NIGALE

SICHUAN NIGALE BIOTECHNOLOGY Co., Ltd.

Product Certification

Quality record number: JL-ZL-342-03

1.Product information

Ref Number		Product Name	Disposable Plasma Apheresis Set
Lot Number	4117250917	Date of Manufacture	17/09/2025
Model Number	P-4117	Sterile Load Number	2509174 2509175 2509176
Product description	Bowl■ / Tubing■ / Bag■ / Bottle□ / Needle□		
Date of Sterilization	17/09/2025	Quantity	20046
Expiration Date	16/09/2029	Type of Sterilization	EO

2.Test

Control and Tests	Reference	Acceptable Limits	Results
Physical Tests	ISO3826-1:2019 + Internal Methods	Must be within the limits indicated for each Test	PASS
Leakage controls	ISO3826-1:2019 + Internal Methods	No leakage is allowed on visual inspection	PASS
Tensile strength of line Connectors	ISO3826-1:2019 + Internal Methods	Must resist a pull force of 20 N for 15 s.	PASS
LAL-Test	EP 2.6.14 2018:20614 Method A	＜0.5IU/ml	PASS
Sterility Test	EP 2.6.1 2011:20601 EP 5.1.2 2017:50102 4-1-1. Ethylene oxide sterilization ATCC 9372	Must be sterile	PASS
Water-soluble extracts	EP 3.3.5 2020:30305	Must be within the limits indicated for each Test	PASS
Residual EO	EP 2.2.28 2023:20228	Must be within the limits indicated for each Test	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.

四川南格尔生物科技有限公司 检验专用章

Name: He Jun Title: QC Manager Date: (1) September 29, 2025

Add: No. 28 Kuixing Road, Jianyang, Sichuan, P.R. China, 641400
Fax: +86 2885195886
Tel: +86 28 85130655