



Product Service

CERTIFICATE

No. Q5 17 03 44751 089

Holder of Certificate: **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



Certification Mark:



Scope of Certificate: Design and development, production and distribution of Active medical devices (intended) for monitoring, diagnosis, anesthesia, breathing and intensive care; In-vitro diagnostic instruments; Non-active accessories for breathing therapy and anesthesia; In-vitro diagnostic reagents and kits (intended) for hematology, clinical chemistry, immunology and cell analysis (For detail information see following pages)

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1705528

Valid from: 2017-09-01

Valid until: 2020-08-31

Date, 2017-06-28

Stefan Preiß



Page 1 of 3



Product Service

CERTIFICATE**No. Q5 17 03 44751 089****Applied Standard(s):**

EN ISO 13485:2016
 Medical devices - Quality management systems -
 Requirements for regulatory purposes
 (ISO 13485:2016)
 DIN EN ISO 13485:2016

Facility(ies):

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

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

Shenzhen Mindray Biomedical Electronics Co., Ltd.
1203 Nanhuan Avenue, Guangming District, 518106
Shenzhen, PEOPLE'S REPUBLIC OF CHINA



Product Service

Attachment for Certificate No. Q5 17 03 44751 089
Dated: 2017-06-28

For the product(s)/product category (ies):

Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood pressure Monitor, Defibrillator/Monitor and Accessories, Electrocardiograph, Wearable ECG Recorder,
 Anesthesia Machine and Accessories, Ventilator,
 Infusion Pump, Syringe Pump, Enteral Feeding Pump, Infusion Supervision System,
 Ultrasonic Diagnostic Equipment and Accessories,
 Digital Radiography System, Radiography System, Magnetic Resonance Imaging System
 Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader,
 Microplate Washer for invitro diagnostic use, Chemiluminescence Immunossay Analyzer,
 Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker&Stainer,
 Glycohemoglobin Analyzer, Specific Protein Analyzer,
 Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer,
 Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassav Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer,
 Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask,
 Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

Munich, CRT, 2017-06-28

Stefan Preiß

Page 3 of 3