



America

CERTIFICATE

No. QS5 17 07 44751 097

Certificate Holder:

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 Medical Electronic Equipment (Including 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 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, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger,

Standard(s):

ISO 9001:2015

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.:

M2606

Effective Date:

2017-07-01

Expiry Date:

2020-06-30

Earl Buckmiller

Director, Quality Systems & MS Cert. Body



Page 1 of 3

TÜV SÜD America Inc.
10 Centennial Drive
Peabody, MA 01960
USA

TÜV®





America

CERTIFICATE

No. QS5 17 07 44751 097

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 and Distribution of Medical Electronic Equipment (Including 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 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, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

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

Design and Development, Manufacturing of 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, Ventilator, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Magnetic Resonance Imaging System. Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

Effective Date: 2017-07-01
 Expiry Date: 2020-06-30

Earl Buckmiller
 Director, Quality Systems & MS Cert. Body

Page 2 of 3

TÜV SÜD America Inc.
 10 Centennial Drive
 Peabody, MA 01960
 USA

TÜV®





America

CERTIFICATE

No. QS5 17 07 44751 097

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
1203 Nanhuan Avenue
Guangming District
518016 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of Medical Electronic Equipment (Including 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 (Ultrasonic Transducer), 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 Immunoassay 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

Effective Date: 2017-07-01
Expiry Date: 2020-06-30

Earl Buckmiller
 Director, Quality Systems & MS Cert. Body

Page 3 of 3

TÜV SÜD America Inc.
 10 Centennial Drive
 Peabody, MA 01960
 USA

TÜV®



认证证书

证书号: **QS5 17 07 44751 097**



America

证书持有者:

深圳迈瑞生物医疗电子股份有限公司
中国深圳市南山区高新技术产业园科技南十二路
迈瑞大厦
邮编: **518057**

组织机构代码:

914403007084678371

认证标志:



认证范围:

设计和开发、生产和销售: 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、无线心电采集记录器、麻醉机和附件、呼吸机、输液泵、注射泵、营养泵、输液监护管理系统、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、磁共振成像系统、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、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

认证标准:

ISO 9001:2015

TÜV SÜD America Inc. 认证机构证明上述公司已经建立并保持满足上述所列标准要求的质量管理体系。

报告号:

M2606

生效日期:

2017-07-01

到期日期:

2020-06-30

本证书信息可在国家认证认可监督管理委员会官方网站(www.cnca.gov.cn)上查询。
获证组织必须定期接受监督审核并经审核合格此证书方继续有效。

Earl Buckmiller
Director, Quality Systems & MS Cert. Body

第1页共3页
TÜV SÜD America Inc.
10 Centennial Drive
Peabody, MA 01960
USA

TÜV®





认证证书

证书号: **QS5 17 07 44751 097**

深圳迈瑞生物医疗电子股份有限公司
中国深圳市南山区高新技术产业园科技南十二路迈瑞大厦
邮编: **518057**

设计和开发、生产和销售: 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、无线心电采集记录器、麻醉机和附件、呼吸机、输液泵、注射泵、营养泵、输液监护管理系统、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、磁共振成像系统、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、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。

深圳迈瑞生物医疗电子股份有限公司
中国深圳市南山区西丽镇白芒百旺信高科技工业园9-13栋
邮编: **518108**

设计和开发、生产:

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、无线心电采集记录器、麻醉机、呼吸机、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、磁共振成像系统、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。

生效日期: **2017-07-01**
到期日期: **2020-06-30**

本证书信息可在国家认证认可监督管理委员会官方网站(www.cnca.gov.cn)上查询。
获证组织必须定期接受监督审核并经审核合格此证书方继续有效。

Earl Buckmiller
Director, Quality Systems & MS Cert. Body

第2页共3页

TÜV SÜD America Inc.
10 Centennial Drive
Peabody, MA 01960
USA





认证证书

证书号: **QS5 17 07 44751 097**

深圳迈瑞生物医疗电子股份有限公司
中国深圳市光明新区南环大道1203号
邮编: **518106**

设计和开发、生产:

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、无线心电采集记录器、麻醉机和附件、呼吸机、输液泵、注射泵、营养泵、输液监护管理系统、超声诊断设备和附件(超声探头)、数字化医用X射线摄影系统、医用X射线摄影系统、磁共振成像系统、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、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。

生效日期: **2017-07-01**
到期日期: **2020-06-30**

本证书信息可在国家认证认可监督管理委员会官方网站(www.cnca.gov.cn)上查询。
获证组织必须定期接受监督审核并经审核合格此证书方继续有效。

Earl Buckmiller
Director, Quality Systems & MS Cert. Body

第3页共3页
TÜV SÜD America Inc.
10 Centennial Drive
Peabody, MA 01960
USA

