ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 067972 0007 Rev. 01

Facility(ies):

Sichuan Nigale Biotechnology Co., Ltd.
No.28 Kuixing Road, 641400 Jianyang, Sichuan, PEOPLE'S REPUBLIC OF CHINA

Sichuan Nigale Biotechnology Co., Ltd.
4th F, No.2 Factory Building, Shiyang Industrial Park, No.55, Section 5th, Qingyun Village, Hi-Tech District, 610041 Chengdu, PEOPLE'S REPUBLIC OF CHINA

Digitally signed by Şarco Alexandru
Date: 2023.06.14 11:43:27 EEST
Reason: MoldSign Signature
Location: Moldova

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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A4 / 07.17

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 067972 0007 Rev. 01

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 Category(ies): **Disposable Plastic Blood Bag,**
Disposable Plasma Apheresis Set,
Disposable Blood Component Apheresis Set,
Disposable Blood Collection and Transfusion Set,
Disposable Blood Bag with In-line Leukoreduced Filter,
Plasma Separator, Blood Component Separator,
Blood Cell Processor

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: SH19517EXT01

Valid from: 2019-07-14
Valid until: 2024-07-13

Date, 2019-05-17

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 067972 0007 Rev. 02

Manufacturer:

Sichuan Nigale Biotechnology Co., Ltd.
No.28 Kuixing Road
641400 Jianyang, Sichuan
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

**Disposable Plastic Blood Bag,Disposable Plasma Apheresis Set,
Disposable Blood Component Apheresis Set,
Disposable Blood Collection and Transfusion Set,
Disposable Blood Bag with In-line Leukoreduced Filter,
Plasma Separator, Blood Component Separator,
Blood Cell Processor**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II.
This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 067972 0007 Rev. 02

Report No.: SH19517EXT01

Valid from: 2021-05-25

Valid until: 2024-05-26

Date, 2021-05-25

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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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): Ⅱa,rule3
Conformity Assessment Route: AnneⅨ 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

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 deliveryed with poisonous volatile substance, avoided sleet and sunshine, and prevented weight.The appropriate weather condition is —20℃～50℃，relative humidity<90%. The apheresis set is stored in a shady, dry, draftiness and clean room which temperature is 5℃～40℃ and relative humidity<80%.

File Name	Declaration of Conformity of the Plasma Separator		
File No.	NGL XJC 2000-CEA-03-01		
Execution Date	2013-11-9		
Distributing Departments	Hospital products division general manager	Equipment production and technology director for hospital products divisionr	Equipment technology department of hospital products division
	Quality department of hospital products division	E. U. Representative	

	Revision No.	Reason and Content	Execution Date
Modified Record	01	Modify the related contents ,according to the latest EC certification requirements of Sichuan Nigale Biological Technology Co., Ltd No.1 Modify the "manufacturer and its address" No.2 Modify the"European representative" No.3Modify the "(EC)Certificate(s) code " No.4 Modify the"expire date of the Certificate"	2014-09-19
	02	Modify the related content: according to the requirements of the latest EC certification to modify the following several aspects. No.1 Modify the manufacturer name No.2Modify the (EC)Certificate(s) code No.3Modify general manager signature	2015-1-11
	03	Modify the related content: according to the requirements of the latest EC certification to modify the following several aspects. No.1 Increase the conformity Declaration No.2 Increase the NBOG Code No.3Modify the (EC)Certificate(s) code No.4Modify general manager signature	2018-1-16
	04	Modify the related content: according to the requirements of the latest EC certification to modify the following several aspects. No.1Modify the (EC)Certificate(s) code No.2Modify general manager signature	2019-6-17
	05	Modify the related content: No.1 (EC)Certificate(s) code No.2 delete "Date of issue"	2019-8-01
	06	Modify Name from Feng Ronghua to Lu Yan	2020-06-10

