



报告编号 Certificate No: (2023) W 10073



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苏州市信义检测技术研究有限公司
Suzhou Xinyi Inspection Technology Research Co., Ltd.

检测证书 Test certificate

委托单位 Consignor	奥力拓医用包装材料（苏州）有限公司 Oliver Healthcare Packaging (Suzhou) Co., Ltd.
通讯地址 Address	苏州市漕湖街道春耀路 27 号 NO. 27 Chun Yao Road, Caohu Street, Suzhou
洁净区名称 Sample name	XC CR2 洁净室 XC CR2 Cleanroom
洁净室名称 Sample specification	生产洁净室 CR2 Production Cleanroom CR2 (ISO Class 7/ 10,000) 包装缓冲间 CR2 Packing Buffer Room CR2 (ISO Class 7/ 10,000)
依据标准 Test standard	1. 洁净室及相关受控环境，第 1 部分：粒子浓度的空气洁净度分级 ISO 14644-1: 2015 Cleanrooms and associated controlled environments Part 1: Classification of air cleanliness by particle concentration 2. 无菌医疗器械生产管理规范 YY/T 0033-2000 Good manufacture practice for sterile medical devices
检测结论 Conclusion	现场经测试，上述指定区域符合 14644-1: 2015 和 YY/T 0033: 2000 的 标准要求。空气洁净度符合 (ISO 7 级) 的验收标准。 As per guidelines of ISO 14644-1:2015 & YY/T 0033:2000, the designated areas listed above have met the acceptance criteria for Air Cleanliness, ISO Class 7 under At Operational Condition.

审核
Authorized by

职务
Position

总工程师
Chief Engineer

检测日期
Test date
有效期
Cal due to

2023.10.07
2024.10.06



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