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TEST REPORT

CUSTOMER : Salamander Jewelry Co.,Ltd.

M/C : SHINVA

Document No. : TR-EO-005280120

MODEL : XG 1 SERIES

Date : 28/1/2020

SERIAL No. : 070997

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PRODUCT : ORDER NO. 2292922

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 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	-
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

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EXHAUST:04H 00MIN TOTAL :12H 27MIN
PRETT :01H 27MIN STERI :07H 00MIN
ACTUAL TIME

05:32:03 STEILIZATION SUCCESS
END 05:31:52 053,7C 000kPa
      05:31:52 053,7C 000kPa
      01:32:55 053,9C -014kPa
EXHAUST 01:30:52 054,0C 000kPa
      01:24:22 054,1C 000kPa
      01:14:22 054,2C 000kPa
      01:04:22 054,2C 000kPa
      00:54:21 054,3C 000kPa
      00:44:21 054,3C 000kPa
      00:34:21 054,5C 000kPa
      00:24:21 054,6C 000kPa
      00:14:21 054,6C 001kPa
      00:04:21 054,7C 000kPa
      23:54:21 054,9C 000kPa
      23:44:21 054,9C 001kPa
      23:34:21 055,1C 000kPa
      23:24:21 055,2C 000kPa
      23:14:21 055,2C 000kPa
      23:04:21 055,3C 000kPa
      22:54:21 055,3C 000kPa
      22:44:21 055,3C 002kPa
      22:34:21 055,4C 002kPa
      22:24:21 055,4C 000kPa
      22:14:21 055,4C 001kPa
      22:04:21 055,5C 000kPa
      21:54:21 055,3C 001kPa
      21:44:21 055,5C 001kPa
      21:34:21 055,5C -001kPa
      21:24:21 055,5C 001kPa
      21:14:21 055,6C 000kPa

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21:04:21 055,7C 001kPa
20:54:21 055,9C 001kPa
20:44:21 056,0C 001kPa
20:34:21 056,1C 001kPa
20:24:21 056,1C 001kPa
20:14:21 056,3C 001kPa
20:04:21 056,5C 001kPa
19:54:21 056,5C 001kPa
19:44:21 056,6C 001kPa
19:34:21 056,8C 001kPa
19:24:21 056,8C 003kPa
19:14:21 057,2C 001kPa
19:04:21 057,3C 002kPa
18:54:21 057,6C 001kPa
18:44:21 057,8C 002kPa
18:34:21 058,0C 137kPa
STERI 18:31:33 058,1C 235kPa
      18:24:21 058,4C -028kPa
18:17:59 CHARGE TIME TOO LONG
      18:14:21 058,5C -029kPa
      18:04:21 058,8C -030kPa
      17:54:21 059,3C -029kPa
ADD EO 17:47:59 059,6C -089kPa
      17:44:21 059,6C -001kPa
HUMID1 17:37:56 059,4C -091kPa
PRETT 17:34:21 059,2C 000kPa
PREHEAT 17:05:10 057,2C 000kPa
STATE TIME TEMP PRE

RUN COUNT : 2793
EO PRE :060kPa VENT TIME:04H 00M
STERI TEMP: 056,0C STERI TIME:07H 00M
PRO TYP 17:05:10 057,2C 000kPa
START TIME: 2020-01-27 17:05:03

