



# 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:G10679720007Rev.02](http://www.tuvsud.com/ps-cert?q=cert:G10679720007Rev.02)

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**Date,** 2021-05-25

Christoph Dicks  
Head of Certification/Notified Body