



Disposable Plasma Apheresis Set

Instruction

【Product name】 Disposable Plasma Apheresis Set

【Specification】 P-1000B1、P-1000B2、P-1000B3、P-3000、P-3001、P-4004、P-4007、P-4009、P-4011、P-4013、P-4014、P-4017、P-4117、P-4018、P-4019、P-4319、P-4021、P-4023、P-4025、P-4026、P-4027、P-4028、P-4217、P-5000、P-6000、P-6001、P-6002、P-6003、P-6004、P-6005、P-6006。

【Name of registrant】 Sichuan Nigale Biotechnology Co.,Ltd.

【Residence of registrant】 No.28 Kuixing Road, Dongxi Town, Jianyang City

【Registrant's after-sales service unit】 Sichuan Nigale Biotechnology Co.,Ltd.

【Registrant's contact information】 Hotline: 400-606-9696

Fax: 028-27091757 Zip code: 641400 Website: <http://www.ngl-cn.com>

【Name of manufacturer】 Sichuan Nigale Biotechnology Co.,Ltd.

【Residence of manufacturer】 No.28 Kuixing Road, Dongxi Town, Jianyang City

【Production address of manufacturer】 No.28 Kuixing Road, Dongxi Town, Jianyang City, Sichuan

【Contact information of manufacturer】 Hotline: 400-606-9696

Fax: 028-27091757 Zip code: 641400 Website: <http://www.ngl-cn.com>

【Production license number】

Sichuan Food Pharmaceutical Supervision Equipment Production License No. 20160004

【Number of medical device registration certificate】 20183451761

【Product technical requirement number】 20183451761

【Product performance and application】 It is suitable for separating the plasma together with plasma separator. It mainly applies for blood component separator which is driven by Bowl Technology. It can realize the collection of blood as well as the separating of plasma and erythrocyte.

【Main structure composition of product】 The product is composed of all or part of those parts: Separating bowl, plasma tubes, venous needle, bag/bottle (plasma collection bag/bottle, transfer bag, mixed bag, and waste liquid bag).

【Product installation and use instructions】

1. Install the disposable plasma apheresis set into the separator according to the installation steps of the supporting equipment.
2. Use the equipment correctly according to the operation manual.
3. After use, it should be handled according to the specific requirements of users.

【Taboos】 N/A

【Cautions】

- This product is sterilized by ethylene oxide. It is sterilized, pyrogen-free. It is not used repeatedly and must be destroyed after use.
- Careful inspection must be carried out before use. Packaging damage and parts falling off are prohibited.
- Please use before the valid date.

【Warnings and prompts】

- This product is not suitable for children, newborns, premature infants and other minors and low blood volume population.
- This set is made from medical PVC material in which DEHP is used as a plasticizer.
- The use of this product must conform to the requirements of relevant operational norms and relevant regulations of the medical department, and is limited to the use of specially trained medical personnel.

【Product maintenance】 This product is for one-time use only.

【Storage and transportation】 The product should be stored in the temperatures 5°C~40°C and relative humidity < 80%, no corrosive gas, good ventilation and clean indoors. It should avoid rain, snow, direct sunshine and heavy pressure. This product can be transported by general means of transport or by ways confirmed by a contract. It should not be mixed with toxic, harmful and volatile substances. It should avoid rain and snow drench, direct sunshine and heavy pressure. The suitable climate conditions are -20°C~50°C, and the relative humidity is less than 90%.

【Date of manufacture】 Shown on the inner package.

【Expiration date】 Shown on the inner package.

【Spare parts list】 No

【Symbolic explanation】



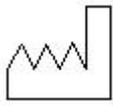
Ethylene Oxide Sterilization



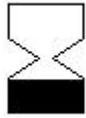
Disposable



Batch No.



Mfg. Date



Exp. Date



Code No.



Precautions



Manufacturer



Representative Authorized by EU



Presence of phthalate

Date of preparation or revision: Nov. 05, 2019