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PRODUCT : ORDER NO. 2168692

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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