ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ 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 18 03 44751 113

Manufacturer:

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

Mindray Building
Keji 12th Road South
High-Tech Industrial Park
Nanshan
518057 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)

Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):

Patient Monitoring Devices, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Ambulatory Blood Pressure Monitor, Pulse Oximeter, Temperature Probe, SPO2 Sensors, External Defibrillator Paddles, Anaesthetic Vaporizer, Defibrillator/Monitor, Electrocardiograph, Wearable ECG Recorder, Anesthesia Machine, Ventilator, Ultrasonic Diagnostic Equipment, Ultrasonic Transducer, Digital Radiography System, Radiography System, Magnetic Resonance Imaging System

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.: SH1805531

Valid from: 2018-07-09
Valid until: 2020-02-21

Date, 2018-07-09

Stefan Preiß

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

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Facility(ies):

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Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

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