	07	Modify the related content: No.1Modify the NBOG Code No.2Modify the Conformity Assessment Route No.3Modify the Expire date of the Certificate No.4Modify the Start of CE Marking	2020-10-20
	08	Modify the related content: No.1 (EC)Certificate(s) code No.2 Modify the Start of CE Marking No.3 Modify the Expire date of the Certificate	2021-06-05

Declaration of Conformity of the Plasma Separator

1. Overview

To ensure that the *Declaration of Conformity* of the product with CE-marking is under control, that the product is in accordance with requirements of MDD/93/42/EEC before the release of *Declaration of Conformity*. The company established a control procedure for the product with CE-marking to draw up, sign and submit its *Declaration of Conformity*. The quality department is responsible for drawing up, the management representative guarantees the product is in accordance with MDD93/42/EEC, and the general manager is in charge of signing officially.

2. Assurance of conformity

Before drawing up the declaration, it is necessary to ensure the product is complied with MDD93/42/EEC and confirms the completion of the following tasks.

2.1 Classification of products.

2.2 Validation of certification route.

2.3 The product has been in accordance with the basic requirements in MDD93/42/EEC Appendix I.

2.4 The product has been in accordance with the requirements of harmonized standard and relative regulations.

2.5 The technical documentations have been drawn up according to MDD/93/42/EEC.

2.6 The quality assurance system of product is in accordance with MDD/93/42/EEC.

2.7 The above tasks have been approved by notified body.

3. The Contents of the Declaration of Conformity

Declaration of Conformity

Manufacturer: Sichuan Nigale Biotechnology Co., Ltd.

Address of Manufacturer: No.28 Kuixing Road 641400 Jianyang, Sichuan, PEOPLE'S REPUBLIC OF CHINA

Address of Facility: 4th F, No.2 Factory Building , Shiyang Industrial Park , No.55, Section 5th, Qingyun Village, Hi-tech District, 610041 Chengdu, PEOPLE'S REPUBLIC OF CHINA

European representative: Shanghai International Holding Corp. GmbH (Europe)

Address of European representative: Eiffestrasse 80, 20537 Hamburg, Germany

Product Name:Plasma Separator

Model Number:NGL XJC2000, DigiPla 80, DigiPla 90

NBOG Code:MD1101_2

GMDN Code:16405

Classification(MDD, Annex Ⅸ): Ⅱb , Rule 11

Conformity Assessment Route: Annex Ⅱ excluding (4)

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

Gerneral 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: May 26, 2024

Start of CE Marking: May25, 2021

Place, Date of issue: Chengdu

Signature: Lu Yan

Name : Lu Yan

Position: General Manager of Device Department

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 067972 0006 Rev. 01

Holder of Certificate: **Sichuan Nigale Biotechnology Co., Ltd.**
No.28 Kuixing Road
641400 Jianyang, Sichuan
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development,
Production and Distribution of
Disposable Plasma Apheresis Set,
Disposable Blood Cell Apheresis Set,
Disposable Blood Component Apheresis Set,
Disposable Blood Collection and Transfusion Set,
Disposable Infusion Set, Disposable Plastic Blood Bag,
Disposable Blood Bag with In-line Leukoreduced Filter,
Disposable Autologous Blood Salvage Set,
Disposable Blood Lipid Apheresis Set,
Plasma Separator, Blood Component Separator,
Autologous Blood Salvage Collector,
Blood Lipid Separator, Blood Cell Processor**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 067972 0006 Rev. 01

Report No.: SH2051701

Valid from: 2021-01-01

Valid until: 2023-12-31

Date, 2020-12-30

Christoph Dicks
Head of Certification/Notified Body

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 067972 0006 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Sichuan Nigale Biotechnology Co., Ltd.
No.28 Kuixing Road, 641400 Jianyang, Sichuan, PEOPLE'S REPUBLIC OF CHINA

Design and Development,
Production and Distribution of
Disposable Plasma Apheresis Set,
Disposable Blood Cell Apheresis Set,
Disposable Blood Component Apheresis Set,
Disposable Blood Collection and Transfusion Set,
Disposable Infusion Set, Disposable Plastic Blood Bag,
Disposable Blood Bag with In-line Leukoreduced Filter,
Disposable Autologous Blood Salvage Set,
Disposable Blood Lipid Apheresis Set

Sichuan Nigale Biotechnology Co., Ltd.
4th F, No.2 Factory Building, Shiyang Industrial Park, No.55, Section 5th, Qingyun Village, Hi-Tech District, 610041 Chengdu, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of Plasma Separator, Blood Component Separator, Autologous Blood Salvage Collector, Blood Lipid Separator, Blood Cell Processor

.

