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TEST REPORT

CUSTOMER : Salamander Jewelry Co.,ltd.

M/C : SHINVA

Document No. : TR-EO-001010920

MODEL : XG 1 SERIES

Date : 1/9/2020

SERIAL No. : 070997

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PRODUCT : ORDER NO. 2313545

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

EXHAUST:04H 00MIN TOTAL :11H 53MIN			
PRETT :00H 54MIN STERI :07H 00MIN			
ACTUAL TIME			
=====			
05:05:18	STERILIZATION SUCCESS		
END	05:05:07	061,00	002kPa
	05:05:07	061,00	002kPa
	01:05:57	062,10	-015kPa
EXHAUST	01:04:07	062,20	002kPa
	00:59:57	062,20	002kPa
	00:49:57	062,20	002kPa
	00:39:57	062,20	002kPa
	00:29:57	062,30	002kPa
	00:19:57	062,30	002kPa
	00:09:57	062,30	002kPa
	23:59:57	062,30	002kPa
	23:49:57	062,30	002kPa
	23:39:57	062,40	002kPa
	23:29:57	062,40	002kPa
	23:19:57	062,40	002kPa
	23:09:57	062,50	002kPa
	22:59:57	062,50	002kPa
	22:49:57	062,60	002kPa
	22:39:57	062,60	002kPa
	22:29:57	062,60	002kPa
	22:19:57	062,60	002kPa
	22:09:57	062,60	002kPa
	21:59:57	062,60	002kPa
	21:49:57	062,60	002kPa
	21:39:57	062,70	002kPa
	21:29:57	062,70	002kPa
	21:19:57	062,70	002kPa
	21:09:57	062,70	002kPa

	20:59:57	062,70	003kPa
	20:49:57	062,70	003kPa
	20:39:57	062,70	002kPa
	20:29:57	062,60	003kPa
	20:19:57	062,60	003kPa
	20:09:57	062,50	003kPa
	19:59:57	062,50	003kPa
	19:49:57	062,40	003kPa
	19:39:57	062,40	003kPa
	19:29:57	062,40	003kPa
	19:19:57	062,30	003kPa
	19:09:57	062,20	003kPa
	18:59:57	062,20	003kPa
	18:49:57	062,10	003kPa
	18:39:57	061,90	004kPa
	18:29:57	061,80	068kPa
	18:19:57	061,80	212kPa
	18:09:57	061,60	311kPa
STERI	18:04:12	061,60	311kPa
	17:59:57	061,60	-028kPa
ADD ED	17:53:15	061,50	-086kPa
	17:49:57	061,50	000kPa
HUMID1	17:43:12	061,50	-087kPa
PRETT	17:39:57	061,40	001kPa
PREHEAT	17:10:24	060,80	001kPa
STATE	TIME	TEMP	PRE
=====			
RUN COUNT : 0133			
ED PRE	:060kPa	VENT TIME:04H 00M	
STERI TEMP:	065,00	STERI TIME:07H 00M	
PRE TIP	17:10:24	060,80	001kPa
START TIME: 2020-01-31 17:10:16			

