ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ 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 17 10 82515 005

Manufacturer:

Nanjing Superstar Medical Equipment Co., Ltd.
The 2nd and 3rd Floors, No.6 Building
No.9 Bofu Road
Yanjiang industrial Development Zone, Liuhe District
211505 Nanjing
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):

Anaesthesia Systems, Ventilators, CPAP Systems

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.: SH17736EXT01

Valid from: 2018-03-05
Valid until: 2023-02-28

Date, 2018-03-05

Stefan Preiß

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

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Nanjing, PEOPLE'S REPUBLIC OF CHINA

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