

11.1、职业健康安全管理体系认证证书

Certificate CN19/32315

The management system of

**Shenzhen Mindray Bio Medical Electronics
Co., Ltd.**

Unified Social Credit Code: 914403007084676371

Business Registration Address: 1-4F, Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan District, Shenzhen City, Guangdong Province, P.R. China

Business Operation Address: Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan District, Shenzhen City, Guangdong Province, P.R. China

has been assessed and certified as meeting the requirements of

ISO 45001:2018

For the following activities

The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 05 July 2023 until 17 December 2025 and remains valid subject to satisfactory surveillance audits.
Issue 3. Certified since 18 December 2019
Multiple certificates have been issued for this scope. The main certificate is numbered CN19/32315
Certified activities performed by additional sites are listed on subsequent pages.

Jonathan M. Hall

Authorised by
Jonathan Hall
Global Head - Certification Services

SGS United Kingdom Ltd
Rosemore Business Park, Ellesmere Port, Cheshire, CH65 2EN, UK
t+44 (0)151 350-6666 - www.sgs.com



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Page 1 of 4

Certificate CN19/32315, continued

Shenzhen Mindray Bio Medical Electronics Co., Ltd.



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ISO 45001:2018

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, 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 in vitro 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, Infusion pump, Syringe pump, Enteral feeding pump, Infusion supervision system.



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Certificate CN19/32315, continued

Shenzhen Mindray Bio Medical Electronics Co., Ltd.

ISO 45001:2018

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Issue 3

Sites

Shenzhen Mindray Bio Medical Electronics Co., Ltd.
Unified Social Credit Code: 914403007084678371
Business Registration Address: 1-4F, Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan District, Shenzhen City, Guangdong Province, P.R. China
Business Operation Address: Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan District, Shenzhen City, Guangdong Province, P.R. China
Design and Development, 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, 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, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag, Infusion pump, Syringe pump, Enteral feeding pump, Infusion supervision system.

Shenzhen Mindray Scientific Research Co., Ltd.
Unified Social Credit Code: 91440300MA5H927D7B
Business Registration Address: 4F, Building 3B, Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan District, Shenzhen City, Guangdong Province, P.R. China
Business Operation Address: Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan District, Shenzhen City, Guangdong Province, P.R. China
Design and Development, 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, 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, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag, Infusion pump, Syringe pump, Enteral feeding pump, Infusion supervision system.

Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Guangming Production Factory
Unified Social Credit Code: 914403003426616166
Business Registration Address: NO. 1203 Nanhuan Road, YuTang Street, Guangming District, Shenzhen City, Guangdong Province, P.R. China
Business Operation Address: NO. 1203 Nanhuan Road, YuTang Street, Guangming District, Shenzhen City, Guangdong Province, P.R. China



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Certificate CN19/32315, continued

Shenzhen Mindray Bio Medical Electronics Co., Ltd.

ISO 45001:2018

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Production 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, 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, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag, Design of 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

Shenzhen Mindray Scientific Co., Ltd.

Unified Social Credit Code: 91440300763451547B

Business Registration Address: 6F, Building 2# NO. 1203 Nanhuan Road, YuTang Street, Guangming District, Shenzhen City, Guangdong Province, P.R. China

Business Operation Address: 6F, Building 2# NO. 1203 Nanhuan Road, YuTang Street, Guangming District, Shenzhen City, Guangdong Province, P.R. China

Production of Infusion pump, Syringe pump, Enteral feeding pump, Infusion supervision system.



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职业健康安全管理体系认证证书

主证书编号: CN19/32315

此为证书 CN19/32315 译本

下述组织

深圳迈瑞生物医疗电子股份有限公司

SGS

统一社会信用代码: 914403007084678371
注册地址: 深圳市南山区高新技术产业园科技南十二路迈瑞大厦 1~4 层
经营地址: 中国广东省深圳市南山区高新技术产业园科技南十二路迈瑞大厦
的管理体系已经过审核, 并被证明符合下述要求
ISO 45001:2018



所涉及的活动范围覆盖

证书的注册范围显示在第二页上

此证书的有效期自 2023 年 07 月 06 日 至 2026 年 12 月 17 日 并须经过符合要求的监督审核保持有效
版本号 3, 初始注册日期 2019 年 12 月 18 日
在此范围内出具了多张证书, 主证书编号为 CN19/32315
在其它场所实施的认证活动在后续页面上列出

Jonathan M. Hall

签署
Jonathan Hall
Global Head -
Certification Services
SGS United Kingdom Ltd
Rosemore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
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第 1 页共 4 页

职业健康安全管理体系认证证书

主证书编号: CN19/32315

此为证书 CN19/32315 译本

下述组织

深圳迈瑞生物医疗电子股份有限公司

SGS

ISO 45001:2018

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、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、酶式细胞仪用试剂、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、热交换器、过滤器、呼吸囊、输液泵、注射泵、营养泵、输液监护管理系统



