



Sichuan Nigale Biotechnology Co., Ltd.

Declaration of Conformity

Manufacturer: Sichuan Nigale Biotechnology Co., Ltd.

No.28 Kuixing Road, 641400 Jianyang, Sichuan, PEOPLE'S REPUBLIC OF CHINA

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)

Eiffestrasse 80, 20537 Hamburg, GERMANY

Product Name: Disposable Plasma Apheresis set

Model Number: 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.

UMDNS Code: 16901

NBOG Code: MD0102

Classification (MDD, Annex IX): II a, rule3

Conformity Assessment Route: Annex III.1

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for this DoC.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 5 September 2007

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany

NB Identification number: 0123

(EC) Certificate(s): G1 067972 0007 Rev.02

Expire date of the Certificate: 2024-05-26

Start of CE Marking: 091103

Place, Date of Issue: Jianyang, 2021-05-27

Signature: Liu Nanjian

Name: Liu nanjian

Position: General Manager



Introduction of product

1 Company Introduction

Sichuan Nigale Biotechnology Co., Ltd. was jointly established in September 1994 by Sichuan Academy of Medical Science and its affiliated hospital in Jianyang. At present, its headquarters is located in Chengdu High-tech Development Zone. While the production base of medical disposable product is located in Jianyang. Beijing Nigale as its fully-owned subsidiary company which is responsible for running oversea business and international co-operation is located Beijing. Today's Nigale has grown into a national leader in the manufacturing, selling and services of blood processing systems in China.

2 Introduction of product

Together with plasma collector, the disposable apheresis set is used for separating, collecting and returning blood cell. Using computer technology, peristaltic pump without pollution when transporting and blood apheresis technology. It collects whole blood into bowl by pump. Due to the different density, blood components is separated in centrifugal machine by high rolling to get high-quality plasma. And it ensures other components isn't destroyed and returned to donors. The disposable plasma apheresis set is disposable sterile consumables for plasma collection machines produced by Sichuan Nigale Biotechnology Co., Ltd. and Haemonetics's PCS2.

The disposable plasma apheresis set is mainly composed of centrifugal bowl, tubing system (incl. blood filter and DPM), needle set and collecting bag (bottle). See the following table for specifications and models. The needle tube is dorsal pore. The needle handle is double-vane. The type of needle is 16G. There is relevant protecting jacket or bacteria filtering devices in each mouth of the product.

Model Number	REF	Structure Introduction
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P-3000	ASN00P3000	Bowl part: bowl Tubing part: tubing, AC line with spike Needle part: needle set Bag part: one(1) x 1000ml collection bag
P-1000B1、 P-1000B2、 P-1000B3	ASNP1000B1 ASNP1000B2 ASNP1000B3	Bowl part: bowl Tubing part: tubing, saline line with spike Bag part: mixed bag, collection bag, waste bag
P-3001	ASN00P3001	Bowl part: bowl Tubing part: tubing, AC line with spike Needle part: needle set Bag part: saline line with spike, one(1) x 1000ml collection bag
P-4004	ASN00P4004	Bowl part: bowl Tubing part: tubing with luer lock connection, AC line with spike Bag part: one(1) x1200ml collection bag with clamp
P-4007	ASN00P4007	Bowl part: bowl Tubing part: tubing with luer lock connection, AC line with spike Bag part: one(1) x 1200ml collection bag with two transfusion ports, saline line with spike, air filter, Vacutainer
P-4009	ASN00P4009	Bowl part: bowl Tubing part: tubing with luer lock connection , Vacutainer, AC line with spike Bag part: one(1) x 1000ml collection bag with two transfusion ports, saline line with spike
P-4011	ASN00P4011	Bowl part: bowl Tubing part: tubing, AC line with spike Needle part: needle set Bag part: two(2) x 1200ml collection bags with two transfusion ports and luer lock connection, saline line



