

Wuxi Zhushi Sterilization Factory

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|-------------|-----------------|-------------------------|-----|
| File Number | SZLF/ST01 05-02 | Version/revision number | B/1 |
|-------------|-----------------|-------------------------|-----|

Certification of EO GAS Sterilization

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|--|--|---|-----------|---|---|---------------------|---|
| Customer | Kwadron Sp. z o.o. sp. k. | | | | | | |
| Product codes | Product name | Lot No | | | | | |
| / | Kwadron Cartiridge System / Kwadron Optima | 0000-9999 | | | | | |
| Sterilization mode | Chamber NO. | Cartridge type | | | | | |
| EO-Gas | 2# | 0,18; 0,20; 0,25; 0,30; 0,35; 0,40mm RL; RS; MG; FL; SEM; TRL; ERL; CF | | | | | |
| Stelization parameters | | Validated | Tolerance | | | Actual | |
| Preconditioning temperature (°C) | | 50 | ±4 | | | 50.5-53.5 | |
| Preconditioning RH (RH %) | | 55 | ±10 | | | 49-55 | |
| Preconditioning Time (min) | | 360 | ±20 | | | 350 | |
| Initial Evacuation Vacuum (kpa) | | -25 | ±2 | | | -25 | |
| Keep Pressure (min) | | 20 | ±10 | | | 15 | |
| Weight of EO Injection (kg/25m3) | | 15 | ±1.25 | | | 15 | |
| Rate of EO Injection (kpa/min) | | 0.5 | ±0.2 | | | 0.5 | |
| EO-Concentration (mg/L) | | 600 | ±50 | | | 600 | |
| EO Injection Pressure Changed (kpa) | | >25 | // | | | S:-25.0E: 8.0 | |
| Exposure Time (min) | | 720 | ±20 | | | 720 | |
| Sterilization Temperature (°C) | | 52 | ±3 | | | 50.5-53.5 | |
| Chamber RH of Sterilization (%RH) | | 55 | ±10 | | | 49.5-55.5 | |
| Post Evacuation Vacuum (kpa) | | -20 | ±2 | | | -20.5 | |
| The Number of ventilator (times) | | 6 | // | | | 6 | |
| Aeration Temperature (°C) | | 42 | ±5 | | | 38.5-40.5 | |
| Aeration Time (day) | | 7 | // | | | 7 | |
| Strain | Bocillus Ptrophoeus ATCC9372 | Nominal Population (cfu/unit) | | | | 1.7x10 ⁶ | |
| Lot NO. | 200825 | D-Value (min) | | | | 3 | |
| Culture temp. | 36°C | Culture time (days) | | | | 7 | |
| Culture date | 2020-2023 | | | | | | |
| Culture time | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Observed item | - | - | - | - | - | - | - |
| Positive control | + | + | + | + | + | + | + |
| BI test of sterility | Conformity | | | | | | |
| <p align="center">Conclusion:</p> <p align="center">The sterilization cycles was performed as per the validated parameters with no deviations. The sterile Assurance Level (SAL) of 10⁶ is assured</p> | | | | | | | |

Approved by: *Jach L.K.*

Company stamp:

