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M/C : SHINVA

Document No. : TR-EO-009261020

MODEL : XG 1 SERIES

Date : 26/10/2020

SERIAL No. : 070997

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PRODUCT : ORDER NO. 2321822

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 | COMIN | TOTAL | :11H 47MIN |
| PRETT | :00H 47MIN | STERI | :07H 00MIN |
| ACTUAL TIME | | | |
| 05:35:52 STEILIZATION SUCCESS | | | |
| END | 05:35:41 | 061,9C | 001kPa |
| | 05:35:41 | 061,9C | 001kPa |
| | 01:36:16 | 063,1C | -015kPa |
| EXHAUST | 01:34:41 | 063,2C | 006kPa |
| | 01:28:11 | 063,2C | 006kPa |
| | 01:18:11 | 063,3C | 007kPa |
| | 01:08:11 | 063,4C | 007kPa |
| | 00:58:11 | 063,6C | 007kPa |
| | 00:48:11 | 063,7C | 007kPa |
| | 00:38:11 | 063,9C | 007kPa |
| | 00:28:11 | 063,9C | 007kPa |
| | 00:18:11 | 064,0C | 007kPa |
| | 00:08:11 | 064,1C | 007kPa |
| | 23:58:11 | 064,2C | 007kPa |
| | 23:48:11 | 064,3C | 007kPa |
| | 23:38:11 | 064,4C | 007kPa |
| | 23:28:11 | 064,4C | 007kPa |
| | 23:18:11 | 064,6C | 008kPa |
| | 23:08:11 | 064,5C | 008kPa |
| | 22:58:11 | 064,6C | 008kPa |
| | 22:48:11 | 064,8C | 008kPa |
| | 22:38:11 | 064,8C | 008kPa |
| | 22:28:11 | 064,9C | 008kPa |
| | 22:18:11 | 064,9C | 008kPa |
| | 22:08:11 | 065,1C | 008kPa |
| | 21:58:11 | 065,1C | 008kPa |
| | 21:48:11 | 065,1C | 008kPa |

| | | | |
|------------------|---------------------|-------------|---------|
| | 21:38:11 | 065,1C | 009kPa |
| | 21:28:11 | 065,1C | 009kPa |
| | 21:18:11 | 065,1C | 009kPa |
| | 21:08:11 | 065,1C | 009kPa |
| | 20:58:11 | 065,1C | 009kPa |
| | 20:48:11 | 065,1C | 009kPa |
| | 20:38:11 | 065,1C | 009kPa |
| | 20:28:11 | 065,1C | 009kPa |
| | 20:18:10 | 065,1C | 010kPa |
| | 20:08:10 | 065,1C | 010kPa |
| | 19:58:10 | 065,1C | 010kPa |
| | 19:48:10 | 065,0C | 010kPa |
| | 19:38:10 | 064,9C | 010kPa |
| | 19:28:10 | 064,7C | 010kPa |
| | 19:18:10 | 064,3C | 011kPa |
| | 19:08:10 | 063,6C | 011kPa |
| | 18:58:10 | 063,0C | 011kPa |
| | 18:48:10 | 062,1C | 058kPa |
| | 18:38:10 | 060,7C | 252kPa |
| STERI | 18:35:36 | 060,6C | 311kPa |
| ADD ED | 18:31:30 | 060,4C | -087kPa |
| | 18:28:10 | 060,2C | 002kPa |
| HUMIDI | 18:21:28 | 060,3C | -087kPa |
| PRETT | 18:18:10 | 059,7C | 002kPa |
| PREHEAT | 17:49:17 | 057,7C | 002kPa |
| STATE | TIME | TEMP | PRE |
| RUN COUNT : 0210 | | | |
| ED PRE | :060kPa | VENT TIME: | 04H 00M |
| STERI TEMP: | 055,0C | STERI TIME: | 07H 00M |
| PRO TYP | 17:49:17 | 057,7C | 002kPa |
| START TIME: | 2020-10-25 17:49:10 | | |

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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 |
|--------------------------|---|-------|----------|----------------|-----------------|
| TDI-Z-TBCSH-1.2-10.0 | STERILE TITANIUM HINGED SEGMENT RING FOR TDI | | | 200 | |
| Z-TMBL-1.2-8.0-3-HP | STERILE TITANIUM MICRO BARBELL | | | 300 | |
| Z-TMBL-1.2-9.0-3-HP | STERILE TITANIUM MICRO BARBELL | | LOT-0206 | 100 | 25 Oct 20 |
| Z-INMLBSJ1-1.2-10.0-2-CR | STERILE SURGICAL STEEL INTERNALLY THREADED ROUND PRONG SET JEWELED MICRO LABRET | | | 10 | |
| Z-MLBJ-1.2-10.0-3-CR | STERILE SURGICAL STEEL JEWELED MICRO LABRET | | | 250 | |
| Z-PRTA-8.0-70.0 | STERILE DISPOSABLE MULTI ANGLED RECEIVING TUBE 8.0MM | | | 5000 | |
| PT-Z-PRTA-8.0-70.0 | STERILE DISPOSABLE MULTI ANGLED RECEIVING TUBE FOR PTIT ROC | | | 355 | |

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