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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
THD-Z-RGBC-1.0-10.0-4	STERILE ROSE GOLD PVD COATED SURGICAL STEEL BALL CLOSURE RING FOR THENDRO			500	
THD-Z-RGBC-1.0-8.0-3	STERILE ROSE GOLD PVD COATED SURGICAL STEEL BALL CLOSURE RING FOR THENDRO			500	
THD-Z-RGBC-1.2-10.0-4	STERILE ROSE GOLD PVD COATED SURGICAL STEEL BALL CLOSURE RING FOR THENDRO			700	
THD-Z-RGBC-1.2-6.0-3	STERILE ROSE GOLD PVD COATED SURGICAL STEEL BALL CLOSURE RING FOR THENDRO			200	
THD-Z-RGBC-1.2-8.0-3	STERILE ROSE GOLD PVD COATED SURGICAL STEEL BALL CLOSURE RING FOR THENDRO			500	
THD-Z-RGBL-1.6-10.0-4	STERILE ROSE GOLD PVD COATED SURGICAL STEEL BARBELL FOR THENDRO			400	
THD-Z-RGBL-1.6-14.0-5	STERILE ROSE GOLD PVD COATED SURGICAL STEEL BARBELL FOR THENDRO			500	
THD-Z-RGBL-1.6-18.0-5	STERILE ROSE GOLD PVD COATED SURGICAL STEEL BARBELL FOR THENDRO			200	
THD-Z-RGBL-1.6-20.0-5	STERILE ROSE GOLD PVD COATED SURGICAL STEEL BARBELL FOR THENDRO			200	
THD-Z-RGBNDJOP-1.6-10.0-5/8-CR	STERILE ROSE GOLD PVD COATED SURGICAL STEEL DOUBLE OPTIMA CRYSTALS NAVEL BANANA FOR THENDRO			198	
THD-Z-RGCB-1.6-10.0-4	STERILE ROSE GOLD PVD COATED SURGICAL STEEL CIRCULAR BARBELL FOR THENDRO			198	
THD-Z-RGCNO-1.0-6.5-1.8	STERILE ROSE GOLD PVD COATED SURGICAL STEEL CURVED BALL NOSE STUD FOR THENDRO			400	
THD-Z-RGJNO-0.8-6.5-2.35-CR	STERILE ROSE GOLD PVD COATED SURGICAL STEEL SWAROVSKI CRYSTAL JEWELLED CURVED NOSE STUD FOR THENDRO			600	
THD-Z-RGLB-1.6-10.0-4	STERILE ROSE GOLD PVD COATED SURGICAL STEEL LABEL FOR THENDRO			300	
THD-Z-RGMBL-1.2-10.0-3	STERILE ROSE GOLD PVD COATED SURGICAL STEEL MICRO BARBELL FOR THENDRO			1500	
THD-Z-RGMBL-1.2-8.0-3	STERILE ROSE GOLD PVD COATED SURGICAL STEEL MICRO BARBELL FOR THENDRO			1500	
THD-Z-RGMBN-1.2-10.0-2.5	STERILE ROSE GOLD PVD COATED SURGICAL STEEL CURVED MICRO BARBELL FOR THENDRO		LOT-0180	300	27 Jan 20
THD-Z-RGMBN-1.2-8.0-2.5	STERILE ROSE GOLD PVD COATED SURGICAL STEEL CURVED MICRO BARBELL FOR THENDRO			300	
THD-Z-RGMCB-1.2-10.0-4	STERILE ROSE GOLD PVD COATED SURGICAL STEEL MICRO CIRCULAR BARBEL FOR THENDRO			400	
THD-Z-RGMLB-1.2-10.0-3	STERILE ROSE GOLD PVD COATED SURGICAL STEEL MICRO LABRET FOR THENDRO			800	
THD-Z-BNDJ-1.6-10.0-5/8-AB	STERILE SURGICAL STEEL DOUBLE JEWELLED NAVEL BANANA FOR THENDRO			200	
THD-Z-BNDJ-1.6-10.0-5/8-AQ	STERILE SURGICAL STEEL DOUBLE JEWELLED NAVEL BANANA FOR THENDRO			300	
THD-Z-JNO-1.0-6.5-2.35-AB	STERILE SURGICAL STEEL JEWELLED CURVED NOSE STUD FOR THENDRO			700	
THD-Z-JNO-1.0-6.5-2.35-BZ	STERILE SURGICAL STEEL JEWELLED CURVED NOSE STUD FOR THENDRO			200	
THD-Z-JNO-1.0-6.5-2.35-CR	STERILE SURGICAL STEEL JEWELLED CURVED NOSE STUD FOR THENDRO			1200	
THD-Z-JNO-1.0-6.5-2.35-JE	STERILE SURGICAL STEEL JEWELLED CURVED NOSE STUD FOR THENDRO			400	
THD-Z-SBNDJ-1.6-10.0-4/6-AB	STERILE SURGICAL STEEL DOUBLE JEWELLED MINI NAVEL BANANA FOR THENDRO			200	
THD-Z-SBNDJ-1.6-10.0-4/6-CR	STERILE SURGICAL STEEL DOUBLE JEWELLED MINI NAVEL BANANA FOR THENDRO			400	
THD-Z-SBNDJ-1.6-10.0-4/6-SA	STERILE SURGICAL STEEL DOUBLE JEWELLED MINI NAVEL BANANA FOR THENDRO			100	
Z-BL-1.6-10.0-5	STERILE SURGICAL STEEL BARBELL			20	
Z-BL-1.6-12.0-4	STERILE SURGICAL STEEL BARBELL			40	
Z-BL-1.6-14.0-4	STERILE SURGICAL STEEL BARBELL			50	
Z-BL-1.6-16.0-4	STERILE SURGICAL STEEL BARBELL			20	
Z-BL-1.6-44.0-5	STERILE SURGICAL STEEL BARBELL			10	
Z-BNDJ-1.6-12.0-5/8-AQ	STERILE SURGICAL STEEL DOUBLE JEWELLED NAVEL BANANA			15	
Z-BNDJ-1.6-12.0-5/8-BZ	STERILE SURGICAL STEEL DOUBLE JEWELLED NAVEL BANANA			10	
Z-CB-1.6-9.0-3	STERILE SURGICAL STEEL CIRCULAR BARBELL			30	

