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TEST REPORT

CUSTOMER : Salamander Jewelry Co.,Ltd.

M/C : SHINVA

Document No. : TR-EO-001060818

MODEL : XG 1 SERIES

Date : 6/8/2018

SERIAL No. : 070997

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PRODUCT : ORDER NO. 2233881

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			
Sten 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 DOMIN TOTAL :12H 01MIN			
PRETT :00H 55MIN STERI :07H 00MIN			
ACTUAL TIME			
18:44:45 STEILIZATION SUCCESS			
END	18:44:54	058,90	-005kPa
	18:44:54	058,90	-005kPa
	14:47:19	058,30	-014kPa
	14:43:04	058,30	001kPa
EXHAUST	14:42:54	058,30	002kPa
	14:33:04	058,20	002kPa
	14:23:04	058,40	001kPa
	14:13:04	058,30	001kPa
	14:03:04	058,40	004kPa
	13:53:04	058,30	002kPa
	13:43:04	058,20	001kPa
	13:33:04	058,20	002kPa
	13:23:04	058,10	003kPa
	13:13:04	058,20	002kPa
	13:03:04	058,20	001kPa
	12:53:04	058,00	002kPa
	12:43:04	058,10	002kPa
	12:33:04	058,20	002kPa
	12:23:04	058,20	002kPa
	12:13:04	058,10	002kPa
	12:03:04	058,30	003kPa
	11:53:04	058,10	002kPa
	11:43:04	058,00	003kPa
	11:33:04	057,80	003kPa
	11:23:04	057,80	003kPa
	11:13:04	057,80	003kPa
	11:03:04	058,00	002kPa
	10:53:04	057,60	003kPa
	10:43:04	057,50	003kPa
	10:33:04	057,50	002kPa

	10:23:04	057,50	003kPa
	10:13:04	057,40	003kPa
	10:03:04	057,50	005kPa
	09:53:04	057,30	002kPa
	09:43:04	057,20	003kPa
	09:33:04	057,20	003kPa
	09:23:04	057,00	004kPa
	09:13:04	056,60	003kPa
	09:03:04	056,50	003kPa
	08:53:04	056,40	004kPa
	08:43:04	056,20	004kPa
	08:33:04	055,90	004kPa
	08:23:04	056,30	003kPa
	08:13:04	056,00	001kPa
	08:03:04	056,00	003kPa
	07:53:04	055,90	006kPa
	07:43:04	056,10	311kPa
STERI	07:42:56	056,10	311kPa
	07:33:04	056,50	-028kPa
ADD ED	07:29:56	056,40	-081kPa
	07:23:04	056,40	-004kPa
HUMIDI	07:19:38	056,40	-078kPa
PRETT	07:13:04	056,30	000kPa
PREHEAT	06:43:43	056,60	-001kPa
STATE	TIME	TEMP	PRE

RUN COUNT : 1918			
ED PRE	:060kPa	VENT TIME:	04H 00M
STERI TEMP:	056,00	STERI TIME:	07H 00M
PRO TIP	06:43:43	056,60	-001kPa
START TIME: 2018-06-04 06:43:36			