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第 2 页共 4 页

职业健康安全管理体系认证证书

主证书编号: CN19/32315

此为证书 CN19/32315 译本, 续

深圳迈瑞生物医疗电子股份有限公司

SGS

ISO 45001:2018

版本号 3

场所

深圳迈瑞生物医疗电子股份有限公司

统一社会信用代码: 914403007084678371

注册地址: 深圳市南山区高新技术产业园科技南十二路迈瑞大厦1~4层

经营地址: 中国广东省深圳市南山区高新技术产业园科技南十二路迈瑞大厦

设计和开发、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、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、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、输液泵、注射泵、营养泵、输液监护管理系统)

深圳迈瑞科学仪器有限公司

统一社会信用代码: 91440300MA5H927D7B

注册地址: 深圳市南山区粤海街道高新区社区南山区高新片区科技南十二路迈瑞大厦3座4层

经营地址: 中国广东省深圳市南山区高新技术产业园科技南十二路迈瑞大厦

设计和开发、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、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、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、输液泵、注射泵、营养泵、输液监护管理系统)

深圳迈瑞生物医疗电子股份有限公司光明生产厂

统一社会信用代码: 914403003426616186

注册地址: 深圳市光明区玉塘街道南环大道1203号

经营地址: 中国广东省深圳市光明区玉塘街道南环大道1203号

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、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、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、热湿交换器、过滤器、呼吸囊

设计: 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



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第 3 页共 4 页

职业健康安全管理体系认证证书

主证书编号: CN19/32315

此为证书 CN19/32315 译本, 续

深圳迈瑞生物医疗电子股份有限公司

SGS

ISO 45001:2018

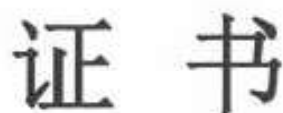
深圳迈瑞科技有限公司
统一社会信用代码: 914403007894515478
注册地址: 深圳市光明区玉塘街道南环大道 1203 号 2 号楼 6 楼
经营地址: 中国深圳市光明区玉塘街道南环大道 1203 号 2 号楼 6 楼
生产: 输液泵, 注射泵, 营养泵, 输液监护管理系统



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第 4 页共 4 页



认证部

茲證明

浙江优亿医疗器械股份有限公司

中国浙江省台州市仙居县白塔镇仙居县经济开发区白塔区块优亿路8号

邮政编码: 317300

在以下适用范围

建立了职业健康安全管理体系

视频内窥镜产品（包括可视喉镜、可视软性喉镜、可视硬性喉镜、视频耳镜、视频鼻镜、视频喉镜）及配件、肺活量计、一次性使用喉镜片、一次性使用全包喉镜片、一次性使用吸罩气道导管、一次性使用可视吸罩气道导管、一次性使用气管插管、一次性使用可视气管插管、一次性使用无菌腹腔镜穿刺器、一次性单孔腹腔镜穿刺器、一次性使用内窥镜套管、一次性使用支气管封堵器、一次性医用水凝胶眼贴的研发、生产和销售。

通过审核, 订单编号: 7482341292

证明该体系满足

ISO 45001:2018

的要求。

本证书的有效期限从2021年12月19日至2024年12月18日。

证书注册号: 12 117 61964 TMS

Head of Certification Body
蘇尼星, 2021年12月20日





Zhejiang UE Medical Corp.
No. 8, Youyi Road, Baita Economic Development Zone,
Baita Town, Xianju County,
Taizhou City, Zhejiang Province, P. R. China
Post Code: 317300

**Design, Production and Sales for the Video Endoscope Products
(include Video Laryngoscopes, Flexible Videoscope, Video Stylets,
Video Otoscope, Video Nasoscope) and Accessories, Vital Capacity Meter,
Laryngoscope Blade for Single Use, Disposable Medical Laryngeal Masks,
Disposable Tracheal Intubation, Disposable Laparoscopic Puncture Device,
Disposable Endoscopic Cannula, Disposable Bronchial Occluder,
Disposable Medical Hydrogel Eye Patch**

ISO 45001:2018

are fulfilled.

The certificate is valid from **2021-12-19** until **2024-12-18**.
Certificate Registration No.: **12 117 61964 TMS**.

Head of Certification Body
Munich, 2021-12-20





认证证书

苏州好博医疗器械股份有限公司

统一社会信用代码: 91320585569107240F

注册地址: 江苏省太仓市浏河镇紫藤路8号

生产/经营地址: 江苏省太仓市浏河镇紫藤路8号

职业健康安全管理体系

符合标准: **GB/T 45001-2020 /ISO 45001:2018**

认证范围: 医疗器械组装与销售(资质许可范围内)

初次注册日期: 2022-01-06

发放/改版日期: 2022-01-06

注册编号: KC112F6030S

失效日期: 2025-01-05



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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

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上海开成认证
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签发人

上海开成认证有限公司

中国上海市杨浦区宁国路313弄7号602

11.2、环境管理体系认证证书



Certificate CN17/31686

The management system of

Shenzhen Mindray Bio Medical Electronics Co., Ltd.