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CODE	Iteme	Color	Lot. No	TOTAL QUANTITY	STERILIZED DATE
Z-CNOD-1.0-6.5-1.5	STERILE SURGICAL STEEL CURVED NOSE STUD			20	
Z-IBNNDJ-1.6-11.0-5/8-CR	STERILE SURGICAL STEEL INTERNALLY THREADED DOUBLE SWAROVSKI CRYSTAL JEWELLED NAVEL BANANA			30	
Z-MBN-1.2-8.0-3	STERILE SURGICAL STEEL MICRO CURVED BARBELL			50	
Z-MLB-1.2-10.0-3	STERILE SURGICAL STEEL MICRO LABRET			50	
Z-MLB-1.2-11.2-3	STERILE SURGICAL STEEL MICRO LABRET			20	
Z-MLB-1.2-7.0-3	STERILE SURGICAL STEEL MICRO LABRET			20	
Z-TNO-0.8-6.5-2	STERILE TITANIUM CURVED BALL NOSE STUD			25	
Z-MBN-1.2-10.0-3	STERILE SURGICAL STEEL MICRO CURVED BARBELL			996	
Z-MBN-1.2-8.0-3	STERILE SURGICAL STEEL MICRO CURVED BARBELL			200	
Z-TMBL-1.2-10.0-3-HP	STERILE TITANIUM MICRO BARBELL			50	
Z-BNJ-1.6-12.0-5/8-CR	STERILE SURGICAL STEEL JEWELLED NAVEL BANANA			166	
Z-JNO-1.0-6.5-2.35-CR	STERILE SURGICAL STEEL JEWELLED CURVED NOSE STUD			495	
Z-LB-1.6-10.0-3	STERILE SURGICAL STEEL LABRET			12	
Z-LB-1.6-12.0-4	STERILE SURGICAL STEEL LABRET			10	
Z-LJNO-0.8-6.5-2.35-CR	STERILE SURGICAL STEEL LARGE CURVE JEWELLED NOSE STUD			305	
Z-TBL-1.6-12.0-5-HP	STERILE TITANIUM BARBELL			34	
Z-TMLB-1.2-8.0-3-HP	STERILE TITANIUM MICRO LABRET			64	
Z-XMLB-1.1.2-10.0-3/3B-CL	STERILE BIOFLEX MICRO LABRET WITH STEEL BALL			12	
TDI-Z-TINBL-1.6-10.0-4	STERILE TITANIUM INTERNALLY THREADED BARBELL FOR TDI			100	
TDI-Z-TINBL-1.6-12.0-4	STERILE TITANIUM INTERNALLY THREADED BARBELL FOR TDI			100	
TDI-Z-TINBL-1.6-14.0-5	STERILE TITANIUM INTERNALLY THREADED BARBELL FOR TDI		LOT-0180	50	27 Jan 20
Z-MCB-1.2-8.0-3	STERILE SURGICAL STEEL MICRO CIRCULAR BARBELL			10	
Z-BL-1.6-12.0-5	STERILE SURGICAL STEEL BARBELL			109	
Z-BL-1.6-38.0-4	STERILE SURGICAL STEEL BARBELL			15	
Z-BNN-1.6-12.0-5/8	STERILE SURGICAL STEEL NAVEL BANANA			30	
Z-JNO90-0.8-6.5-1.8-CR	STERILE SURGICAL STEEL JEWELLED CURVED NOSE STUD			20	
Z-MLB-1.2-11.2-3	STERILE SURGICAL STEEL MICRO LABRET			23	
Z-SES1-3-CR	SURGICAL STEEL ROUND PRONG SET JEWELLED EAR STUDS PAIR			20	
Z-SES1-3-JE	SURGICAL STEEL ROUND PRONG SET JEWELLED EAR STUDS PAIR			10	
Z-MLB-1.2-8.0-3	STERILE SURGICAL STEEL MICRO LABRET			522	
Z-BC-1.2-10.0-4	STERILE SURGICAL STEEL BCR			410	
Z-MLB-1.2-12.0-3	STERILE SURGICAL STEEL MICRO LABRET			276	
Z-BC-1.2-8.0-4	STERILE SURGICAL STEEL BCR			20	
Z-BL-1.6-10.0-5	STERILE SURGICAL STEEL BARBELL			25	
Z-BL-1.6-44.0-4	STERILE SURGICAL STEEL BARBELL			10	
Z-CB-1.6-9.0-3	STERILE SURGICAL STEEL CIRCULAR BARBELL			10	
Z-PRTA-8.0-70.0	STERILE DISPOSABLE MULTI ANGLED RECEIVING TUBE 8.0MM			800	
Z-SES1-3-CR	SURGICAL STEEL ROUND PRONG SET JEWELLED EAR STUDS PAIR			150	
THD-Z-NO-1.0-6.5-2.5	STERILE SURGICAL STEEL 1.2MM THREADING CURVED NOSE STUD WITH BALL FOR THENDRO			500	
Z-BL-1.6-16.0-5	STERILE SURGICAL STEEL BARBELL			209	
Z-MLB-1.2-10.0-3	STERILE SURGICAL STEEL MICRO LABRET			433	
Z-TBN-1.6-12.0-4-HP	STERILE TITANIUM CURVED BARBELL			100	
Z-MBN-1.2-10.0-3	STERILE SURGICAL STEEL MICRO CURVED BARBELL			15	
Z-MCB-1.2-8.0-3	STERILE SURGICAL STEEL MICRO CIRCULAR BARBELL			10	
QL-Z-BKFBC-1.0-9.0-3	STERILE BLACK PVD SURGICAL STEEL FIXED BEAD RING FOR QUILLIAN NO CARD			50	
QL-Z-ZGJMB-1.2-3-CR	STERILE ZIRCON GOLD PVD COATED SWAROVSKI CRYSTAL JEWELLED MICRO BALL FOR QUILLIAN NO CARD			30	
Z-BL-1.6-18.0-5	STERILE SURGICAL STEEL BARBELL			114	

