



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



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



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No. G1 067972 0007 Rev. 01

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**



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

Stefan Preiß

Date, 2017-12-04
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