SICHUAN NIGALE BIOTECHNOLOGY Co., Ltd.
四川南格尔生物科技有限公司

Product Certification
产品报告

Quality record number：JL-ZL-342-02
质量记录编号：JL-ZL-342-02

1.Product information
1.产品信息

Ref Number 货号		Product Name 产品名称	Disposable Plasma Apheresis Set 一次性使用单采血浆分离器
Lot Number 生产批号	P-4117 240928	Date of Manufacture 生产日期	28/09/2024
Model Number 型号	P-4117	Sterile Load Number 灭菌批号	240928 2
Product description 产品描述	Bowl■ / Tubing■ / Bag■ / Bottle□ / Needle□ 分离杯/血浆管路/血浆收集袋/血浆收集瓶/静脉穿刺器		
Date of Sterilization 灭菌日期	28/09/2024	Quantity 数量	5038
Expiration Date 有效期至	27/09/2028	Type of Sterilization 灭菌方法	EO

2.Test
2.测试

Control and Tests 检验项目	Reference 检验方法	Acceptable Limits 可接受限度	Results 检验结果
Physical Tests 物理性能	ISO3826-1:2019 + Internal Methods	Must be within the limits indicated for each Test 必须在每项测试规定的限制范围内	PASS
Leakage controls 密封性	ISO3826-1:2019 + Internal Methods	No leakage is allowed on visual inspection 目视检查不允许有泄漏	PASS
Tensile strength of line Connectors 强度	ISO3826-1:2019 + Internal Methods	Must resist a pull force of 20 N for 15 s. 必须承受 20N 的拉力，持续 15 秒	PASS
LAL-Test 细菌内毒素	EP 2.6.14 2018:20614 Method A	＜0.5IU/ml 小于 0.5EU/ml	PASS
Sterility Test 无菌	EP 2.6.1 2011:20601 EP 5.1.2 2017:50102 4-1-1. Ethylene oxide sterilization ATCC 9372	Must be sterile 应无菌生长	STERILE
Water-soluble extracts 水溶出物	EP 3.3.5 2020:30305	Must be within the limits indicated for each Test 必须在每项测试规定的限制范围内	PASS
Residual EO 环氧乙烷残留量	EP 2.2.28 2023:20228	Must be within the limits indicated for each Test 必须在每项测试规定的限制范围内	PASS

2.1.Nigale sterile disposables are manufactured from materials tested and certified to be safe for use in short duration (less than 24 hours) circulating blood contact applications. Fluid path materials meet European Pharmacopoeia standards and meet the requirements for biocompatibility and biological safety.

2.2. Physical Testing

The standards of the NMPA Good Manufacturing Practices are met. PVC tubing and bags correspond to EP/DAB VI 1.2.1.1 and VI 2.2.2.2.

2.3. Sterility and Pyrogenicity

The product is sterile and pyrogen-free. It meets the requirements of EP. The sterilization process has been validated following EN ISO 11737.2-2020 Guidelines.
Nigale, hereby, certifies that the listed batch meets all above mentioned requirements and all Nigale defined requirements for performance, safety, sterility and pyrogenicity.

I certify that appropriate controls are in place to assure records are reviewed prior to release of product for distribution and that the authorization to release products for distribution is limited and controlled. The above products are according to 93/42/EEC.

检验专用章 (1)

Name 姓名: He Jun 何军 Title 职务: QC Manager Date 日期: October 16, 2024

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