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## TEST REPORT

CUSTOMER : Salamander Jewelry Co.,Ltd.

**M/C** : SHINVA

Document No. : TR-EO-005300620

**MODEL** : XG 1 SERIES

Date : 30/6/2020

**SERIAL No.** : 070997

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PRODUCT : ORDER NO. 2306512

### 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	-
<b>Humidification</b>			
Humidity (%)	50%-90%	87%	-
<b>Sterilization</b>			
Steri Temp	55.0 - 59.0 (°C)	55.0 (°C)	-
Jacket Temp	60.0 - 65.0 (°C)	65.0 (°C)	-
<b>Gas Injection</b>			
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)	-
<b>Exposure</b>			
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	-
<b>Exhaust</b>			
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	-
<b>Storage</b>			
Storage Time	≥ 48 hour	≥ 48 hour	-
<b>Chemical tested, Sterile Strip</b>			
EO sterilization temperatures 55-60 C° Time sterile by EO 7 hours .	Brown	Brown	Pass
<b>Biological Test</b>			
EZ Test Biological Indicator	Brown	Brown	Pass
24 hour results for EO	Red	Red	Pass

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## SAMPLE SLIP PARAMETER

EXHAUST:04H 00MIN TOTAL :11H 50MIN			
PRETT :00H 49MIN STERI :07H 00MIN			
ACTUAL TIME			
08:19:40 STEILIZATION SUCCESS			
END	08:19:29	060,4C	-001kPa
	08:19:29	060,4C	-001kPa
	04:20:13	060,3C	-015kPa
EXHAUST	04:18:29	060,3C	010kPa
	04:17:59	060,3C	010kPa
	04:07:59	060,3C	010kPa
	03:57:59	060,3C	010kPa
	03:47:59	060,3C	010kPa
	03:37:59	060,2C	010kPa
	03:27:59	060,2C	010kPa
	03:17:59	060,2C	010kPa
	03:07:59	060,2C	010kPa
	02:57:59	060,2C	010kPa
	02:47:59	060,1C	010kPa
	02:37:59	060,2C	010kPa
	02:27:59	060,1C	010kPa
	02:17:59	060,1C	010kPa
	02:07:59	060,1C	010kPa
	01:57:59	060,1C	010kPa
	01:47:59	060,1C	010kPa
	01:37:59	060,1C	010kPa
	01:27:59	060,0C	010kPa
	01:17:59	060,0C	010kPa
	01:07:59	060,0C	010kPa
	00:57:59	059,9C	010kPa
	00:47:59	059,8C	010kPa
	00:37:59	059,8C	010kPa
	00:27:59	059,7C	010kPa

	00:17:59	059,6C	010kPa
	00:07:59	059,5C	010kPa
	23:57:59	059,5C	010kPa
	23:47:59	059,4C	010kPa
	23:37:59	059,3C	010kPa
	23:27:59	059,3C	010kPa
	23:17:59	059,3C	010kPa
	23:07:59	059,2C	010kPa
	22:57:59	059,0C	011kPa
	22:47:59	059,0C	011kPa
	22:37:59	058,9C	011kPa
	22:27:59	058,9C	011kPa
	22:17:59	058,8C	011kPa
	22:07:59	058,6C	011kPa
	21:57:59	058,6C	011kPa
	21:47:59	058,5C	011kPa
	21:37:59	058,3C	061kPa
	21:27:59	058,3C	237kPa
STERI	21:18:58	058,3C	311kPa
	21:17:59	058,3C	012kPa
ADD EO	21:11:24	058,4C	-085kPa
	21:07:59	058,4C	001kPa
HUMIDI	21:01:21	058,3C	-084kPa
PRETT	20:57:59	058,3C	002kPa
PREHEAT	20:29:34	057,6C	002kPa
STATE	TIME	TEMP	PRE
RUN COUNT : 0039			
EO PRE	:050kPa	VENT TIME:04H 00M	
STERI TEMP:	055,0C	STERI TIME:07H 00M	
PRO TIP	20:29:34	057,6C	002kPa
START TIME: 2020-06-29 20:29:26			

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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-TBC-1.6-12.0-5-HP	STERILE TITANIUM BALL CLOSURE RING			10	
Z-TBL-1.6-38.0-5-HP	STERILE TITANIUM BARBELL			10	
Z-TJNO-1.0-6.5-2.35-HP-CR	STERILE TITANIUM JEWELLED CURVED NOSE STUD			84	
Z-XBL-3-1.6-16.0-5-CL	STERILE BIOFLEX BARBELL WITH TITANIUM BALLS			10	
PT-Z-TBL-1.6-16.0-5	STERILIZED TITANIUM BARBELL FOR PTIT ROC			62	
PT-Z-TBL-1.6-18.0-5	STERILIZED TITANIUM BARBELL FOR PTIT ROC			51	
PT-Z-TBNJ-1.6-10.0-5/8-CR	STERILE TITANIUM JEWELLED NAVAL BANANA FOR PTIT ROC			110	
PT-Z-TJNO-0.8-6.5-2.35-CR	STERILE TITANIUM JEWELLED CURVED NOSE STUD FOR PTIT ROC			266	
PT-Z-TMBL-1.2-10.0-3-HP	STERILE TITANIUM MICRO BARBELL FOR PTIT ROC			159	
PT-Z-TMBL-1.2-8.0-3-HP	STERILE TITANIUM MICRO BARBELL FOR PTIT ROC			222	
PT-Z-TMLB-1.2-10.0-3	STERILE TITANIUM MICRO LABRET FOR PTIT ROC		LOT-0192	302	29 Jun 20
PT-Z-TMLB-1.2-8.0-3	STERILE TITANIUM MICRO LABRET FOR PTIT ROC			438	
PT-Z-TMLB-1.2-9.0-3	STERILE TITANIUM MICRO LABRET FOR PTIT ROC			102	
PT-Z-TMLBJ-1.2-12.0-2.5-CR	STERILE TITANIUM MICRO LABRET WITH JEWELLED BALL FOR PTIT ROC			53	
PT-Z-TMLBJ-1.2-8.0-2.5-CR	STERILE TITANIUM MICRO LABRET WITH JEWELLED BALL FOR PTIT ROC			215	
PT-Z-XBL-1-1.6-16.0-5-CL	STERILE BIOFLEX BARBELL WITH STEEL BALLS FOR PTIT ROC			66	
Z-INMLBJ-1.2-10.0-2-CR	STERILE SURGICAL STEEL INTERNALLY THREADED JEWELLED MICRO LABRET			50	
Z-SES1-4-CR	SURGICAL STEEL ROUND PRONG SET JEWELLED EAR STUDS PAIR			50	
Z-PRTA-6.0-70.0	STERILE DISPOSABLE MULTI ANGLED RECEIVING TUBE			48	
Z-GSCNEEDLES-1.2-24.0	STERILE CURVED STAINLESS STEEL NEEDLE			10	
Z-PNV-CRE	STERILE DISPOSAL ROUND CLAMPS			465	
QL-Z-ZGFBC-1.0-7.0-3	STERILE ZIRCON GOLD PVD SURGICAL STEEL FIXED BEAD RING FOR QUILLIAN NO CARD			50	
QL-Z-ZGFBC-1.0-9.0-3	STERILE ZIRCON GOLD PVD SURGICAL STEEL FIXED BEAD RING FOR QUILLIAN NO CARD			50	
Z-MCB-1.2-8.0-3	STERILE SURGICAL STEEL MICRO CIRCULAR BARBELL			12	

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