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Document No. : TR-EO-003160117

Date : 16/1/2017

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PRODUCT : ORDER NO. 2171088

#### 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    | -      |
| <b>Humidification</b>   |                  |           |        |
| Humidity (%)  | 50%-90%          | 87%       | -      |
| <b>Sterilization</b>  |                  |           |        |
| Steri Temp  | 55.0 - 59.0 (°C) | 55.0 (°C) | -      |
| Jacket Temp   | 60.0 - 65.0 (°C) | 65.0 (°C) | -      |
| <b>Gas Injection</b>  |                  |           |        |
| 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)   | -      |
| <b>Exposure</b>   |                  |           |        |
| 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   | -      |
| <b>Exhaust</b>  |                  |           |        |
| 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     | -      |
| <b>Storage</b>  |                  |           |        |
| Storage Time  | ≥ 48 hour        | ≥ 48 hour | -      |
| <b>Chemical tested, Sterile Strip</b>                               |                  |           |        |
| EO sterilization temperatures 55-60 C° Time sterile by EO 7 hours . | Brown            | Brown     | Pass   |
| <b>Biological Test</b>  |                  |           |        |
| EZ Test Biological Indicator  | Brown            | Brown     | Pass   |
| 24 hour results for EO  |                  | Red       | Pass   |

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