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TEST REPORT

CUSTOMER : Salamander Jewelry Co.,Ltd.

M/C : SHINVA

Document No. : TR-EO-007310320

MODEL : XG 1 SERIES

Date : 31/3/2020

SERIAL No. : 070997

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PRODUCT : ORDER NO. 2299503

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 54MIN | |
|--------------------------------|----------|------------------|---------|
| PRETT :00H 52MIN | | STERI :07H 00MIN | |
| ACTUAL TIME | | | |
| 04:51:12 STERILIZATION SUCCESS | | | |
| END | 04:51:01 | 056,30 | 000kPa |
| | 04:51:01 | 056,30 | 000kPa |
| | 00:51:54 | 056,10 | -015kPa |
| EXHAUST | 00:49:01 | 056,10 | -001kPa |
| | 00:45:31 | 056,10 | -001kPa |
| | 00:35:31 | 056,10 | -001kPa |
| | 00:25:31 | 056,10 | -001kPa |
| | 00:15:31 | 056,10 | -001kPa |
| | 00:05:31 | 056,10 | -001kPa |
| | 23:55:31 | 056,10 | -001kPa |
| | 23:45:31 | 056,10 | -001kPa |
| | 23:35:31 | 056,10 | -002kPa |
| | 23:25:31 | 056,10 | -001kPa |
| | 23:15:31 | 056,10 | -001kPa |
| | 23:05:31 | 056,00 | -001kPa |
| | 22:55:31 | 056,00 | -001kPa |
| | 22:45:31 | 056,00 | -002kPa |
| | 22:35:31 | 056,00 | -001kPa |
| | 22:25:31 | 056,00 | -001kPa |
| | 22:15:31 | 055,90 | -001kPa |
| | 22:05:31 | 055,90 | 000kPa |
| | 21:55:31 | 055,80 | -001kPa |
| | 21:45:31 | 055,80 | -001kPa |
| | 21:35:31 | 055,70 | -001kPa |
| | 21:25:31 | 055,70 | -001kPa |
| | 21:15:31 | 055,60 | -001kPa |
| | 21:05:31 | 055,70 | 000kPa |
| | 20:55:31 | 055,50 | 000kPa |

| | | | |
|---------------------------------|----------|--------------------|---------|
| | 20:45:31 | 055,50 | -001kPa |
| | 20:35:31 | 055,30 | 000kPa |
| | 20:25:31 | 055,20 | 000kPa |
| | 20:15:31 | 055,10 | -001kPa |
| | 20:05:31 | 055,10 | 000kPa |
| | 19:55:31 | 055,00 | 000kPa |
| | 19:45:31 | 055,00 | 000kPa |
| | 19:35:31 | 054,90 | 000kPa |
| | 19:25:31 | 054,90 | -001kPa |
| | 19:15:31 | 054,90 | 001kPa |
| | 19:05:31 | 054,80 | 000kPa |
| | 18:55:31 | 054,70 | 000kPa |
| | 18:45:31 | 054,80 | 001kPa |
| | 18:35:31 | 054,80 | 001kPa |
| | 18:25:31 | 054,80 | 003kPa |
| | 18:15:31 | 054,80 | 058kPa |
| | 18:05:31 | 054,80 | 140kPa |
| | 17:55:31 | 054,70 | 311kPa |
| STERI | 17:49:07 | 054,70 | 311kPa |
| | 17:45:00 | 054,80 | -031kPa |
| ADD ED | 17:39:10 | 054,80 | -090kPa |
| | 17:35:31 | 054,80 | -001kPa |
| HUMID | 17:29:04 | 055,00 | -088kPa |
| PRETT | 17:25:30 | 055,10 | 000kPa |
| PREHEAT | 16:56:51 | 054,80 | 001kPa |
| STATE | TIME | TEMP | PRE |
| RUN COUNT : 2917 | | | |
| ED PRE | :050kPa | VENT TIME:04H 00M | |
| STERI TEMP: | 055,00 | STERI TIME:07H 00M | |
| PRO TIP | 16:56:51 | 054,80 | 001kPa |
| START TIME: 2020-03-30 16:56:43 | | | |

