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

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

Digitally signed by Apostol Eduard
Date: 2021.03.19 17:03:35 EET
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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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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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

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

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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.

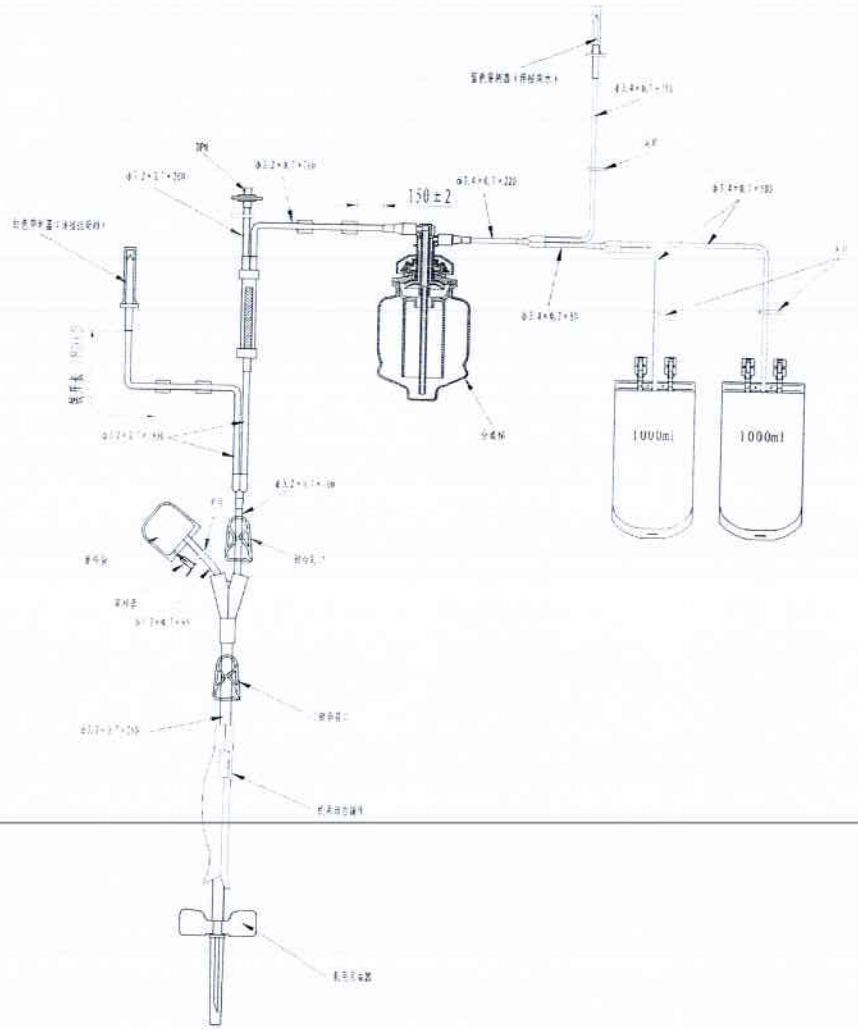
有效期至　2023 年 10 月 25 日
This certificate remains valid until 25/10/2023

发证机关：
Issued By

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

P-4019(Moldova)-01



技术要求

1. 整套产品组装时应平整，软管不得有扭曲现象；
2. 各粘接处不得有渗漏现象，产品内腔不得有堵塞；
3. 在十万级净化间加工完成。

标记	处数	分区	更改文件号	签名	年月日
设计	标准化	工艺	审核	批准	日期 2017.8.3

一次性使用单采血浆分离器

P-4019(Moldova)-01

共 张	第 张	数量	重量	比例
共 张	第 1 张			

四川省格尔生物科技有限公司

底图
底图总号
装订号
日期 签字