



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	苏州相城开发区春耀路 27 号 27 Chunyao Road, Xiangcheng District, Suzhou, Jiangsu, P.R. China	
洁净区名称 Sample name	洁净室 Clean room	
洁净室名称 Sample specification	更衣室 2 Gowning room 2	(ISO Class 7/ 10,000)
	缓冲室 Buffer room	(ISO Class 7/ 10,000)
	生产洁净室 Production clean room	(ISO Class 7/ 10,000)
	物料缓冲间 Material buffer room	(ISO Class 7/ 10,000)
	物料/工具间 Material/Tooling room	(ISO Class 8/ 100,000)
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 ISO14644-1: 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 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 0033: 2000 的标准要求。空气洁净度符合 (ISO 7/ISO 8 级) 的验收标准。 As per guidelines of ISO 14644-1:2015 & YY 0033:2000, the designated areas listed above have met the acceptance criteria for Air Cleanliness, ISO Class 7/ISO Class 8 under At Operational Condition.	

审核
Authorized by

职务
Position

总工程师
Chief Engineer



检测日期
Test date 2020.11.09
有效期
Cal due to 2021.11.08