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## TEST REPORT

CUSTOMER : Salamander Jewelry Co.,Ltd.

**M/C** : SHINVA

Document No. : TR-EO-004070220

**MODEL** : XG 1 SERIES

Date : 7/2/2020

**SERIAL No.** : 070997

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PRODUCT : ORDER NO. 2293868

### 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 strat 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 :12H 00MIN	
PRETT :01H 00MIN		STERI :07H 00MIN	
ACTUAL TIME			
05:01:33 STERILIZATION SUCCESS			
END	05:01:22	059,20	001kPa
	05:01:22	059,20	001kPa
	01:02:22	060,00	-014kPa
	01:01:52	060,10	000kPa
EXHAUST	01:00:22	060,10	000kPa
	00:51:52	060,20	000kPa
	00:41:52	060,30	001kPa
	00:31:52	060,30	000kPa
	00:21:52	060,40	000kPa
	00:11:52	060,60	-001kPa
	00:01:52	060,70	000kPa
	23:51:52	060,70	001kPa
	23:41:52	060,70	001kPa
	23:31:52	060,80	001kPa
	23:21:52	060,80	000kPa
	23:11:52	060,80	001kPa
	23:01:52	060,80	001kPa
	22:51:52	060,80	000kPa
	22:41:52	060,90	000kPa
	22:31:52	061,00	000kPa
	22:21:52	061,00	001kPa
	22:11:52	061,00	000kPa
	22:01:52	061,00	000kPa
	21:51:52	061,00	001kPa
	21:41:52	061,00	000kPa
	21:31:52	060,90	001kPa
	21:21:52	060,80	001kPa
	21:11:52	060,70	001kPa
	21:01:52	060,60	001kPa

	20:51:52	060,50	001kPa
	20:41:52	060,50	001kPa
	20:31:52	060,40	001kPa
	20:21:52	060,30	001kPa
	20:11:52	060,10	001kPa
	20:01:52	050,00	002kPa
	19:51:52	059,70	001kPa
	19:41:52	059,60	001kPa
	19:31:52	059,30	001kPa
	19:21:52	058,80	001kPa
	19:11:52	058,30	001kPa
	19:01:52	057,80	001kPa
	18:51:52	057,50	001kPa
	18:41:52	057,20	001kPa
	18:31:52	056,90	001kPa
	18:21:52	056,60	002kPa
	18:11:52	056,30	002kPa
	18:01:52	056,30	153kPa
STERI	18:00:50	056,20	229kPa
	17:51:52	056,20	-029kPa
	17:41:52	056,20	-030kPa
ADD EO	17:35:29	056,40	-068kPa
	17:31:52	056,40	000kPa
HUMIDI	17:25:28	056,40	-089kPa
PRETT	17:21:52	056,40	000kPa
PREHEAT	16:53:28	056,10	000kPa
STATE	TIME	TEMP	PRE

  

RUN COUNT : 2805			
EO PRE	:060kPa	VENT TIME:	04H 00M
STERI TEMP:	056,00	STERI TIME:	07H 00M
PRO TYP	16:53:28	056,10	000kPa
START TIME: 2020-02-06 16:53:20			

