

司帝瑞（镇江）消毒服务有限公司  
STERIL(ZHENJIANG) STERILIZATION SERVICE CO.,LTD  
环氧乙烷灭菌批记录  
EO STERILIZE BATCH RECORD

Furnace No箱号: 01

Date日期: 2023-11-21

Sterilization灭菌批号: DFKJ202311-0755

Article 物品名称	Batch No 生产批号	Specification型号	Quantity 数量	Remark 备注	Required Operation During Sterilization Cycle 灭菌过程操作要求		
					Required 操作要求	Actual 实际值	
Tattoo Cartridge Needles	DFKJ202311-0755	I003RLL ,etc	10000		Temperature(°C) 温度	50°C±8°C	S:48.0 E:53.5
					Pressure(Kpa) 压力	- 15Kpa±5Kpa	- 16.3
					Humidity(%RH) 湿度	54%±10%	59.9~61.9
					Exposure time(min) 灭菌时间	600min	600min
					Speed of Air Removal(Kpa/min)抽真空速率	3~7	4.2
					Speed of Aeration(Kpa/min) 换气速率	4~10	7
					Weight of Eo used Before(kg) 加药前重量	52	52
					Weight of Eo used After(kg) 加药后重量	40	40
					Weight of Eo used (kg) 加药重量	12	12
					Pressure Changed(Kpa) 加药前后压力	960	960

Required Operation 操作要求	Start Time 开始时间	Eng Time 结束时间	Actual Time 实际时间	Sterilization Information 灭菌情况	Release 验收
Conditioning 预热	16:48	17:16	28min	设备运行正常, 参数控制符合要求。	<input checked="" type="checkbox"/> Passed 合格 <input type="checkbox"/> Rejected 拒收 <input type="checkbox"/> Hold 待定 
Air Removal 抽真空	17:16	17:20	4min		
Pressure Time 保压时间	17:20	17:28	8min		
Eo injection 充入环氧乙烷	17:28	17:48	20min	灭菌后化学指示卡由红变蓝	
Exposure time 灭菌时间	17:48	3:48	600min	Injector加药者 Opreator操作者 Super主管	
Eo removal 清除环氧乙烷	3:48	4:08	20min	李方廷 李方廷 汪佳佳	
Flushing 清理完毕	4:08	4:18	10min	Li Guangting Li Guangting Wang Jiajia	

CERTIFICATE OF STERILIZATION

STERILIZATION No. DFKJ202311-0755

We state that below products are sterilized for ZHENJIANG DINGFENG  
NEEDLES MANUFACTURING TECHNOLOGY CO.,LTD.

Customer

Yiwu Wenmei Import and Export Co., Ltd

ADD: No. 788 Chengdian South Road,  
Yiwu City, Jinhua City, Zhejiang Province

Product name:	Tattoo Cartridge Needles
Lot Number:	DFKJ202311-0755
Quantity:	100 cartons
Date of sterilization:	2023-11
Expiry Date:	2028-10
The method of sterilization:	By EO Gas
Spore test results:	Eligible

(Please see the attached appendix "Test report")



CERTIFICATED BY:Mr.WANGXIAOFANG(Principal)  
ZHENJIANG CITY RUNZHOU DISTRICT  
STERILIZATION STATION  
ISO No.DFKJ202311-0755  
Date: 2023-11-21