

### Report Test

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**LOT No:** 0865/2024  
**Date:** 07 October 2024

#### 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   |

*Malairak Lappho*

(.....)

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