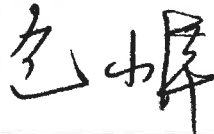


苏州市信义检测技术研究有限公司  
Suzhou Xinyi Inspection Technology Research Co., Ltd.

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

2025.09.16  
2026.09.15



地址: 苏州工业园区苏虹东路 188 号方正产业园 B 栋 307 单元  
Address: No. 188, Suhong East Road, Founder Industrial Park Blk B#307, SIP

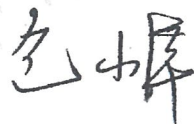
电话 Tel: 0512-62931371  
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苏州市信义检测技术研究有限公司  
Suzhou Xinyi Inspection Technology Research Co., Ltd.

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 CR1 洁净室 XC CR1 Cleanroom
洁净室名称 Sample specification	包装缓冲间 CR1 Packaging Buffer Room CR1 (ISO Class 7/ 10,000) 生产洁净室 CR1 Production Cleanroom CR1 (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) 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  
Verified



职务  
Position

总工程师  
Chief Engineer



检测日期  
Test date  
2026.01.08  
有效期  
Cal due to  
2027.01.07