

环氧乙烷灭菌报告 (工艺参数)

EO Sterilization Examining Report

客户名称 Customer name: COSMY
产品名称 Product Name: 一次性使用换药包 Disposable dressing set
产品批号 Lot number: FJ2023041701/MJ2023041102
产品数量 Quantity: 66 箱
灭菌方式 Sterilization method: EO 气体灭菌 EO gas sterilization
灭菌日期 Sterilization date: 2022.12.29
灭菌批号 Sterilization lot number: 20221229-237B
设备编号 equipment number: ZHYK-SB-237B

入柜最小启动温度 22℃。当产品温度低于 22℃，开始柜内预热。产品温度 $\leq 0^{\circ}\text{C}$ ，预热 7h； $10^{\circ}\text{C} \geq$ 产品温度 $> 0^{\circ}\text{C}$ 时，预热 6h； $22^{\circ}\text{C} >$ 产品温度 $> 10^{\circ}\text{C}$ 时，预热 4h。
The minimum start temperature into the cabinet is 22℃. When the product temperature is below 22℃, start preheating in the cabinet. Product temperature $\leq 0^{\circ}\text{C}$, preheating 7h; $10^{\circ}\text{C} \geq$ product temperature $> 0^{\circ}\text{C}$, preheating 6h; $22^{\circ}\text{C} >$ product temperature $> 10^{\circ}\text{C}$, preheating 4h.

灭菌 Sterilization

灭菌参数 Sterilization parameters	设定值 Set value	允许偏差 Allowable deviation	实际值 Actual value
保温温度 (℃) Holding temperature (℃)	50	± 5	51
保温时间 (min) Holding time (min)	≥ 60	/	60
预真空 (kPa) forevacuum (kPa)	-15	± 2	-15
真空速率 (kPa/min) Vacuum Rates (kPa / min)	≤ 4.0	/	1.5
保压时间 (min) Pressure holding time (min)	10	± 1	10
灭菌湿度 (%RH) Sterilization humidity (% RH)	30-80	/	52
灭菌剂加入量 (Kpa) Sterilizer-added amount (Kpa)	13	± 1	12.83
灭菌温度 (℃) Sterilization temperature (℃)	50	± 5	52
灭菌时间 (min) Sterilization time (min)	480	± 1	480

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HUNAN YONGLING MEDICAL INSTRUMENT CO.,LTD
YL-ZG-145

置换真空度 (kPa) Displacement Vacuum Degree (kPa)	-15	±2	-15				
换气次数 (Times) Aeration times	≥4	/	5				
通风时间 (min) Ventilation time	60	/	60				
微生物种类 Species of microorganisms	萎缩芽孢杆菌 ATCC9372 Bacillus atrophy ATCC9372		芽孢含量 (cfu/unit) Spore content (cfu / unit) 1.8×10 ⁶				
BI 批号 BI lot number	20221020		D 值 (min) D value (min) 2.9				
培养温度 Cultivate temperature	30-35℃		培养时间 (days) Culture time (days) 7				
培养时间 incubation time	2023.01.03-2023.01.11						
培养时间 (day) Culture time (day)	1 st	2 nd	3 rd	4 th	5 th	6 th	7 th
观察记录 Record of observation	-	-	-	-	-	-	-
阳性对照 positive control	+	+	+	+	+	+	+
生物指示物无菌试验结果 Results of the sterility test for the biological indicators	<input checked="" type="checkbox"/> 合格 Qualified <input type="checkbox"/> 不合格 Unqualified						
<p>结论：以上产品进行常规环氧乙烷灭菌，各项灭菌参数合格，无菌水平 10⁻⁶ 得到保证，产品允许放行。 Conclusion: The above products are sterilized by conventional ethylene oxide, all sterilization parameters are qualified, the sterility level of 10⁻⁶ is guaranteed, and the products are allowed to release.</p>							

批准 Approve by:

报告日期 report date:

盖章 seal: