



Certificate

No. Q5 067972 0006 Rev. 02

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
Sterile Disposable Plasma Apheresis Set,
Sterile Disposable Blood Cell Apheresis Set,
Sterile Disposable Blood Component Apheresis Set,
Sterile Disposable Blood Collection and Transfusion Set,
Sterile Disposable Infusion Set, Disposable Plastic Blood
Bag,
Sterile Disposable Blood Bag with In-line Leukoreduced
Filter,
Sterile Disposable Autologous Blood Salvage Set,
Sterile 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. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_067972_0006_Rev.02)

Report No.: SH2351701

Valid from: 2024-01-01
Valid until: 2026-12-31

Date, 2023-11-29



Christoph Dicks
Head of Certification/Notified Body

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Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

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
Sterile Disposable Plasma Apheresis Set,
Sterile Disposable Blood Cell Apheresis Set,
Sterile Disposable Blood Component Apheresis Set,
Sterile Disposable Blood Collection and Transfusion Set,
Sterile Disposable Infusion Set, Disposable Plastic Blood Bag,
Sterile Disposable Blood Bag with In-line Leukoreduced Filter,
Sterile Disposable Autologous Blood Salvage Set,
Sterile 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