



Benannt durch/Designated by  
 Zentralstelle der Länder  
 für Gesundheitsschutz  
 bei Arzneimitteln und  
 Medizinprodukten  
 ZLG-B5-244.10.08  
 www.zlg.de



Product Service

## 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. 01**

**Manufacturer:** **Sichuan Nigale Biotechnology Co., Ltd.**  
 No.28 Kuixing Road  
 641400 Jianyang, Sichuan  
 PEOPLE'S REPUBLIC OF CHINA

**EC-Representative:** Shanghai International Holding Corp. GmbH (Europe)  
 Eiffestraße 80, 20537 Hamburg, GERMANY

**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. See also notes overleaf.

**Report No.:** SH19517EXT01

**Valid from:** 2019-07-14

**Valid until:** 2024-07-13

**Date,** 2019-05-17

Stefan Preiß