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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-TBCH-1.2-12.0-4	STERILE TITANIUM BALL CLOSURE RING WITH HEMATITE BALL FOR PTIT ROC			95	
PT-Z-TCB-1.6-12.0-4	STERILE TITANIUM 90 DEGREE STAPLE BARBELL FOR PTIT ROC			47	
PT-Z-TJNO-0.8-6.5-2.35-CR	STERILE TITANIUM JEWELLED CURVED NOSE STUD FOR PTIT ROC			483	
PT-Z-TMBL-1.2-10.0-3-HP	STERILE TITANIUM MICRO BARBELL FOR PTIT ROC			108	
PT-Z-TMBL-1.2-8.0-3-HP	STERILE TITANIUM MICRO BARBELL FOR PTIT ROC			182	
PT-Z-TMBN-1.2-10.0-3	STERILE TITANIUM MICRO CURVED BARBELL FOR PTIT ROC			235	
PT-Z-TMBN-1.2-12.0-3	STERILE TITANIUM MICRO CURVED BARBELL FOR PTIT ROC			115	
PT-Z-TMBN-1.2-8.0-3	STERILE TITANIUM MICRO CURVED BARBELL FOR PTIT ROC			216	
PT-Z-TMCB-1.2-10.0-3	STERILE TITANIUM MICRO CIRCULAR BARBELL FOR PTIT ROC			168	
PT-Z-TMLBJ-1.2-10.0-2.5-CR	STERILE TITANIUM MICRO LABRET WITH JEWELLED BALL FOR PTIT ROC			149	
PT-Z-XMLB-1.1.2-12.0-3/4B-CL	STERILE BIOFLEX MICRO LABRET WITH STEEL BALL FOR PTIT ROC			58	
Z-BL-1.6-19.0-5	STERILE SURGICAL STEEL BARBELL			50	
Z-BNJ-1.6-10.0-5/8-CR	STERILE SURGICAL STEEL JEWELLED NAVEL BANANA			45	
Z-MCB-1.2-10.0-3	STERILE SURGICAL STEEL MICRO CIRCULAR BARBELL			50	
PT-Z-INP-1.2-50.0	STERILE SURGICAL STEEL INTERNALLY THREADED INSERTION PINS FOR PTIT ROC			128	
PT-Z-PRTA-8.0-70.0	STERILE DISPOSABLE MULTI ANGLED RECEIVING TUBE FOR PTIT ROC			143	
PT-Z-TBCH-1.2-8.0-4	STERILE TITANIUM BALL CLOSURE RING WITH HEMATITE BALL FOR PTIT ROC		LOT-0199	101	31 Aug 20
PT-Z-TBCH-1.6-12.0-4	STERILE TITANIUM BALL CLOSURE RING WITH HEMATITE BALL FOR PTIT ROC			51	
PT-Z-TCB-1.6-8.0-4	STERILE TITANIUM 90 DEGREE STAPLE BARBELL FOR PTIT ROC			25	
PT-Z-TJNO-0.8-6.5-2.35-CR	STERILE TITANIUM JEWELLED CURVED NOSE STUD FOR PTIT ROC			837	
PT-Z-TST-1.6-32.0-4	STERILE TITANIUM 90 DEGREE STAPLE BARBELL FOR PTIT ROC			10	
Z-BL-1.6-44.0-4	STERILE SURGICAL STEEL BARBELL			10	
Z-LJNO-1.0-6.5-1.8-CR	STERILE SURGICAL STEEL LARGE CURVE JEWELLED NOSE STUD			10	
Z-MCB-1.2-12.0-3	STERILE SURGICAL STEEL MICRO CIRCULAR BARBELL			11	
Z-SES1-2.5-CR	SURGICAL STEEL ROUND PRONG SET JEWELLED EAR STUDS PAIR			20	
QL-Z-MBNDJ-1.2-10.0-2.5-CR	STERILE SURGICAL STEEL DOUBLE JEWELLED MICRO CURVED BARBELL FOR QUILLIAN NO CARD			50	
QL-Z-TINPDJ-1.6-2.0-4-AB	STERILE TITANIUM INTERNALLY THREADED DERMAL ANCHOR WITH JEWELLED DISC FOR QUILLIAN NO CARD			20	
QL-Z-TINPDJ-1.6-2.0-4-JE	STERILE TITANIUM INTERNALLY THREADED DERMAL ANCHOR WITH JEWELLED DISC FOR QUILLIAN NO CARD			20	
QL-Z-PRTA-8.0-70.0	STERILE DISPOSABLE MULTI ANGLED RECEIVING TUBE FOR QUILLIAN NO CARD			100	
Z-XBNNJ-1.1.6-12.0-5/8-CL-CR	BIOFLEX JEWELLED NAVEL BANANA WITH SURGICAL STEEL BALL			100	
Z-LJNO-1.0-6.5-1.8-CR	STERILE SURGICAL STEEL LARGE CURVE JEWELLED NOSE STUD			100	
Z-PSTC-CRE	STERILE DISPOSAL SLOTTED ROUND CLAMPS			6	
PT-Z-TJNO-0.8-6.5-2.35-CR	STERILE TITANIUM JEWELLED CURVED NOSE STUD FOR PTIT ROC			159	
PT-Z-TMBN-1.2-14.0-3	STERILE TITANIUM MICRO CURVED BARBELL FOR PTIT ROC			100	
Z-BL-1.6-22.0-6	STERILE SURGICAL STEEL BARBELL			10	
PT-Z-XMLB-1.1.2-12.0-3/4B-CL	STERILE BIOFLEX MICRO LABRET WITH STEEL BALL FOR PTIT ROC			78	

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CODE	Iteme	Color	Lot. No	TOTAL QUANTITY	STERILIZED DATE
Z-LJNO-S-0.8-19.0-1.8-CR	STERILE SURGICAL STEEL SWAROVSKI CRYSTAL JEWELLED STRAIGHT NOSE STUD 19MM			70	
Z-SES1-3-CR	SURGICAL STEEL ROUND PRONG SET JEWELLED EAR STUDS PAIR			100	
TDI-Z-TBNJ-OP-1.6-10.0-5/8-RO	STERILE TITANIUM JEWELLED NAVEL BANANA FOR TDI			30	
PT-Z-PRTA-8.0-70.0	STERILE DISPOSABLE MULTI ANGLED RECEIVING TUBE FOR PTIT ROC			220	
TDI-Z-TBL-1.6-22.0-5	STERILE TITANIUM BARBELL FOR TDI			100	
Z-PNV-CRE	STERILE DISPOSAL ROUND CLAMPS		LOT-0199	463	31 Aug 20
Z-PNV-CRE	STERILE DISPOSAL ROUND CLAMPS			629	
Z-PSSP-CRE	STERILE DISPOSAL SLOTTED PENNINGTONS			79	
Z-PRTA-8.0-70.0	STERILE DISPOSABLE MULTI ANGLED RECEIVING TUBE 8.0MM			35	
Z-PRTA-8.0-70.0	STERILE DISPOSABLE MULTI ANGLED RECEIVING TUBE 8.0MM			150	
THD-Z-TMLB-1.2-10.0-3	STERILE TITANIUM MICRO LABRET FOR THENDRO			1000	

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