

## Report Test

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We erased their address from this document.

**LOT No :** 0531/2022  
**Date :** 1 December 2022

### Determination of Sterilization Operation Specification

| Item Detail                                                           | Specification | Setting   | Result |
|-----------------------------------------------------------------------|---------------|-----------|--------|
| Chamber Setting Temperature                                           | 40.0-55.5 °C  | 45.0 °C   |        |
| Vacuum pressure                                                       | 40-60 kPa     | 60 kPa    |        |
| Vacuum Time                                                           | 50-60 min     | 60 min    |        |
| <b>Humidification</b>                                                 |               |           |        |
| Humidity                                                              | 50.0-90.0%    | 20.2 %    |        |
| <b>Sterilization</b>                                                  |               |           |        |
| Sterilization Temperature                                             | 40.0-55.5 °C  | 43.5 °C   |        |
| <b>Gas Injection</b>                                                  |               |           |        |
| Final pressure                                                        | 0-10 kPa      | 4 kPa     |        |
| Final temperature of vaporizer                                        | 40.0-55.5 °C  | 44.8 °C   |        |
| <b>Exposure</b>                                                       |               |           |        |
| Temperature at start point of Exposure time period                    | 40.0-55.5 °C  | 43.3 °C   |        |
| Temperature at finish point of Exposure time period                   | 40.0-55.5 °C  | 46.0 °C   |        |
| Exposure Time                                                         | 120-240 min   | 180 min   |        |
| <b>Exhaust</b>                                                        |               |           |        |
| Exhaust Time                                                          | 60-80 min     | 75 min    |        |
| First Vacuum pressure                                                 | 0-2 kPa       | 1.5 kPa   |        |
| Second Vacuum pressure                                                | 0-2 kPa       | 1.5 kPa   |        |
| Third Vacuum pressure                                                 | 0-2 kPa       | 1.5 kPa   |        |
| Fourth Vacuum pressure                                                | 0-2 kPa       | 1.5 kPa   |        |
| Fifth Vacuum pressure                                                 | 0-2 kPa       | 1.5 kPa   |        |
| <b>Storage</b>                                                        |               |           |        |
| Storage Time                                                          | ≥ 48 hour     | ≥ 48 hour |        |
| <b>Chemical Test</b>                                                  |               |           |        |
| EO sterilization temperature 40-55°C, Time Sterilization by EO 3hours | Blue          | Red       | Pass   |
| <b>Biological Test</b>                                                |               |           |        |
| EZ Test Biological Indicator                                          | Green         | Green     | Pass   |

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