

Certificate of Sterilization

WUXIAN STERILIZATION STATION (STERILIZATION OF XIANGCHENG DISTRICT OF SUZHOU, CHINA)

WE CERTIFY HERE OBSIDIAN NEEDLES BRAND PRODUCTS: PIERCING NEEDLE EXPORT BY WUJIANG CITY WORLDFUL TRADE CO., LTD AND MANUFACTURED BY WUJIANG PRECISION METAL PRODUCTS CO., LTD

2" Coated

LOT NO#: 231201

GAUGE: 16G、18G、20G

EXP DATE: 12/2026

HAS BEEN STERILIZATION USING THE EO GAS METHOD OF STERILIZATION FOR A PERIOD OF 12 HOURS AND THAT ALL STERILIZATION EQUIPMENT AND PROCEDURES HAVE BEEN INSPECTED AND FOUND ACCEPTABLE BY ALL THE APPROPRIATE PUBLIC HEALTH OFFICIALS OF OUR CITY AND COVERING BODY.

Suzhou City Xiangcheng District Sterilization Station



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3" Coated

LOT NO#: 230301

GAUGE: 10G、12G、13G、14G、15G、16G、18G、20G

EXP DATE: 03/2026

HAS BEEN STERILIZATION USING THE EO GAS METHOD OF STERILIZATION FOR A PERIOD OF 12 HOURS AND THAT ALL STERILIZATION EQUIPMENT AND PROCEDURES HAVE BEEN INSPECTED AND FOUND ACCEPTABLE BY ALL THE APPROPRIATE PUBLIC HEALTH OFFICIALS OF OUR CITY AND COVERNING BODY.

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苏州市相城区消毒站

Suzhou City Xiangcheng District Sterilization Station

环氧乙烷灭菌批记录(EO-Sterilization Batch Report)

Furnace No箱号: Y1-01

Sterilization No.灭菌批号: 240301

Date 日期: 2024-03-20

Article Name 物品名称	Production No 生产批号	Expiration Date 有效期	Specification 规格/型号	Remark 备注	Parameters During Sterilization Cycle 灭菌过程参数	Required 设定值	Actual 实际值
Piercing Needles	240301	03/2027	16G、18G、20G	OBSIDIAN	灭菌温度Chamber Temperature while Sterilization(°C)	47-53	S:48.5 E: 52.6
					灭菌压力Chamber Pressure while Sterilization(kPa)	-30—20	S:-27.1 E:-15.5
					灭菌湿度Chamber Humidity while Sterilization(%RH)	40-80	33.5-52.8
					灭菌时间Exposure time(min)	480	480
					预真空度Pre-Vacuum Value(kPa)		
					加湿压力幅度Pressure Amplitude while Humidifying(kPa)		
					加湿前后压力Pressure Changed while Humidifying(kPa)		
					加药压力幅度Pressure Amplitude while EO Injection(kPa)		
					加药前后压力Pressure Changed while EO Injection(kPa)	//	S:-69.2 E: -35.2
					加药重量Weight of EO used(kg)	3.8-4.2	12

Sterilization Phase 灭菌过程	Start Time 开始时间	End Time 结束时间	Actual Time 实际时间	Sterilization Information 灭菌情况	Release 验收
预热 Conditioning	9: 17	13: 17	240	Normal 正常	<input checked="" type="checkbox"/> Passed 合格 <input type="checkbox"/> Rejected 拒收 <input type="checkbox"/> Hold 待定 Injector 加药者 <u>刘志成</u> Operator 操作员 EO Manger 灭菌主管 <u>徐仁余</u> Micro Lab Manger 质检员 <u>张</u> QA Manger 主管 <u>张</u>
抽真空 Air Removal	13: 17	13: 24	7	Normal 正常	
保压时间 Pressure Time	13: 24	13: 29	5	Normal 正常	
充入EO EO Injection	13: 35	13: 50	15	Normal 正常	
灭菌时间 Exposure Time	13: 50	21: 50	480	Normal 正常	
换气时间 EO Removal	21: 50	22: 16	26		
清理完毕 Finishing	22: 16	22: 48	32		

