

SUZHOU WUXIAN STERILIZATION STATION
QINGTAI VILLAGE, HUANGQIAO TOWN, WUXIAN CITY, JIANGSU PROVINCE
P.R.O. CHINA

STERILIZATION CERTIFICATE

TYPE OF PRODUCT SUBJECT TO STERILIZATION: Transparent film dressing
"Ratio Skin Protection"

TYPE OF STERILIZATION: EO GAS

ITEM NO: RATIO SKIN PROTECTION

DATE OF STERILIZATION: DEC 2019

EXPIRE DATE: 12-2022

LOT NO: 122022

We hereby certify that the above mentioned item which were sterilized by EO Gas
on Dec. 2020 with the Lot No. 122022



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


Chacmber No. 灭菌器编号: SSB-001A

Sterilezation No. 灭菌批号: 265

Date 日期: 19-12-7

Order 班次: 1

Article Name 货物名称	Production No 生产批号	Specification 规格/型号	Quantity 数量	Remark 备注	Parameters During Sterilization Cycle 灭菌过程参数	
					Required 设定值	Actual 实际值
					灭菌温度Chamber Temperature while Sterilization (°C)	55.0 Min 53.2 Max 58.1
无菌敷贴	E191119	6×7cm	20000片	B191205	灭菌压力Chamber pressure while Sterilization (kPa)	NA Min 11.2 Max 19.7
无菌敷贴	E191202	6×7cm	20000片	B191205	灭菌湿度Chamber Humidity while Sterilization (% RH)	NA Min 34.9 Max 49.8
无菌敷贴	E191201	10×15cm	30000片	B191206	灭菌时间Exposure Time(min)	480 479
块式格卷材 Transperent film dressing	20191125	15cm×10m	1000卷 1000 rolls	50箱 50 cartons	预真空度Pre-Vacuum (kPa)	-25.0 -25.1
					加湿压力幅度Pressure Amplitude while Humidifying(kPa)	1.0 1.2
					加湿前后压力Pressure Changed while Humidifying(kPa)	NA B -24.7 E -23.5
					加药压力幅度Pressure Amplitude while EO Injection(kPa)	80.0 43.2
					加药前后压力Pressure Changed while EO Injection(kPa)	NA B -23.5 E 19.7
					加药重量Weight of EO used (kg)	5.1kg

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
加热 Heating	11:29	12:43	74	 <p> <input checked="" type="checkbox"/> Passed 合格 <input type="checkbox"/> Rejected 拒收 <input type="checkbox"/> Hold 待定 </p>
加温 Heat keeping	12:43	13:44	61	
预真空 Pre Vacuum	13:44	13:49	5	
保压 Leak test	13:49	13:54	5	<p> 朱春生 _____ 朱春生 _____ Injector 加药者 Operator 操作员 朱春生 _____ EO Manager 灭菌主管 </p>
加湿 Steam Injection	13:54	14:16	22	
加药 EO Injection	14:16	14:46	30	<p> 陈松松 _____ Mirco Lab Manager 质检员 吴斌 _____ QA Manager 质量主管 </p>
灭菌 Exposure	14:46	22:45	479	
清洗 Flushing	22:45	23:01	16	
通风 Aeration	23:01	23:32	31	