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

TÜV SÜD
Product Service

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

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

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