



Certificate

No. Q5 044751 0164 Rev. 06

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, Service 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). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 044751 0164 Rev. 06

Report No.: SH2405501

Valid from: 2024-08-15
Valid until: 2026-08-31

Date, 2024-08-15

Christoph Dicks
Head of Certification/Notified Body

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Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

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

Design and Development, Production, Service 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)

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

Design and Development, Production, Service and Distribution of:
Active Medical Devices(intended) for monitoring, diagnosis,
anesthesia, breathing and intensive care; In-vitro Diagnostic
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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, Anesthesia Machine and accessories, Ventilator, Air compressor, Endoscope Camera System, Endoscope Light Source and accessories, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for invitro diagnostic use, Chemiluminescence Immunoassay 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 Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Coagulation Analyzer and Accessories, Coagulation Reagents, Calibrators and Controls for Coagulation Analyzer, Automated Digital Cell Morphology Analyzer, Ion-Selective Electrodes, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag, Tympanic Thermometer, Microbial Analysis System, Reagents for Urine Analyzer, Generator, Nasal Mask/Nasal Prong, Detector and Imaging System.



认证证书

证书号. Q5 044751 0164 Rev. 06

证书持有者：

深圳迈瑞生物医疗电子股份有限公司

中华人民共和国深圳市南山区高新技术产业园科技南十二路迈瑞大厦
518057

认证标志：



认证范围：

设计和开发、生产、服务和分销：有源医疗器械用于
监护、诊断、麻醉、呼吸和重症监护；体外诊断设备；
无源附件用于呼吸治疗和麻醉；体外诊断试剂和试剂盒
用于血球、临床生化、免疫及细胞分析。(具体信息范围
见附件)

认证机构TÜV SÜD产品服务有限公司证明上述公司已经建立并运行了满足所列标准要求的质量管理体系。
TÜV 南德集团检测、认证、审定与核查准则所有适用要求也须得到遵守。详情及证书有效期请见
www.tuvsud.com/ps-cert?q=cert:Q5 044751 0164 Rev. 06

报告号： SH2405501

生效期： 2024-08-15

有效期： 2026-08-31

发证日期, 2024-08-15

Christoph Dicks

Head of Certification/Notified Body

认证证书

证书号. Q5 044751 0164 Rev. 06

认证标准：

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
医疗器械 - 质量管理体系 - 用于法规的要求

生产场地：

深圳迈瑞生物医疗电子股份有限公司
中华人民共和国深圳市南山区高新技术产业园科技南十二路迈瑞大厦
518057

设计和开发、生产、服务和分销：有源医疗器械用于监护、诊断、麻醉、呼吸和重症监护；体外诊断设备；无源附件用于呼吸治疗和麻醉；体外诊断试剂和试剂盒用于血球、临床生化、免疫及细胞分析。(具体信息见附件)

深圳迈瑞生物医疗电子股份有限公司
中华人民共和国深圳市光明区南环大道1203号 518106

设计和开发、生产、服务和分销：有源医疗器械用于监护、诊断、麻醉、呼吸和重症监护；体外诊断设备；无源附件用于呼吸治疗和麻醉；体外诊断试剂和试剂盒用于血球、临床生化、免疫及细胞分析。(具体信息见附件)

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覆盖产品范围为:

医用电子设备（包括病人监护仪和附件、生命体征监测仪、中心监护系统、数字遥测监护系统、血氧饱和度监护仪、体温探头、流量传感器、动态血压监测仪、除颤监护仪和附件、心电图机、麻醉机和附件、呼吸机、空压机、内窥镜摄像系统、冷光源及附件、超声诊断设备和附件、数字化医用X射线摄影系统、医用X射线摄影系统、血液细胞分析仪、生化分析仪、尿液分析仪、酶标仪、体外诊断用洗板机、全自动化学发光免疫分析仪、流式细胞仪、（全自动）样本处理系统、全自动推片染色机、糖化血红蛋白分析仪、特定蛋白免疫分析仪），以及血液细胞分析仪用试剂、生化分析仪用试剂、化学发光免疫试剂、化学发光免疫校准品和质控品、流式细胞仪用试剂、糖化血红蛋白分析仪用试剂、糖化血红蛋白分析仪用校准品和质控品、凝血仪器及附件、凝血试剂、凝血校准质控品、全自动细胞形态学分析仪、离子选择性电极、一次性麻醉面罩、可复用的麻醉面罩、呼吸面罩、一次性呼吸回路、可复用的呼吸回路、热湿交换器、过滤器、呼吸囊、红外耳温计、微生物分析用仪器、尿液分析仪用试剂、压力发生器、鼻罩/鼻塞、探测器及成像系统