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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-TBL-1.6-14.0-5 | STERILIZED TITANIUM BARBELL FOR PTIT ROC | | | 384 | |
| PT-Z-TBL-1.6-16.0-5 | STERILIZED TITANIUM BARBELL FOR PTIT ROC | | | 150 | |
| PT-Z-TBL-1.6-18.0-5 | STERILIZED TITANIUM BARBELL FOR PTIT ROC | | | 52 | |
| PT-Z-TBL-1.6-20.0-5 | STERILIZED TITANIUM BARBELL FOR PTIT ROC | | | 216 | |
| PT-Z-TBL-1.6-22.0-5 | STERILIZED TITANIUM BARBELL FOR PTIT ROC | | | 217 | |
| PT-Z-TBNJ-1.6-10.0-5/8-CR | STERILE TITANIUM JEWELLED NAVEL BANANA FOR PTIT ROC | | | 113 | |
| PT-Z-TBNJ-1.6-12.0-5/8-CR | STERILE TITANIUM JEWELLED NAVEL BANANA FOR PTIT ROC | | | 127 | |
| PT-Z-TCB-1.6-10.0-4 | STERILE TITANIUM 90 DEGREE STAPLE BARBELL FOR PTIT ROC | | | 44 | |
| PT-Z-TCB-1.6-8.0-4 | STERILE TITANIUM 90 DEGREE STAPLE BARBELL FOR PTIT ROC | | | 32 | |
| PT-Z-TMBL-1.2-10.0-3-HP | STERILE TITANIUM MICRO BARBELL FOR PTIT ROC | | | 444 | |
| PT-Z-TMBL-1.2-8.0-3-HP | STERILE TITANIUM MICRO BARBELL FOR PTIT ROC | | | 612 | |
| PT-Z-TMCB-1.2-8.0-3 | STERILE TITANIUM MICRO CIRCULAR BARBELL FOR PTIT ROC | | | 232 | |
| PT-Z-TMLB-1.2-10.0-3 | STERILE TITANIUM MICRO LABRET FOR PTIT ROC | | | 795 | |
| PT-Z-TMLB-1.2-12.0-3 | STERILE TITANIUM MICRO LABRET FOR PTIT ROC | | | 176 | |
| PT-Z-TMLB-1.2-8.0-3 | STERILE TITANIUM MICRO LABRET FOR PTIT ROC | | | 389 | |
| PT-Z-TMLBJ-1.2-12.0-2.5-CR | STERILE TITANIUM MICRO LABRET WITH JEWELLED BALL FOR PTIT ROC | | | 79 | |
| PT-Z-TMLBJ-1.2-8.0-2.5-CR | STERILE TITANIUM MICRO LABRET WITH JEWELLED BALL FOR PTIT ROC | | LOT-0186 | 155 | 30 Mar 20 |
| PT-Z-TST-1.6-32.0-4 | STERILE TITANIUM 90 DEGREE STAPLE BARBELL FOR PTIT ROC | | | 22 | |
