

Yiwu EO Sterilization Technology CO., Ltd.

义乌市亿欧灭菌技术有限公司

地址：浙江省义乌市佛堂镇双峰路 517 号 Building 5, No. 517 Shuangfeng Road, Fotang Town, Yiwu city, Zhejiang
编号 No.: WT-202408

Certification of EO Gas Sterilization

灭菌证明

Products Name 产品名称	Type/Size 型号规格	LOT No.批号	Quantity 数量
见明细	见明细	见明细	1571 盒
Sterilization agent:灭菌方法	Ethylene Oxide (100%)		
Sterile No.:灭菌批号	24082021		
Sterilization date:灭菌日期	2024.08.20		
Precondition parameters 预处理参数		Specification 操作要求	Reached values 实际值
Internal chamber temperature during action time (°C) 温度		50±10	50.5-53.5
Internal chamber Reactive humidity during action time (%)湿度		40~80%	47.3~72.3
Internal chamber time during action time (min)时间		720±30	720
Sterilization parameters 灭菌参数			
Internal chamber temperature during action time (°C) 温度		50±5	50.1~53.1
Internal chamber Reactive humidity during action time (%)湿度		40~80%	47~70.1
Pressure difference before and after injection EO (Kpa)压力		30±2	30.0
Agent concentration (mg/L)浓度		500±50	489.5
Duration faction time (minutes)灭菌时间		360±10	360
Flushing cycles (times)清洗次数		≥3	3
Outgassing parameters 解析参数		☒ N/A ☐ If applicable	
Internal chamber temperature during action time (°C) 温度		50±10	
Internal chamber time during action time (hr.)时间		≥24	
Evaluation of sterilization parameters 结论		☒ conformity ☐ non-conformity	
The above products are sterilized by EO gas normally, and realized sterility.以上产品由环氧乙烷灭菌, 已经灭菌完成。			

Compiled by: Terry

Date:

2024.08.27

Approved by: 吴晨康

Date:

2024.8.27

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Goods name	Lot	ITEM	CTNS	BOXES
Nuclear Needles	202408	1204RL	1	64
	202408	1207RL	2	128
	202408	1208RL	1	64
	202408	1201RLT	1	64
	202408	1205RLT	2	128
	202408	1209RLT	1	64
	202408	1005RLT	2	128
	202408	1205M-1	1	64
	202408	1223M-1	1	28
	202408	823M-1		18
	202408	1403RL	1	32
	202408	1405RL		32
	202408	817M-1	1	32
	202408	1407RL		32
	202408	1015M-1	1	32
	202408	1409RL		32
	202408	1209MC-1	3	192
	202408	1211MC-1	1	64
	202408	1213MC-1	1	64
	202408	1215MC-1	1	64
	202408	1225MC-1	1	53
	202408	1013MC-1	1	64
	202408	1208RS-1	2	128
Total1			25	1571

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2024.08.27