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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-MCB-1.2-10.0-3	STERILE SURGICAL STEEL MICRO CIRCULAR BARBELL			210	
TDI-Z-TCB-1.6-10.0-4	STERILE TITANIUM 90 DEGREE STAPLE BARBELL FOR TDI			50	
TDI-Z-TBC-1.2-8.0-4	STERILE TITANIUM BALL CLOSURE RING FOR TDI			100	
TDI-Z-TBC-1.2-10.0-4	STERILE TITANIUM BALL CLOSURE RING FOR TDI			100	
TDI-Z-TBC-1.6-14.0-5	STERILE TITANIUM BALL CLOSURE RING FOR TDI			25	
TDI-Z-TBNJ-OP-1.6-10.0-5/8-CR	STERILE TITANIUM JEWELLED NAVEL BANANA FOR TDI	CR		50	
TDI-Z-TMBN-1.2-12.0-3	STERILE TITANIUM MICRO CURVED BARBELL FOR TDI			100	
TDI-Z-TBNN-1.6-10.0-5/8	STERILE TITANIUM NAVEL BANANA FOR TDI			50	
TDI-Z-TMLB-1.2-12.0-3	STERILE TITANIUM MICRO LABRET FOR TDI			100	
TDI-Z-TMLBJ-1.2-8.0-2.5-CR	STERILE TITANIUM MICRO LABRET WITH JEWELLED BALL FOR TDI	CR		200	
Z-CB-1.6-8.0-4	STERILE SURGICAL STEEL CIRCULAR BARBELL			50	
Z-BC-1.6-12.0-4	STERILE SURGICAL STEEL BCR			130	
Z-BL-1.6-16.0-5	STERILE SURGICAL STEEL BARBELL			67	
Z-TINDAD-1.6-2.5-4-HP	STERILE TITANIUM INTERNALLY THREADED DERMAL ANCHOR WITH ROUND DISC			21	
Z-LJNO-0.8-6.5-2.35-CR	STERILE SURGICAL STEEL LARGE CURVE JEWELLED NOSE STUD	CR		330	
Z-TBC-2.5-18.0-6	STERILE TITANIUM BALL CLOSURE RING			20	
PT-Z-TBL-1.6-22.0-5	STERILIZED TITANIUM BARBELL FOR PTIT ROC		LOT-0134	59	4 Aug 18
PT-Z-TBNDJ-1.6-12.0-5/8-CR	STERILE TITANIUM DOUBLE JEWELLED NAVEL BANANA FOR PTIT ROC	CR		55	
TDI-Z-TMBN-1.2-10.0-3	STERILE TITANIUM MICRO CURVED BARBELL FOR TDI			167	
TDI-Z-BL-1.6-16.0-5	STERILE SURGICAL STEEL BARBELL FOR TDI			100	
TDI-Z-BL-1.6-18.0-5	STERILE SURGICAL STEEL BARBELL FOR TDI			50	
TDI-Z-BL-1.6-20.0-5	STERILE SURGICAL STEEL BARBELL FOR TDI			50	
TDI-Z-TMBN-1.2-8.0-3	STERILE TITANIUM MICRO CURVED BARBELL FOR TDI			200	
TDI-Z-TBNDJ-OP-1.6-10.0-5/8-CR	STERILE TITANIUM JEWELLED NAVEL BANANA FOR TDI	CR		150	
Z-MBL-1.2-8.0-3	STERILE SURGICAL STEEL MICRO BARBELL			100	
Z-BNDJ-1.6-12.0-5/8-CR	STERILIZED TITANIUM CURVED BARBELL FOR TDI	CR		134	
Z-MBN-1.2-12.0-3	STERILE SURGICAL STEEL MICRO CURVED BARBELL			141	
Z-MLB-1.2-8.0-3	STERILE SURGICAL STEEL MICRO LABRET			168	
PT-Z-TBNJ-1.6-12.0-5/8-CR	STERILE TITANIUM JEWELLED NAVEL BANANA FOR PTIT ROC	CR		54	
PT-Z-TMCB-1.2-10.0-3	STERILE TITANIUM LABRET FOR TDI			100	
Z-TMBN-1.2-10.0-3	STERILE TITANIUM MICRO CURVED BARBELL			50	
Z-BL-1.6-44.0-4	STERILE SURGICAL STEEL BARBELL			50	
Z-BNDJ-1.6-12.0-5/8-CR	STERILE SURGICAL STEEL DOUBLE JEWELLED NAVEL BANANA	CR		130	
Z-INMLBJ-1.2-8.0-2-CR	STERILE SURGICAL STEEL INTERNALLY THREADED JEWELLED MICRO LABRET	CR		70	
Z-PNV-CRE	STERILE DISPOSAL ROUND CLAMPS			1,371	
TDI-Z-BKBC-1.2-10.0-4	STERILE BLACK PVD COATED SURGICAL STEEL BALL CLOSURE RING FOR TDI			50	
TDI-Z-BKCN-0.8-6.5-2	STERILE BLACK PVD COATED SURGICAL STEEL CURVED BALL NOSE STUD FOR TDI			50	
Z-TJNO-1.0-6.5-2-CR	STERILE TITANIUM JEWELLED CURVED NOSE STUD	CR		70	

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CODE	Iteme	Color	Lot. No	TOTAL QUANTITY	STERILIZED DATE
TDI-Z-TJNO-OP-1.0-6.5-2-CR	STERI LECZECH CRYSTAL CURVED NOSE STUD FOR TDI	CR		300	
PT-Z-TMBN-1.2-12.0-3	STERILE TITANIUM MICRO CURVED BARBELL FOR PTIT ROC			53	
TDI-Z-MTST-1.2-10.0-3	STERILE TITANIUM 90 DEGREE STAPLE MICRO BARBELL FOR TDI			50	
TDI-Z-TBL-1.6-10.0-4	STERILE TITANIUM BARBELL FOR TDI			100	
Z-BC-1.2-12.0-4	STERILE SURGICAL STEEL BCR		LOT-0134	90	4 Aug 18
THD-Z-TMBL-1.2-10.0-3	STERILE TITANIUM MICRO BARBELL FOR THENDRO			200	
Z-XCN-7-1.6-18.0-5/8-CL-CR	STERILE BIOFLEX JEWELLED CUP NAVEL BANANA WITH JEWELLED STEEL BALL	CR		50	
Z-XCN-1-1.6-12.0-5/8-CL-CR	STERILE BIOFLEX JEWELLED CUP NAVEL BANANA WITH STEEL BALL	CR		40	
PT-Z-TMLBJ-1.2-8.0-2.5-CR	STERILE TITANIUM MICRO LABRET WITH JEWELLED BALL FOR PTIT ROC	CR		142	
TDI-Z-BC-1.2-12.0-4	STERILE SURGICAL STEEL BALL CLOSURE RING FOR TDI			50	

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