054,70	001kPa
	20:20:20	054,80	001kPa
	20:10:20	054,90	001kPa
	20:00:20	054,90	-001kPa
	19:50:20	054,90	001kPa
	19:40:20	055,00	001kPa
	19:30:20	055,10	000kPa
	19:20:20	055,20	000kPa
	19:10:20	055,20	001kPa
	19:00:20	055,30	001kPa
	18:50:20	055,40	001kPa
	18:40:20	055,40	018kPa
	18:30:20	055,40	037kPa
	18:20:20	055,40	049kPa
	18:10:20	055,40	104kPa
	18:00:20	055,40	311kPa
STERI	17:55:20	055,50	247kPa
	17:50:20	055,90	-029kPa
ADD EO	17:44:00	056,00	-089kPa
	17:40:20	056,10	000kPa
HUMID1	17:33:58	056,20	-090kPa
PRETT	17:30:20	056,10	000kPa
PRHEAT	17:01:11	055,80	000kPa
STATE	TIME	TEMP	PRE

RUN COUNT : 2963			
EO PRE	:050kPa	VENT TIME:04H 00M	
STERI TEMP	:055,00	STERI TIME:07H 00M	
PRD TYP	17:01:11	055,80	000kPa
START TIME : 2020-04-27 17:01:04			

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PROCESS FLOW CHART OF STERILIZATION

- > loading > into the chamber > door close > program starts
- > preprocessing > EO entry > sterilization
- > later processing > ventilation > air entry > the end
- > door open > unloading.

We here by certificate that following products were sterilized by E.O. at CITY MEDICAL SUPPLY CO.,LTD .

The result of sterilization by biological indicator are passed.

CODE	Iteme	Color	Lot. No	TOTAL QUANTITY	STERILIZED DATE
Z-GSNEEDLES-1.6-48.0	STERILIZED STAINLESS STEEL NEEDLE			7071	
Z-GSNEEDLES-1.6-48.0	STERILIZED STAINLESS STEEL NEEDLE			2200	
Z-GSNEEDLES-0.8-48.0	STERILIZED STAINLESS STEEL NEEDLE			550	
Z-GSNEEDLES-1.6-48.0	STERILIZED STAINLESS STEEL NEEDLE			9750	
Z-GSNEEDLES-0.8-48.0	STERILIZED STAINLESS STEEL NEEDLE			300	
PT-Z-TMLBJ-1.2-10.0-3-CR	STERILE TITANIUM MICRO LABRET WITH JEWELLED BALL FOR PTIT ROC			150	
THD-Z-CNOD-1.0-6.5-2.5	STERILE SURGICAL STEEL CURVED NOSE STUD FOR THENDRO		LOT-0188	400	27 Apr 20
Z-BCSH-1.2-10.0	STERILE SURGICAL STEEL HINGED SEGMENT RING			50	
TDI-Z-TINBL-1.6-36.0-5	STERILE TITANIUM INTERNALLY THREADED BARBELL FOR TDI			50	
PT-Z-TBCH-1.2-10.0-4	STERILE TITANIUM BALL CLOSURE RING WITH HEMATITE BALL FOR PTIT ROC			154	
Z-BC-1.2-12.0-4	STERILE SURGICAL STEEL BCR			98	
Z-BC-1.6-10.0-4	STERILE SURGICAL STEEL BCR			67	
THD-Z-TBC-1.2-12.0-4	STERILE TITANIUM BALL CLOSURE RING FOR THENDRO			300	
THD-Z-TBC-1.6-10.0-4	STERILE TITANIUM BALL CLOSURE RING FOR THENDRO			600	
THD-Z-TLB-1.6-8.0-4	STERILE TITANIUM LABRET FOR THENDRO			200	

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