

Wuxi Zhushi Sterilization Factory

File Number	SZLF/ST01_05-02	Version/revision number	B/1
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Certification of EO GAS Sterilization

Date: 5-02-2022

Customer	TCM Supply Corporation DBA: WorldWide Tattoo Supply						
Product codes	Product name	Lot No					
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Sterilization mode	Chamber NO.	Cartridge type					
EO-Gas	2#	0.25; 0.30; 0.35mm 0.25, 0.30, 0.35mm : RSB; RLB; M1B; M1TB; M1TB-T					
Sterilization 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	2022 - 2025						
Culture time	1	2	3	4	5	6	7
Observed item	-	-	-	-	-	-	
Positive control	+	+	+	+	+	+	+
BI test of sterility				Conformity			
Conclusion: The sterilization cycles was performed as per the validated parameters with no deviations. The sterile Assurance Level (SAL) of 10 ⁶ is assured							

Approved by: *Jah L.K.*.....

Company stamp:

