

**Wuxi Zhushi Sterilization Factory**

File Number	SZLF/ST01 05-02	Version/revision number	B/1
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**Certification of EO GAS Sterilization**

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 <sup>6</sup>	
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"><b>Conclusion:</b></p> <p align="center">The sterilization cycles was performed as per the validated parameters with no deviations. The sterile Assurance Level (SAL) of 10<sup>6</sup> is assured</p>							

Approved by: *Jach L.K.*

Company stamp:

