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 14 10 44751 047

Manufacturer:

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

Mindray Building
Keji 12th Road South
Hi-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, Defibrillator/Monitor, Electrocardiograph, Anesthesia Machine, Ventilator, Ultrasonic Diagnostic Equipment, Digital Radiography System, Magnetic Resonance Imaging System, Ultrasonic transducer, SPO2 Sensors, Body Cavity Temperature Probe, Disposable Pressure Transducer, Ambulatory Blood pressure Monitor, External Defibrillator Paddles, Anaesthetic Vaporizer Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag, Disposable Infusion Sets, Disposable Transfusion Sets

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.: SH14055EXT01
Valid from: 2015-02-22
Valid until: 2020-02-21

Date, 2015-01-21

Hans-Heiner Junker

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

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Facility(ies):

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, 518057 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

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Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Buildings 9-13, Baiwangxin High-tech Industrial Park, Baimang, Xili Town, Nanshan, 518108 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
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