



Product Service

# CERTIFICATE

No. Q5 17 09 67972 006

**Holder of Certificate:** Sichuan Nigale Biotechnology Co., Ltd.

No.28 Kuixing Road  
641400 Jianyang, Sichuan  
PEOPLE'S REPUBLIC OF CHINA

**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



**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

**Applied Standard(s):**

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

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). See also notes overleaf.

**Report No.:** SH1751712  
**Valid from:** 2018-01-01  
**Valid until:** 2020-12-31

**Date:** 2017-12-04  
Page 1 of 1

*S. Preiß*

Stefan Preiß



DAKKS  
Deutsche  
Akkreditierungsstelle  
D-UM 11324-01-00