



Product Certification

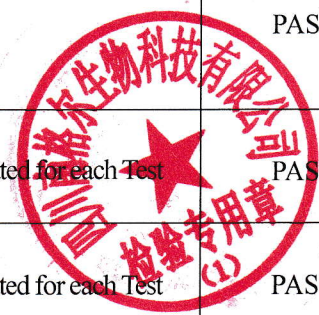
Quality record number: JL-ZL-342-03

1. Product information

| | | | |
|-----------------------|--|-----------------------|---------------------------------|
| Ref Number | ASN00P4217 | Product Name | Disposable Plasma Apheresis Set |
| Lot Number | 4217250801 | Date of Manufacture | 01/08/2025 |
| Model Number | P-4217 | Sterile Load Number | 2508012 2508015 2508016 |
| Product description | Bowl■ / Tubing■ / Bag■ / Bottle□ / Needle□ | | |
| Date of Sterilization | 01/08/2025 | Quantity | 20046 |
| Expiration Date | 31/07/2029 | 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.



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