

# 山东东华医疗科技股份有限公司

## 环氧乙烷灭菌过程记录 Ethylene Oxide Sterilization Process Record

灭菌机编号 Sterilizer: SC050164      灭菌批号 Sterilization Batch: 20190929      日期 Date: 20190929

班次 Order: 1

Article Name物品名称	Lot No.生产批号	Specification规格/型号	CTN/NO;箱数	Quantity数量
Saniderm PU ROLL	053812105	4inX8yd roll	30	
Saniderm PU ROLL	053812105	6inX8yd roll	30	
Saniderm PU dressing	053812105	6inX8in	24	
Saniderm PU dressing	053812105	8inX10in	16	
Saniderm PU ROLL	053812105	10.2inX2yd roll	234	

生产确认	
加药者:	李明华
操作者:	李明华
灭菌主管:	杨洋
品管确认	
质检员:	宋艳
品管部经理:	王继华
确认结果	
验收	<input checked="" type="checkbox"/> 合格 <input type="checkbox"/> 不合格 <input type="checkbox"/> 特定

Process Parameters过程参数	Setting Value 设定值	Actual Value 实际值				Requirement要求		Pass/Fail 合格/不合格
		Min:		Max:		min最小值	max最大值	
Preconditioning Temperature (°C)预处理温度	50.0	Min: 52.7		Max: 54.2		40.0	60.0	Pass
Preconditioning Humidity预处理湿度	—	Min: 47.6		Max: 92.2		0.0	99.0	Pass
Preconditioning Time(KPa)预处理时间	—	55				30.0	150.0	Pass
Vaccum value (KPa)预真空度	-60.0	-60				-61.0	-59.0	Pass
Leak test time(min)泄漏测试时间	5.0	5				1	10	Pass
Pressure change at end of leak test (KPa)泄漏压力值	—	0.2				0.0	3.0	Pass
Pressure change at end of steam injection (KPa)加湿后压力变化值	1.5	1.1		前:-59.7后:-58.6		0.5	3.0	Pass
Pressure change at end of EO injection (KPa)加EO后压力变化值	99.0	90.0		前:-59.0后:31.0		0.0	150.0	Pass
EO weight injected(Kg)加EO量	—					0.0	130.0	Pass
Temperature (T1) during EO exposure(°C)灭菌阶段柜体温度	50.0	Min: 49.6		Max: 51.9		40.0	60.0	Pass
Humidity (RH) during EO exposure(% RH)灭菌阶段柜体湿度	—	Min: 62.7		Max: 75.9		0.0	99.0	Pass
Pressure (P1) during EO exposure (Kpa) 灭菌阶段柜体压力	—	Min: 26.0		Max: 31.0		—	—	Pass
EO dwell (min)灭菌时间	480	481				478	482	Pass
Numbers of air washes空气冲洗次数	4	4				1	5	Pass

Sterilization Process 灭菌过程	Start time 开始时间	End time 结束时间	Time elapsed(min) 耗时
Heating加热	2019/9/29 13:07	2019/9/29 13:08	1
Precondition 预处理	2019/9/29 13:08	2019/9/29 14:03	55
Pre-vacuum初始真空	2019/9/29 14:03	2019/9/29 14:11	8
leak test泄漏检测	2019/9/29 14:11	2019/9/29 14:16	5
steam injection加湿	2019/9/29 14:16	2019/9/29 14:19	3
EO injection加药	2019/9/29 14:19	2019/9/29 15:14	55
EO dwell灭菌	2019/9/29 15:14	2019/9/29 23:15	481
EO Removal EO移除	2019/9/29 23:15	2019/9/29 23:29	14
air washing 空气清洗	2019/9/29 23:29	2019/9/30 0:21	52
flushing通风	2019/9/30 0:21	2019/9/30 1:02	41

# 山东东华医疗科技股份有限公司

## 环氧乙烷灭菌过程记录 Ethylene Oxide Sterilization Process Record

灭菌机编号 Sterilizer: SC050160      灭菌批号 Sterilization Batch: 20190925      日期 Date: 20190925

班次 Order: 1

Article Name物品名称	Lot No.生产批号	Specification规格/型号	CTN/NO;箱数	Quantity数量
Saniderm PU ROLL	053812105	10.2inX8yd roll	431	

生产确认	
加药者:	李明华
操作者:	李明华
灭菌主管:	杨泽
品管确认	
质检员:	宋艳
品管部经理:	王继华
确认结果	
验收	<input checked="" type="checkbox"/> 合格 <input type="checkbox"/> 不合格 <input type="checkbox"/> 待定

