

CERTIFICATE OF CONFORMANCE

产品合格证明

BASIC INFORMATION 基本信息

PRODUCT NAME 产品名称	血清移液管 Serological Pipet	BRAND 品牌	LUXCELL
MANUFACTURER 制造商	上海乐赛生物科技有限公司	DOWNLOAD 下载	www.luxcellsci.com

PRODUCT INFORMATION 产品信息

ITEM# 产品编号	MODEL 规格型号	PACKING SPECIFICATION 包装规格
404050	50ml	无菌, 单只吸塑包装 50支/包, 4包/箱
LOT # 批号	MFG. 生产日期	EXP. 有效期
W211208	20220108	20250108

INSPECTION AND TESTING RESULT 检测结果

TYPE OF TESTING 检测类型	REQUIREMENTS 要求	RESULT 结果
PACKING 包装	按内部检验文件要求	PASS
VISUAL 外观		PASS
PERFORMANCE 性能		PASS
BACTERIAL ENDOTOXIN 细菌内毒素	≤0.5EU/ML	PASS
CYTOTOXICITY 细胞毒性	无细胞毒性反应	PASS
DNASE&RNASE DNA 酶和 RNA 酶	无 DNA 酶和 RNA 酶	PASS

CERTIFICATION STATEMENT 证书声明



This hereby certifies that the part(s) identified above is manufactured and/or distributed according to the requirements of product and quality specifications as maintained in our quality system which is compliant to ISO 13485:2016.

特此证明以上产品批次是按照符合 ISO 13485:2016 质量体系的产品和质量规范要求制造和/或分销的。

Product has been sterilized by Gamma irradiation and dosimetrically released per the requirements of ANSI/AAMI/ISO 11137, "Sterilization of health care products- Radiation". Products meet a minimum Sterility Assurance Level (SAL) of 10⁻⁶.

产品经过伽玛辐射灭菌, 并按照 ANSI/AAMI/ISO 11137 “卫生保健产品的灭菌-辐射”的要求进行剂量释放。产品满足最低无菌保证水平(SAL) 10⁻⁶。

APPROVAL 批准

QUALITY APPROVAL 质量批准	张芳 PRINT NAME 正楷姓名	 SIGNATURE 签名	 2022-12-18 ISSUE DATE 签发日期
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