

| | | | |
|-------------------------------|-----------------------------------------------|----------------------|----------------|
| 环乙灭菌® HUANYI STERILIZATION | 环氧乙烷灭菌报告 Certification of EO Sterilization | 文件编号 Doc. No. | HYST/QR2-25-06 |
| | | 版本编号 Version No.: | 0/B |
| | | 生效日期 Effective date: | 2021-04-05 |

报告编号 Report no.: 2023083014

| | | | | | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|--------------------------|-------------|-------|------------|--------|
| 客户 Customer | 兰溪市卫尔棉签有限公司 | | | | | |
| 产品名称 Product name | 规格 Specification | 批号 Batch | 数量 Quantity | | | |
| Cotton tip Applicator | 7.5cm | G09NB | 120 箱 | | | |
| Sampling Swab | 15cmPP 杆 | 20230512 | 20 箱 | | | |
| Sampling Swab | 15cm 木杆 | 20230512 | 44 箱 | | | |
| 80 支涂液棉签 | 10cm | 20230720 | 32 箱 | | | |
| 灭菌方式 Sterilization mode | 环氧乙烷 EO gas | 灭菌柜编号 Sterilizer no. | HYST/ST-02 | | | |
| 灭菌日期 Sterilization date | 2023-8-21 | 灭菌批号 Sterilization batch | 2023082102A | | | |
| 灭菌参数 Sterilization parameters | 单位 Unit | 要求 Requirements | | | 实际值 Actual | |
| | | 设定 Validated | Min. | Max. | Min. | Max. |
| 产品进入预处理前温度 Loading tem. prior to preconditioning | ℃ | ≥10.0 | 10.0 | / | 32.5 | |
| 预处理温度 Preconditioning temperature | ℃ | 48.0 | 44.0 | 52.0 | 48.0 | 49.9 |
| 预处理湿度 Preconditioning RH | %RH | 55.0 | 30.0 | 80.0 | 49.0 | 64.9 |
| 预处理时间 Preconditioning time | Minute | 360 | 340 | 380 | 360 | |
| 转移时间 Transfer time | Minute | ≤60 | / | 60 | / | |
| 预真空 Initial evacuation depth | kPa | -37.0 | -39.0 | -35.0 | -37.2 | |
| 抽空速率 Evacuation rate | kPa/min | ≤4.0 | / | 4.0 | 1.3 | |
| 保压时间 Pressure holding time | Minute | 20 | 10 | 30 | 20 | |
| 保压压力变化 Leak test pressure rise ΔP | kPa | ≤1.4 | / | 1.4 | 0.6 | |
| 湿气注入时间 (若适用) Moisture injection time (if used) | Minute | 10 | 10 | / | / | |
| EO 导入速率 EO injection rate | kPa/min | 0.5 | 0.3 | 0.7 | 0.7 | |
| 灭菌剂重量 EO Injection weight | kg | 19.0 | 18.5 | 19.5 | 18.9 | |
| EO 导入后压力变化值 Pressure rising after EO injection ΔP | kPa | ≥31.0 | 31.0 | / | S:-36.6 | E:-0.7 |
| | | | | | ΔP:35.9 | |
| EO 浓度 EO concentration commence of exposure (theorical) | mg/l | 600 | 400 | 800 | 585 | |
| 灭菌温度 Exposure temperature | ℃ | 52.0 | 49.0 | 55.0 | 51.9 | 53.6 |
| 灭菌湿度 Exposure RH | %RH | 55.0 | 30.0 | 80.0 | 52.9 | 68.2 |
| 灭菌时间 Exposure time | Minute | 720 | 700 | 740 | 720 | |
| 换气真空度 Post-evacuation depth | kPa | -25.0 | -27.0 | -23.0 | -25.1 | -24.9 |
| 充气压力 Inflation pressure | kPa | -5.0 | -7.0 | -3.0 | -5.1 | -5.0 |
| 换气次数 Number of repetition | Times | ≥6.0 | 6 | / | 6 | |
| 换气时间 Duration of flushing | Minute | 150 | 120 | 180 | 152 | |
| BI 无菌试验结果 BI test of sterility | <input checked="" type="checkbox"/> 合格 Conformity; <input type="checkbox"/> 不合格 non-conformity. | | | | | |
| 结论 Conclusion: 灭菌过程参数和 BI 无菌检测符合 ISO 11135:2014 和确认要求, 产品 SAL(10 ⁻⁶)得到证实, 灭菌过程允许放行。 Above all, sterilization process and BI sterility testing are meeting with EN ISO 11135:2014 and validated requirements, and Sterile Assurance Level (SAL) of 10 ⁻⁶ is achieved and products can be released from sterilization process. | | | | | | |

编制 Preparator: 陈李明

日期 Date: 2023.8.30

批准 Approval(QA): 陈李明

日期 Date: 2023.8.30



浙江环乙灭菌技术有限公司 (章)
Zhejiang Huanyi Sterilization Technology Co., Ltd. (stamp)