| PT-Z-XBL-1-1.6-14.0-5-CL | STERILE BIOFLEX BARBELL WITH STEEL BALLS FOR PTIT ROC | | | 51 | |
| PT-Z-XJNO2-0.8-6.0-1.8-CL-CR | STERILE BIOFLEX JEWELLED CURVED NOSE STUD FOR PTIT ROC | | | 110 | |
| PT-Z-XMLB-1-1.2-8.0-3/4B-CL | STERILE BIOFLEX MICRO LABRET WITH STEEL BALL FOR PTIT ROC | | | 107 | |
| PT-Z-XMLBJ-7-1.2-10.0-3-CL-CR | STERILE BIOFLEX JEWELLED MICRO LABRET FOR PTIT ROC | | | 62 | |
| PT-Z-PRTA-8.0-70.0 | STERILE DISPOSABLE MULTI ANGLED RECEIVING TUBE FOR PTIT ROC | | | 275 | |
| PT-Z-TBCH-1.2-12.0-4 | STERILE TITANIUM BALL CLOSURE RING WITH HEMATITE BALL FOR PTIT ROC | | | 60 | |
| PT-Z-TBL-1.6-14.0-5 | STERILIZED TITANIUM BARBELL FOR PTIT ROC | | | 147 | |
| PT-Z-TBL-1.6-20.0-5 | STERILIZED TITANIUM BARBELL FOR PTIT ROC | | | 166 | |
| PT-Z-TBNJ-1.6-12.0-5/8-CR | STERILE TITANIUM JEWELLED NAVEL BANANA FOR PTIT ROC | | | 220 | |
| PT-Z-TMBL-1.2-8.0-3-HP | STERILE TITANIUM MICRO BARBELL FOR PTIT ROC | | | 214 | |
| PT-Z-TMCB-1.2-10.0-3 | STERILE TITANIUM MICRO CIRCULAR BARBELL FOR PTIT ROC | | | 150 | |
| PT-Z-TMCB-1.2-8.0-3 | STERILE TITANIUM MICRO CIRCULAR BARBELL FOR PTIT ROC | | | 139 | |
| PT-Z-TMLB-1.2-10.0-3 | STERILE TITANIUM MICRO LABRET FOR PTIT ROC | | | 245 | |
| PT-Z-TMLB-1.2-8.0-3 | STERILE TITANIUM MICRO LABRET FOR PTIT ROC | | | 525 | |
| PT-Z-TMLBJ-1.2-8.0-2.5-CR | STERILE TITANIUM MICRO LABRET WITH JEWELLED BALL FOR PTIT ROC | | | 257 | |
| PT-Z-XINNOTJD2-0.8-6.0-2-CL-CR | STERILE BIOFLEX INTERNAL CURVED NOSE STUD WITH TITANIUM JEWELLED DISC FOR PTIT ROC | | | 60 | |
| THD-Z-BC-1.2-8.0-4 | STERILE SURGICAL STEEL BALL CLOSURE RING FOR THENDRO | | | 1200 | |
| THD-Z-BC-1.6-10.0-4 | STERILE SURGICAL STEEL BALL CLOSURE RING FOR THENDRO | | | 200 | |

