



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

Hans-Heiner Junker

**Date,** 2015-01-21



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  
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REPUBLIC OF CHINA

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Rd., Xili Town, Nanshan, 518055 Shenzhen, PEOPLE'S  
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Shenzhen, PEOPLE'S REPUBLIC OF CHINA