ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 14 10 67972 005

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 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,
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.: SH1451709

Valid from: 2014-12-18
Valid until: 2019-07-13

Date, 2014-12-18

Hans-Heiner Junker

Digitally signed by Bolocan Vladimir
Date: 2019.08.21 14:34:23 EEST
Reason: MoldSign Signature
Location: Moldova

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123