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TEST REPORT

CUSTOMER : Salamander Jewelry Co.,Ltd.

M/C : SHINVA

Document No. : TR-EO-001020221

MODEL : XG 1 SERIES

Date : 2/2/2021

SERIAL No. : 070997

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PRODUCT : ORDER NO. 2334606

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 51MIN			
PRETT :00H 51MIN STERI :07H 00MIN			
ACTUAL TIME			
08:06:28 STEILIZATION SUCCESS			
END	08:06:17	060,4C	002kPa
	08:06:17	060,4C	002kPa
	04:07:00	060,8C	-015kPa
EXHAUST	04:05:17	060,9C	009kPa
	04:03:47	060,9C	009kPa
	03:53:47	061,0C	009kPa
	03:43:47	061,1C	009kPa
	03:33:47	061,2C	009kPa
	03:23:47	061,4C	009kPa
	03:13:47	061,5C	009kPa
	03:03:47	061,7C	009kPa
	02:53:47	061,8C	009kPa
	02:43:47	062,1C	009kPa
	02:33:47	062,1C	009kPa
	02:23:47	062,2C	010kPa
	02:13:47	062,5C	010kPa
	02:03:46	062,6C	010kPa
	01:53:46	062,9C	010kPa
	01:43:46	063,0C	010kPa
	01:33:46	063,1C	010kPa
	01:23:46	063,4C	010kPa
	01:13:46	063,6C	010kPa
	01:03:46	063,8C	010kPa
	00:53:46	064,0C	010kPa
	00:43:46	064,2C	010kPa
	00:33:46	064,4C	010kPa
	00:23:46	064,5C	010kPa
	00:13:46	064,8C	010kPa
	00:03:46	064,7C	010kPa
	23:53:46	064,8C	011kPa
	23:43:46	064,9C	011kPa
	23:33:46	065,0C	011kPa
	23:23:46	065,0C	011kPa
	23:13:46	065,2C	011kPa
	23:03:46	065,3C	011kPa
	22:53:46	065,4C	011kPa
	22:43:46	065,5C	011kPa
	22:33:46	065,7C	011kPa
	22:23:46	065,8C	011kPa
	22:13:46	065,9C	011kPa
	22:03:46	066,0C	011kPa
	21:53:46	066,1C	011kPa
	21:43:46	066,0C	056kPa
	21:33:46	065,9C	073kPa
	21:23:46	065,8C	156kPa
	21:13:46	065,5C	311kPa
STERI	21:06:08	065,5C	311kPa
	21:03:46	065,4C	021kPa
ADD ED	20:57:10	065,0C	-067kPa
	20:53:46	064,5C	001kPa
HUMIDI	20:47:08	062,7C	-066kPa
PRETT	20:43:46	061,7C	002kPa
PREHEAT	20:15:05	059,1C	002kPa
STATE	TIME	TEMP	PRE
RUN COUNT : 0361			
ED	PRE :060kPa	VENT TIME:04H 00M	
STERI	TEMP: 035,0C	STERI TIME:07H 00M	
PRD TYP	20:15:05	059,1C	002kPa
START TIME:	2021-02-01 20:14:57		