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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
PT-Z-INP-1.2-50.0	STERILE SURGICAL STEEL INTERNALLY THREADED INSERTION PINS FOR PTIT ROC			133	
PT-Z-INP-1.6-50.0	STERILE SURGICAL STEEL INTERNALLY THREADED INSERTION PINS FOR PTIT ROC			54	
PT-Z-PRTA-8.0-70.0	STERILE DISPOSABLE MULTI ANGLED RECEIVING TUBE FOR PTIT ROC			500	
PT-Z-TBCH-1.2-10.0-4	STERILE TITANIUM BALL CLOSURE RING WITH HEMATITE BALL FOR PTIT ROC			214	
PT-Z-TBCH-1.2-12.0-4	STERILE TITANIUM BALL CLOSURE RING WITH HEMATITE BALL FOR PTIT ROC			80	
PT-Z-TBCH-1.2-8.0-4	STERILE TITANIUM BALL CLOSURE RING WITH HEMATITE BALL FOR PTIT ROC			221	
PT-Z-TBL-1.6-14.0-5	STERILIZED TITANIUM BARBELL FOR PTIT ROC			406	
PT-Z-TBL-1.6-16.0-5	STERILIZED TITANIUM BARBELL FOR PTIT ROC			86	
PT-Z-TBL-1.6-20.0-5	STERILIZED TITANIUM BARBELL FOR PTIT ROC			148	
PT-Z-TBL-1.6-22.0-5	STERILIZED TITANIUM BARBELL FOR PTIT ROC			115	
PT-Z-TBNDJ-1.6-10.0-5/8-CR	STERILE TITANIUM DOUBLE JEWELLED NAVEL BANANA FOR PTIT ROC			88	
PT-Z-TBNDJ-1.6-12.0-5/8-CR	STERILE TITANIUM DOUBLE JEWELLED NAVEL BANANA FOR PTIT ROC			162	
PT-Z-TBNJ-1.6-10.0-5/8-CR	STERILE TITANIUM JEWELLED NAVEL BANANA FOR PTIT ROC			79	
PT-Z-TCB-1.6-10.0-4	STERILE TITANIUM 90 DEGREE STAPLE BARBELL FOR PTIT ROC			74	
PT-Z-TCB-1.6-8.0-4	STERILE TITANIUM 90 DEGREE STAPLE BARBELL FOR PTIT ROC			27	
PT-Z-TJNO-0.8-6.5-2.35-CR	STERILE TITANIUM JEWELLED CURVED NOSE STUD FOR PTIT ROC			1343	
PT-Z-TMBL-1.2-10.0-3-HP	STERILE TITANIUM MICRO BARBELL FOR PTIT ROC		LOT-0181	499	6 Feb 20
PT-Z-TMBL-1.2-8.0-3-HP	STERILE TITANIUM MICRO BARBELL FOR PTIT ROC			1126	
PT-Z-TMBN-1.2-10.0-3	STERILE TITANIUM MICRO CURVED BARBELL FOR PTIT ROC			456	
PT-Z-TMBN-1.2-12.0-3	STERILE TITANIUM MICRO CURVED BARBELL FOR PTIT ROC			185	
PT-Z-TMBN-1.2-8.0-3	STERILE TITANIUM MICRO CURVED BARBELL FOR PTIT ROC			511	
PT-Z-TMCB-1.2-10.0-3	STERILE TITANIUM MICRO CIRCULAR BARBELL FOR PTIT ROC			332	
PT-Z-TMCB-1.2-8.0-3	STERILE TITANIUM MICRO CIRCULAR BARBELL FOR PTIT ROC			273	
PT-Z-TMLB-1.2-10.0-3	STERILE TITANIUM MICRO LABRET FOR PTIT ROC			864	
PT-Z-TMLB-1.2-12.0-3	STERILE TITANIUM MICRO LABRET FOR PTIT ROC			130	
PT-Z-TMLB-1.2-8.0-3	STERILE TITANIUM MICRO LABRET FOR PTIT ROC			1617	
PT-Z-TMLB-1.2-9.0-3	STERILE TITANIUM MICRO LABRET FOR PTIT ROC			791	
PT-Z-TMLBJ-1.2-10.0-2.5-CR	STERILE TITANIUM MICRO LABRET WITH JEWELLED BALL FOR PTIT ROC			365	
PT-Z-TMLBJ-1.2-8.0-2.5-CR	STERILE TITANIUM MICRO LABRET WITH JEWELLED BALL FOR PTIT ROC			647	
PT-Z-TST-1.6-32.0-4	STERILE TITANIUM 90 DEGREE STAPLE BARBELL FOR PTIT ROC			34	
PT-Z-XBL-1-1.6-18.0-5-CL	STERILE BIOFLEX BARBELL WITH STEEL BALLS FOR PTIT ROC			59	
PT-Z-XBL-1-1.6-22.0-5-CL	STERILE BIOFLEX BARBELL WITH STEEL BALLS FOR PTIT ROC			165	
PT-Z-XBL-1-1.6-40.0-5-CL	STERILE BIOFLEX BARBELL WITH STEEL BALLS FOR PTIT ROC			98	
PT-Z-XBNUJ-1-1.6-12.0-5/8-CR	STERILE BIOFLEX JEWELLED NAVEL BANANA WITH SURGICAL STEEL BALL FOR PTIT ROC			56	
PT-Z-XJNO-0.8-6.0-1.8-CL-CR	STERILE BIOFLEX JEWELLED CURVED NOSE STUD FOR PTIT ROC			110	
PT-Z-XMBN-1-1.2-10.0-3-CL	STERILE BIOFLEX MICRO CURVED BARBELL WITH STEEL BALLS FOR PTIT ROC			59	

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PT-Z-XMBN-1-1.2-12.0-3-CL	STERILE BIOFLEX MICRO CURVED BARBELL WITH STEEL BALLS FOR PTIT ROC			50	
PT-Z-XMLB-1-1.2-10.0-3/4B-CL	STERILE BIOFLEX MICRO LABRET WITH STEEL BALL FOR PTIT ROC			204	
PT-Z-XMLB-1-1.2-12.0-3/4B-CL	STERILE BIOFLEX MICRO LABRET WITH STEEL BALL FOR PTIT ROC			62	
PT-Z-XMLB-1-1.2-8.0-3/4B-CL	STERILE BIOFLEX MICRO LABRET WITH STEEL BALL FOR PTIT ROC			151	
PT-Z-XMLBJ-7-1.2-10.0-3-CL-CR	STERILE BIOFLEX JEWELED MICRO LABRET FOR PTIT ROC			126	
Z-TBL-1.6-22.0-5-HP	STERILE TITANIUM BARBELL			30	
TDI-Z-TBCSH-1.2-10.0	STERILE TITANIUM HINGED SEGMENT RING FOR TDI		LOT-0181	100	6 Feb 20
TDI-Z-TINMLB-1.2-10.0-2	STERILE TITANIUM INTERNALLY THREADED MICRO LABRET FOR TDI			100	
Z-GSNEEDLES-0.8-48.0	STERILIZED STAINLESS STEEL NEEDLE			115	
Z-ZGMLBJ-1.2-10.0-3-CR	STERILE ZIRCON GOLD PVD SURGICAL STEEL JEWELED MICRO LABRET			10	
Z-BCSH-1.0-8.0	STERILE SURGICAL STEEL HINGED SEGMENT RING			10	
Z-LJNO-1.0-6.5-2.35-CR	STERILE SURGICAL STEEL LARGE CURVE JEWELED NOSE STUD			467	
TDI-Z-TBCSH-1.2-8.0	STERILE TITANIUM HINGED SEGMENT RING FOR TDI			100	

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