



# 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](http://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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**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