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SERIAL No. : 070997

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Z-BNDJ-1.6-10.0-5/8-CR	STERILE SURGICAL STEEL DOUBLE JEWELLED NAVEL BANANA			94	
TDI-Z-TMCB-1.2-10.0-3	STERILE TITANIUM MICRO CIRCULAR BARBELL FOR TDI			100	
Z-BL-1.6-12.0-4	STERILE SURGICAL STEEL BARBELL			10	
Z-BNJ-1.6-10.0-5/8-CR	STERILE SURGICAL STEEL JEWELLED NAVEL BANANA			10	
Z-PRTA-8.0-70.0	STERILE DISPOSABLE MULTI ANGLED RECEIVING TUBE 8.0MM			300	
Z-JNO90-0.8-6.5-1.8-CR	STERILE SURGICAL STEEL JEWELLED CURVED NOSE STUD			150	
TDI-Z-TBCSH-1.2-10.0	STERILE TITANIUM HINGED SEGMENT RING FOR TDI		LOT-0180	100	27 Jan 20
Z-MBL-1.2-10.0-3	STERILE SURGICAL STEEL MICRO BARBELL			200	
TDI-Z-BKCNO-0.8-6.5-2	STERILE BLACK PVD COATED SURGICAL STEEL CURVED BALL NOSE STUDG FOR TDI			50	
Z-TBC-1.2-9.0-4-HP	STERILE TITANIUM BALL CLOSURE RING			65	
Z-GSNEEDLES-2.0-48.0	STERILIZED STAINLESS STEEL NEEDLE			155	
Z-GSNEEDLES-0.8-48.0	STERILIZED STAINLESS STEEL NEEDLE			153	
Z-MCB-1.2-10.0-3	STERILE SURGICAL STEEL MICRO CIRCULAR BARBELL			500	

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