

江苏鄂氏健康产业有限公司

Jiangsu E Shi Health Industry CO.Ltd.

环氧乙烷灭菌批记录

EO STERILIZE BATCH RECORD

Furnace No箱号: 01

Date日期: 2024-12-14

Sterilization灭菌批号: DFKJ202412-0830

Article 物品名称	Batch No 产批号	Specification型号	Quantity 数量	Remark 备注
Tattoo Cartridge Needles	2024-12	EMALLA ELIOT RLL	2000	Total 2000 Boxes

Required Operation During Sterilization Cycle 灭菌过程操作要求		
	Required 操作要求	Actual 实际值
Temperature(℃) 温度	50℃±8℃	S:48.0 E:53.5
Preesure(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
Preesure 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。	鄂氏健康产业有限公司 灭菌专用章 ☒Passed 合格 ☐Rejected 拒收 ☐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		
Flushing 清理完毕	4:08	4:18	10min	li Guangting Li Guangting Wang Jiajia	

CERTIFICATE OF STERILIZATION

STERILIZATION No. DFKJ202412-0830

We state that below products are sterilized for HANGZHOU WENMEI TECHNOLOGY.CO.LTD.

Customer: HANGZHOU WENMEI TECHNOLOGY.CO.LTD.

ADD : Room 2503, Building 1, Bodi Century Center, Ningwei Street, Xiaoshan District, Hangzhou City, Zhejiang Province

Product name:	Tattoo Cartridge Needles
Lot Number:	DFKJ202412-0830
Quantity:	200cartons
Date of sterilization:	2024-12
Expiry Date:	2029-11
The method of sterilization:	By EO Gas
Spore test results:	Eligible

(Please see the attached appendix"Test report")



CERTIFICATED BY:Mr.CAOYINGLIN(Principal)
YANGZHOU CITY GUANGLING DISTRICT
STERILIZATION STATION
ISO No.DFKJ202412-0830
Date: 2024-12-14