		with spike
P-4013	ASN00P4013	Bowl part: bowl Tubing part: tubing with luer lock connection , Vacutainer, AC line with spike Bag part: one(1)×1000ml collection bag with two transfusion ports, two(2)×500ml collection bags with two transfusion ports, saline line with spike
P-4014	ASN00P4014	Bowl part: bowl, Tubing part: tubing with luer lock connection, AC line with spike Bag part: four(4) x1200 ml collection bags, saline line with spike
P-4017	ASN00P4017	Bowl part: bowl Tubing part: tubing with luer lock connection, AC line with spike Bag part: one(1)×1200ml collection bag, air filter, Vacutainer, saline line with spike
P-4117	ASN00P4117	Bowl part: bowl Tubing part: tubing with luer lock connection, AC line with spike Bag part: one(1)×1200ml collection bag, air filter, Vacutainer, saline line with spike
P-4217	ASN00P4217	Bowl part: bowl Tubing part: tubing with luer lock connection, AC line with Luer Lock Bag part: one(1)×1200ml collection bag, air filter, Vacutainer, saline line with spike
P-4018	ASN00P4018	Bowl part: bowl Tubing part: tubing , AC line with spike



		Needle part: needle set Bag part: four(4) x1000ml collection bags, saline line with spike
P-4019	ASN00P4019	Bowl part: bowl Tubing part: tubing with with luer lock connection, sampling bag, Vacutainer, AC line with spike Needle part: Nipro fistula needle with safety device, Bag part: two(2) x 1000ml collection bags with two transfusion ports
P-4319	ASN00P4319	Bowl part: bowl Tubing part: tubing with luer lock connection, sampling bag, Vacutainer, AC line with spike Needle part: Nipro fistula needle with safety device, Bag part: two(2) x 1000ml collection bags with two transfusion ports, saline line with spike
P-4021	ASN00P4021	Bowl part: bowl Tubing part: tubing with luer lock connection, AC line with spike Bag part: one(1) x1200ml collection bag with two transfusion ports, saline line with spike
P-4023	ASN00P4023	Bowl part: bowl Tubing part: tubing with luer lock connection, sampling bag, Vacutainer, AC line with bacterial filter, drop chamber, spike Needle part: Nipro fistula needle with safety device, Bag part: one(1) x 1200ml collection bag with two transfusion ports, three(3) x 600ml storage bags with two transfusion ports, saline line with bacterial filter, spike



P-4025	ASN00P4025	Bowl part: bowl, Tubing part: tubing with luer lock connection, AC line with spike Bag part: one(1) x1200ml collection bag with two transfusion ports
P-4026	ASN00P4026	Bowl part: bowl, Tubing part: tubing with luer lock connection, sampling bag, Vacutainer, AC line with spike Needle part: Nipro fistula needle with safety device, Bag part: one(1) x 1000ml collection bag with two transfusion ports , two(2) x 500ml collection bags with two transfusion ports, saline line with spike
P-4027	ASN00P4027	Bowl part: bowl, Tubing part: tubing , AC line with spike Needle part: Nipro fistula needle with safety device, Bag part: one(1) x 1200ml collection bag, six(6) x 200ml collection bags with one transfusion port, saline line with spike
P-4028	ASN00P4028	Bowl part: bowl, Tubing part: tubing , AC line with spike Needle part: needle set Bag part: six(6) x 1000ml collection bags, saline line with spike
P-5000	ASN00P5000	Bowl part: bowl with one protective jacket Tubing part: tubing with luer lock connection, AC line with spike
P-6000	ASN00P6000	plasma collection bottle, saline line with spike, air filter, Vacutainer
P-6001	ASN00P6001	plasma collection bottle, luer lock connection, air filter, Vacutainer

P-6002	ASN00P6002	bowl
P-6003	ASN00P6003	tubing
P-6004	ASN00P6004	needle set
P-6005	ASN00P6005	plasma collection bottle, saline line with spike, air filter, Vacutainer
P-6006	ASN00P6006	plasma collection bottle, luer lock connection, air filter, Vacutainer

There are two ways of packing 4 components. 1. All of them are packed together and formed an integrated closed system. 2. They are packed separately. Single package is made of polyethylene plastic bag which is pasted medical dialyzing paper. Therefore, it forms an steriler barrier system. The product is assembled in a purifying area which are met ISO 14644-1: 2015 class 8, and then the package is heat healed. The disposable set is sterilized by epoxy ethane, asepsis and pyrogen-free.

The centrifugal bowl isn't delivered with poisonous volatile substance, avoided sleet and sunshine, and prevented weight. The appropriate weather condition is $-20^{\circ}\text{C}\sim 50^{\circ}\text{C}$, relative humidity $<90\%$. The apheresis set is stored in a shady, dry, draftiness and clean room which temperature is $5^{\circ}\text{C}\sim 40^{\circ}\text{C}$ and relative humidity $<80\%$.