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| CODE | Iteme | Color | Lot. No | TOTAL QUANTITY | STERILIZED DATE |
|-----------------------------|-------------------------------------------------------------------------------|-------|----------|----------------|-----------------|
| THD-Z-BL-1.6-16.0-5 | STERILE SURGICAL STEEL BARBELL FOR THENDRO | | | 300 | |
| THD-Z-BL-1.6-22.0-5 | STERILE SURGICAL STEEL BARBELL FOR THENDRO | | | 100 | |
| THD-Z-BN-1.6-14.0-4 | STERILE SURGICAL STEEL CURVED BARBELL FOR THENDRO | | | 200 | |
| THD-Z-MBL-1.2-6.0-3 | STERILE SURGICAL STEEL MICRO BARBELL FOR THENDRO | | | 100 | |
| THD-Z-MCB-1.2-8.0-3 | STERILE SURGICAL STEEL MICRO CIRCULAR BARBELL FOR THENDRO | | | 1000 | |
| THD-Z-MLB-1.2-10.0-3 | STERILIZED SURGICAL STEEL MICRO LABRET FOR THENDRO | | | 1500 | |
| THD-Z-MLB-1.2-12.0-3 | STERILIZED SURGICAL STEEL MICRO LABRET FOR THENDRO | | | 400 | |
| THD-Z-MLB-1.2-6.0-3 | STERILIZED SURGICAL STEEL MICRO LABRET FOR THENDRO | | | 400 | |
| THD-Z-BNDJ-1.6-10.0-5/8-BZ | STERILE SURGICAL STEEL DOUBLE JEWELLED NAVEL BANANA FOR THENDRO | | | 200 | |
| THD-Z-JNO-1.0-6.5-2.35-CR | STERILE SURGICAL STEEL JEWELLED CURVED NOSE STUD FOR THENDRO | | | 1500 | |
| THD-Z-NO-1.0-6.5-2.5 | STERILE SURGICAL STEEL 1.2MM THREADING CURVED NOSE STUD WITH BALL FOR THENDRO | | | 500 | |
| THD-Z-SBNDJ-1.6-10.0-4/6-AB | STERILE SURGICAL STEEL DOUBLE JEWELLED MINI NAVEL BANANA FOR THENDRO | | | 300 | |
| TDI-Z-BC-1.6-10.0-5 | STERILE SURGICAL STEEL BALL CLOSURE RING FOR TDI | | | 25 | |
| TDI-Z-BC-1.6-12.0-5 | STERILE SURGICAL STEEL BALL CLOSURE RING FOR TDI | | | 25 | |
| TDI-Z-MLB-1.2-10.0-3 | STERILIZED SURGICAL STEEL MICRO LABRET FOR TDI | | | 100 | |
| TDI-Z-MLB-1.2-8.0-3 | STERILIZED SURGICAL STEEL MICRO LABRET FOR TDI | | | 300 | |
| Z-BNN-1.6-12.0-5/8 | STERILE SURGICAL STEEL NAVEL BANANA | | LOT-0186 | 10 | 30 Mar 20 |
| Z-TINDAJD-1.6-1.5-3-HP-CR | STERILE TITANIUM INTERNALLY THREADED DERMAL ANCHOR WITH JEWELLED DISC | | | 10 | |
| Z-TMLB-1.2-10.0-3-HP | STERILE TITANIUM MICRO LABRET | | | 35 | |
| Z-LJNO-0.8-6.5-2.35-CR | STERILE SURGICAL STEEL BARBELL | | | 610 | |
| Z-BL-1.6-14.0-5 | STERILE SURGICAL STEEL BARBELL | | | 254 | |
| Z-BL-1.6-34.0-5 | STERILE SURGICAL STEEL BARBELL | | | 59 | |
| PT-Z-TMLB-1.2-8.0-3 | STERILE TITANIUM MICRO LABRET FOR PTIT ROC | | | 1000 | |
| Z-SES1-2.5-CR | SURGICAL STEEL ROUND PRONG SET JEWELLED EAR STUDS PAIR | | | 20 | |
| Z-SES1-4-CR | SURGICAL STEEL ROUND PRONG SET JEWELLED EAR STUDS PAIR | | | 20 | |
| Z-ININP-1.2-50.0 | STERILE SURGICAL STEEL INTERNALLY THREADED INSERTION PINS | | | 10 | |
| Z-ININP-1.6-50.0 | STERILE SURGICAL STEEL INTERNALLY THREADED INSERTION PINS | | | 10 | |
| Z-MBL-1.2-8.0-3 | STERILE SURGICAL STEEL MICRO BARBELL | | | 185 | |
| Z-MCB-1.2-10.0-3 | STERILE SURGICAL STEEL MICRO CIRCULAR BARBELL | | | 215 | |
| Z-JNO90-0.8-6.5-1.8-CR | STERILE SURGICAL STEEL JEWELLED CURVED NOSE STUD | | | 300 | |
| Z-JNO-0.8-6.5-2.35-CR | STERILE SURGICAL STEEL JEWELLED CURVED NOSE STUD | | | 221 | |
| PT-Z-TST-1.6-32.0-4 | STERILE TITANIUM 90 DEGREE STAPLE BARBELL FOR PTIT ROC | | | 10 | |
| TDI-Z-CNO-1.0-6.5-2 | STERILE SURGICAL STEEL CURVED BALL NOSE STUD FOR TDI | | | 100 | |
| Z-MLB-1.2-8.0-3 | STERILE SURGICAL STEEL MICRO LABRET | | | 552 | |
| Z-GSCNEEDLES-1.2-24.0 | STERILE CURVED STAINLESS STEEL NEEDLE | | | 10 | |
| Z-GSNEEDLES-1.2-24.0 | STERILIZED STAINLESS STEEL NEEDLE | | | 100 | |
| Z-SES1-2.5-CR | SURGICAL STEEL ROUND PRONG SET JEWELLED EAR STUDS PAIR | | | 150 | |
| Z-SES1-3-CR | SURGICAL STEEL ROUND PRONG SET JEWELLED EAR STUDS PAIR | | | 100 | |

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