

WUJIANG CITY WORLDFUL TRADE CO; LTD

环氧乙烷灭菌证明 Certification of EO Gas Sterilization

报告编号 Report NO: 2021070019

客户 Customer:	LUCKY'S SUPPLY COMPANY. INC		
产品名称 Product Name	规格 Specification	批号 Lot No.	数量 Quantity
TATTOO CARTRIDGE NEEDLE; CARTRIDGE GRIP	1-9 Liner Bugpin; 1-11 Liner Tight; 1-18 Liner; 7-9 Power Liner Tight; 8-14 Loose Liner; 7-11 Hollow Liner; 3-14 Shader; 8-11 Shader Medium Taper; 5-25 Mag Bugpin; 5-25 Magnum; 5-17 Magnum Curved Bugpin; 5-25 Magnum Curved; GRIPADJ; GRIPFXD	210601	82CTNS

灭菌方式 Sterilization mode	灭菌器 Chamber No:	灭菌日期 Sterilization date	灭菌批号 Ster Lot No.
EO Gas	#2	20210716	210701-5

灭菌参数 Sterilization Parameters	设定 Validated	允许偏差 Tolerance	实际 Actual
预热温度 Preconditioning Temperature(°C)	48	±4	44.8-50.1
预热湿度 Preconditioning RH(%RH)	55	±25	36.7-67.1
预热时间 Preconditioning Time(min)	360	±20	377
预真空 Initial Evacuation Vacuum(kPa)	-37	±2	-37
保压时间 Keep Pressure(min)	20	±10	18
灭菌剂加入量 Weight of EO Injection(kg/25m ³)	20	±0.5	20.1
灭菌剂加入速率 Rate of EO Injection(kg/25m ³)	0.5	±0.2	0.50
灭菌气体浓度 EO Concentration(mg/L)	600	±200	588
EO 注入前后压力值 EO Injection Pressure Changed(kPa)	>31	//	S:-37.5 E:-5.3
作用时间 Exposure Time(min)	720	±20	712
灭菌温度 Sterilization Temperature(°C)	52	±3	50.0-53.3
灭菌湿度 Chamber RH of Sterilization(%RH)	55	±25	39.8-71.9
换气真空度 Post Evacuation Vacuum(kPa)	-25	±2	-24.5
换气次数 The Number of Ventilators(times)	6	//	6
解析温度 Aeration Temperature(°C)	42	±5	39.9-46.3
解析时间 Aeration Time(day)	7	//	7

微生物种类 Strain	Bacillus atropheaus(ATCC9372)	芽孢含量 Nominal population(cfu/unit)	1.7X10 ⁶
BI 批号 Lot No.	210701-5	D 值 D-value(min)	3.0
培养温度 Culture Tem.	36°C	培养时间 Culture time(days)	7

培养日期 Culture Date	2021.07.10--2021.07.16						
培养时间 Culture time(day)	1 st	2 nd	3 rd	4 th	5 th	6 th	7 th
观察记录 Observed Item	-	-	-	-	-	-	-
阳性对照 Positive control	+	+	+	+	+	+	+

生物指示物无菌实验结果 BI test of sterility √合格 Conformity 不合格 non-conformity

结论 Conclusion:
 以上产品进行常规环氧乙烷灭菌，各项灭菌参数合格，无菌水平 10⁻⁶ 得到保证，产品允许放行。
 The sterilization cycles were performed as per the validated parameters with no deviations. The Sterile Assurance Level(SAL) of 10⁻⁶ is assured



报告日期 Report Date 2021.07.16