Process Parameters过程参数	Setting Value 设定值	Actual Value 实际值				Requirement要求		Pass/Fail 合格/不合格
		Min	Max	min最小值	max最大值			
Preconditioning Temperature (°C)预处理温度	50.0	Min: 52.3	Max: 54.2	40.0	60.0	Pass		
Preconditioning Humidity预处理湿度	—	Min: 48.3	Max: 65.3	0.0	99.0	Pass		
Preconditioning Time(KPa)预处理时间	—	57		30.0	150.0	Pass		
Vaccum value (KPa)预真空度	-60.0	-60		-61.0	-59.0	Pass		
Leak test time(min)泄漏测试时间	5.0	5		1	10	Pass		
Pressure change at end of leak test (KPa)泄漏压力值	—	0.2		0.0	3.0	Pass		
Pressure change at end of steam injection (KPa)加湿后压力变化值	1.5	1.0	前:-59.8后:-58.8	0.5	3.0	Pass		
Pressure change at end of EO injection (KPa)加EO后压力变化值	99.0	89.8	前:-59.1后:30.7	0.0	150.0	Pass		
EO weight injected(Kg)加EO量	—			0.0	130.0	Pass		
Temperature (T1) during EO exposure(°C)灭菌阶段柜体温度	50.0	Min: 49.9	Max: 51.0	40.0	60.0	Pass		
Humidity (RH) during EO exposure(% RH)灭菌阶段柜体湿度	—	Min: 60.3	Max: 72.9	0.0	99.0	Pass		
Pressure (P1) during EO exposure (Kpa) 灭菌阶段柜体压力	—	Min: 24.5	Max: 30.7	—	—	Pass		
EO dwell (min)灭菌时间	480	480		478	482	Pass		
Numbers of air washes空气冲洗次数	4	4		1	5	Pass		

Sterilization Process 灭菌过程	Start time 开始时间	End time 结束时间	Time elapsed(min) 耗时
Heating加热	2019/9/25 13:06	2019/9/25 13:07	1
Precondition 预处理	2019/9/25 13:07	2019/9/25 14:04	57
Pre-vacuum初始真空	2019/9/25 14:04	2019/9/25 14:12	8
leak test泄漏检测	2019/9/25 14:12	2019/9/25 14:17	5
steam injection加湿	2019/9/25 14:17	2019/9/25 14:19	2
EO injection加药	2019/9/25 14:19	2019/9/25 15:29	70
EO dwell灭菌	2019/9/25 15:29	2019/9/25 23:29	480
EO Removal EO移除	2019/9/25 23:29	2019/9/25 23:43	14
air washing 空气清洗	2019/9/25 23:43	2019/9/26 0:34	51
flushing通风	2019/9/26 0:34	2019/9/26 1:15	41

# 山东东华医疗科技股份有限公司

## 环氧乙烷灭菌过程记录 Ethylene Oxide Sterilization Process Record

灭菌机编号 Sterilizer: SC050165      灭菌批号 Sterilization Batch: 20190930      日期 Date: 20190930      班次 Order: 1

Article Name物品名称	Lot No.生产批号	Specification规格/型号	CTN/NO;箱数	Quantity数量
Saniderm PU ROLL	053812105	8inX8yd roll	480	

生产确认	
加药者:	李明华
操作者:	李明华
灭菌主管:	杨泽
品管确认	
质检员:	宋艳
品管部经理:	王继华
确认结果	
验收	<input checked="" type="checkbox"/> 合格 <input type="checkbox"/> 不合格 <input type="checkbox"/> 特定

Process Parameters过程参数	Setting Value 设定值	Actual Value 实际值		Requirement要求		Pass/Fail 合格/不合格
		Min	Max	min最小值	max最大值	
Preconditioning Temperature (°C)预处理温度	50.0	Min: 50.4	Max: 52.6	40.0	60.0	Pass
Preconditioning Humidity预处理湿度	—	Min: 44.8	Max: 83.9	0.0	99.0	Pass
Preconditioning Time(KPa)预处理时间	—	71		30.0	150.0	Pass
Vaccum value (KPa)预真空度	-60.0	-60		-61.0	-59.0	Pass
Leak test time(min)泄漏测试时间	5.0	5		1	10	Pass
Pressure change at end of leak test (KPa)泄漏压力值	—	0.3		0.0	3.0	Pass
Pressure change at end of steam injection (KPa)加湿后压力变化值	1.5	1.2	前:-59.7后:-58.5	0.5	3.0	Pass
Pressure change at end of EO injection (KPa)加EO后压力变化值	99.0	92.4	前:-58.9后:33.5	0.0	150.0	Pass
EO weight injected(Kg)加EO量	—	—		0.0	130.0	Pass
Temperature (T1) during EO exposure(°C)灭菌阶段柜体温度	50.0	Min: 49.9	Max: 51.5	40.0	60.0	Pass
Humidity (RH) during EO exposure(% RH)灭菌阶段柜体湿度	—	Min: 60.3	Max: 73.6	0.0	99.0	Pass
Pressure (P1) during EO exposure (Kpa) 灭菌阶段柜体压力	—	Min: 26.2	Max: 33.5	—	—	Pass
EO dwell (min)灭菌时间	480	480		478	482	Pass
Numbers of air washes空气冲洗次数	4	4		1	5	Pass

Sterilization Process 灭菌过程	Start time 开始时间	End time 结束时间	Time elapsed(min) 耗时
Heating加热	2019/9/30 16:09	2019/9/30 16:10	1
Precondition 预处理	2019/9/30 16:10	2019/9/30 17:21	71
Pre-vacuum初始真空	2019/9/30 17:21	2019/9/30 17:29	8
leak test泄漏检测	2019/9/30 17:29	2019/9/30 17:34	5
steam injection加湿	2019/9/30 17:34	2019/9/30 17:37	3
EO injection加药	2019/9/30 17:37	2019/9/30 18:14	37
EO dwell灭菌	2019/9/30 18:14	2019/10/1 2:14	480
EO Removal EO移除	2019/10/1 2:14	2019/10/1 2:28	14
air washing 空气清洗	2019/10/1 2:28	2019/10/1 3:20	52
flushing通风	2019/10/1 3:20	2019/10/1 4:01	41