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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			91	
PT-Z-TCB-1.6-10.0-4	STERILE TITANIUM 90 DEGREE STAPLE BARBELL FOR PTIT ROC			56	
PT-Z-TJNO-0.8-6.5-2.35-CR	STERILE TITANIUM JEWELLED CURVED NOSE STUD FOR PTIT ROC			178	
PT-Z-TMBN-1.2-10.0-3	STERILE TITANIUM MICRO CURVED BARBELL FOR PTIT ROC			128	
PT-Z-TMLB-1.2-12.0-3	STERILE TITANIUM MICRO LABRET FOR PTIT ROC			163	
PT-Z-TMLBJ-1.2-10.0-2.5-CR	STERILE TITANIUM MICRO LABRET WITH JEWELLED BALL FOR PTIT ROC			132	
PT-Z-TMLBJ-1.2-12.0-2.5-CR	STERILE TITANIUM MICRO LABRET WITH JEWELLED BALL FOR PTIT ROC			91	
PT-Z-XBL-1-1.6-40.0-5-CL	STERILE BIOFLEX BARBELL WITH STEEL BALLS FOR PTIT ROC			57	
PT-Z-XJNO-0.8-6.0-2.35-CL-CR	STERILE BIOFLEX JEWELLED CURVED NOSE STUD FOR PTIT ROC			59	
PT-Z-XMLB-1-1.2-10.0-3/4B-CL	STERILE BIOFLEX MICRO LABRET WITH STEEL BALL FOR PTIT ROC			59	
PT-Z-XMLB-1-1.2-8.0-3/4B-CL	STERILE BIOFLEX MICRO LABRET WITH STEEL BALL FOR PTIT ROC			92	
PT-Z-XMLBJ-7-1.2-10.0-3-CL-CR	STERILE BIOFLEX JEWELLED MICRO LABRET FOR PTIT ROC			69	
PT-Z-TMLB-1.2-12.0-3	STERILE TITANIUM MICRO LABRET FOR PTIT ROC			127	
PT-Z-TMLBJ-1.2-10.0-2.5-CR	STERILE TITANIUM MICRO LABRET WITH JEWELLED BALL FOR PTIT ROC		LOT-0221	137	1 Feb 21
PT-Z-TMLB-1.2-10.0-3	STERILE TITANIUM MICRO LABRET FOR PTIT ROC			636	
PT-Z-TMLBJ-1.2-10.0-2.5-CR	STERILE TITANIUM MICRO LABRET WITH JEWELLED BALL FOR PTIT ROC			167	
PT-Z-TMLB-1.2-10.0-3	STERILE TITANIUM MICRO CIRCULAR BARBELL FOR PTIT ROC			388	
PT-Z-TMLBJ-1.2-10.0-2.5-CR	STERILE TITANIUM MICRO LABRET WITH JEWELLED BALL FOR PTIT ROC			120	
TDI-Z-TCOBC-0.8-7.0	STERILE TITANIUM SEAMLESS RING FOR TDI			50	
TDI-Z-TCOBC-0.8-8.0	STERILE TITANIUM SEAMLESS RING FOR TDI			50	
TDI-Z-TCOBC-0.8-9.0	STERILE TITANIUM SEAMLESS RING FOR TDI			50	
TDI-Z-TCOBC-1.0-9.0	STERILE TITANIUM SEAMLESS RING FOR TDI			50	
PT-Z-TBL-1.6-22.0-5	STERILIZED TITANIUM BARBELL FOR PTIT ROC			706	
PT-Z-TJNO-0.8-6.5-2.35-CR	STERILE TITANIUM JEWELLED CURVED NOSE STUD FOR PTIT ROC			2689	
PT-Z-TMLB-1.2-8.0-3	STERILE TITANIUM MICRO LABRET FOR PTIT ROC			4258	
TDI-Z-MCB-1.2-9.0-3	STERILE SURGICAL STEEL MICRO CIRCULAR BARBELL FOR TDI			100	
TDI-Z-MLB-1.2-10.0-3	STERILIZED SURGICAL STEEL MICRO LABRET FOR TDI			100	
TDI-Z-MLB-1.2-12.0-2.5	STERILIZED SURGICAL STEEL MICRO LABRET FOR TDI			100	
Z-TINDAJD-1.6-2.0-4-HP-CR	STERILE TITANIUM INTERNALLY THREADED DERMAL ANCHOR WITH JEWELLED DISC			56	
PT-Z-TMLB-1.2-10.0-3	STERILE TITANIUM MICRO LABRET FOR PTIT ROC			349	
TDI-Z-MBN-1.2-8.0-3	STERILE SURGICAL STEEL MICRO CURVED BARBELL FOR TDI			100	

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