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 067972 0006 Rev. 01

Holder of Certificate: **Sichuan Nigale Biotechnology Co., Ltd.**
No.28 Kuixing Road
641400 Jianyang, Sichuan
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development,
Production and Distribution of
Disposable Plasma Apheresis Set,
Disposable Blood Cell Apheresis Set,
Disposable Blood Component Apheresis Set,
Disposable Blood Collection and Transfusion Set,
Disposable Infusion Set, Disposable Plastic Blood Bag,
Disposable Blood Bag with In-line Leukoreduced Filter,
Disposable Autologous Blood Salvage Set,
Disposable Blood Lipid Apheresis Set,
Plasma Separator, Blood Component Separator,
Autologous Blood Salvage Collector,
Blood Lipid Separator, Blood Cell Processor**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 067972 0006 Rev. 01

Report No.: SH2051701

Valid from: 2021-01-01

Valid until: 2023-12-31

Date, 2020-12-30

Christoph Dicks
Head of Certification/Notified Body

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 067972 0006 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Sichuan Nigale Biotechnology Co., Ltd.
No.28 Kuixing Road, 641400 Jianyang, Sichuan, PEOPLE'S REPUBLIC OF CHINA

Design and Development,
Production and Distribution of
Disposable Plasma Apheresis Set,
Disposable Blood Cell Apheresis Set,
Disposable Blood Component Apheresis Set,
Disposable Blood Collection and Transfusion Set,
Disposable Infusion Set, Disposable Plastic Blood Bag,
Disposable Blood Bag with In-line Leukoreduced Filter,
Disposable Autologous Blood Salvage Set,
Disposable Blood Lipid Apheresis Set

Sichuan Nigale Biotechnology Co., Ltd.
4th F, No.2 Factory Building, Shiyang Industrial Park, No.55, Section 5th, Qingyun Village, Hi-Tech District, 610041 Chengdu, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of Plasma Separator, Blood Component Separator, Autologous Blood Salvage Collector, Blood Lipid Separator, Blood Cell Processor

.

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中华人民共和国
药品GMP证书

CERTIFICATE OF GOOD MANUFACTURING PRACTICES FOR PHARMACEUTICAL PRODUCTS
PEOPLE'S REPUBLIC OF CHINA

证书编号：SC20180057
Certificate No.

企业名称：四川南格尔生物科技有限公司
Manufacturer : Sichuan Nigale Biotechnology Co., Ltd

地　　址：简阳市东溪镇奎星路28号（生产车间：注射剂车间1、2号生产线）
Address : No. 28 Kuixing Road 641400 Jianyang, Sichuan PEOPLE'S REPUBLIC OF CHINA (Production Workshop: Injection Workshop Line No. 1 and Line No. 2)

认证范围：大容量注射剂、小容量注射剂（最终灭菌）
Scope of Inspection : Large Volume Parenteral Solutions, Small Volume Parenteral Solutions (Terminal Sterilization)

经审查，符合中华人民共和国《药品生产质量管理规范》要求。
特发此证。
This is to certify that the above-mentioned manufacturer complies with the requirements of Chinese Good Manufacturing Practices for Pharmaceutical Products.

有效期至　2023 年 10 月 25 日
This certificate remains valid until 25/10/2023

发证机关：
Issued By

四川省食品药品监督管理局 行政审批专用章

Date for Issuing 26/10/2018　　2018 年 10 月 26 日

国家食品药品监督管理总局制
CHINA FOOD AND DRUG ADMINISTRATION