Unified Social Credit Code: 914403007084673371
Business Registration Address: 1-4F, Mindray Building, Keji 12th Road South High-Tech Industrial Park, Nanshan District, Shenzhen City, Guangdong Province, P.R. China
Business Operation Address: Mindray Building, Keji 12th Road South High-Tech Industrial Park, Nanshan District, Shenzhen City, Guangdong Province P.R. China

has been assessed and certified as meeting the requirements of
ISO 14001:2015

For the following activities

The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 09 October 2023 until 08 October 2026 and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 09 October 2017
Multiple certificates have been issued for this scope, the most certificate is numbered CN17/31686
Certified activities performed by additional sites are listed on subsequent pages.





Authorised by
Jonathan Hall
Global Head - Certification Services

SGS United Kingdom Ltd
Roseville Business Park, Elsbamere Park, Cheshire, CH65 3EN, UK
t +44 (0)161 360 6868 • www.sgs.com

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Page 1 of 4



Certificate CN17/31686, continued

Shenzhen Mindray Bio Medical Electronics Co., Ltd.

ISO 14001:2015

SGS

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, 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 in vitro 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, Infusion pump, Syringe pump, Enteral feeding pump, Infusion supervision system.



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Certificate CN17/31686, continued

Shenzhen Mindray Bio Medical Electronics Co., Ltd.

ISO 14001:2015

SGS



Issue 2
Sites
Shenzhen Mindray Bio Medical Electronics Co., Ltd. Unified Social Credit Code: 914403007084678371 Business Registration Address: 1-4F, Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan District, Shenzhen City, Guangdong Province, P.R. China Business Operation Address: Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan District, Shenzhen City, Guangdong Province, P.R. China Design and Development, 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, 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, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag, Infusion pump, Syringe pump, Enteral feeding pump, Infusion supervision system.
Shenzhen Mindray Scientific Research Co., Ltd. Unified Social Credit Code: 91440300MA5H927D7B Business Registration Address: 4F, Building 3#, Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan District, Shenzhen City, Guangdong Province, P.R. China Business Operation Address: Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan District, Shenzhen City, Guangdong Province, P.R. China Design and Development, 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, 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, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag, Infusion pump, Syringe pump, Enteral feeding pump, Infusion supervision system.
Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Guangming Production Factory Unified Social Credit Code: 914403003426F16186 Business Registration Address: NO. 1203 Nanhuai Road, Yu Tang Street, Guangming District, Shenzhen City, Guangdong Province, P.R. China Business Operation Address: NO. 1203 Nanhuai Road, Yu Tang Street, Guangming District, Shenzhen City, Guangdong Province, P.R. China



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Certificate CN17/31686, continuous

Shenzhen Mindray Bio Medical Electronics Co., Ltd.

ISO 14001:2015

Production 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, 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, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter breathing bag, Design of 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

Shenzhen Mindray Scientific Co., Ltd.

Unified Social Credit Code: 91440300763451517B

Business Registration Address: 6F, Building 2# NO. 1203 Nanhuan Road, YuTang Street, Guangming District, Shenzhen City, Guangdong Province, P.R. China

Business Operation Address: 6F, Building 2# NO. 1203 Nanhuan Road, YuTang Street, Guangming District, Shenzhen City, Guangdong Province, P.R. China

Production of Infusion pump, Syringe pump, External feeding pump, Infusion supervision system.



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环境管理体系认证证书

主证书编号: CN17/31686

此为证书 CN17/31686 译本

下述组织

深圳迈瑞生物医疗电子股份有限公司

SGS

统一社会信用代码: 914403007084878371

注册地址: 深圳市南山区高新技术产业园科技南十二路迈瑞大厦1~4层

经营地址: 中国广东省深圳市南山区高新技术产业园科技南十二路迈瑞大厦

的管理体系已经过审核, 并被证明符合下述要求

ISO 14001:2015

所涉及的活动范围覆盖

证书的注册范围显示在第二页上



该证书的有效期限为 2023 年 10 月 09 日至 2026 年 10 月 09 日, 并将在符合要求的监督审核保持有效

版本号 2, 初始注册日期 2017 年 10 月 09 日

在此范围内出具了多张证书, 主证书编号为 CN17/31686

在其它场所实施的认证活动在后续页面上列出

Jonathan Hall

签署

Jonathan Hall

Global Head -

Certification Services

SGS United Kingdom Ltd

Essence Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK

t +44 (0) 151 350-6566 - www.sgs.com



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第 1 页共 4 页

环境管理体系认证证书

主证书编号: CN17/31686

此为证书 CN17/31686 译本

下述组织

深圳迈瑞生物医疗电子股份有限公司

ISO 14001:2015

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、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、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、输液泵、注射泵、营养泵、输液监护管理系统



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第 2 页共 4 页

环境管理体系认证证书

主证书编号: CN17/31686

此为证书 CN17/31686 译本, 续

深圳迈瑞生物医疗电子股份有限公司

SGS

ISO 14001:2015

版本号 2

场所

深圳迈瑞生物医疗电子股份有限公司

统一社会信用代码: 914403007084678371

注册地址: 深圳市南山区高新技术产业园科技南十二路迈瑞大厦 1~4 层

经营地址: 中国广东省深圳市南山区高新技术产业园科技南十二路迈瑞大厦

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深圳迈瑞科学仪器有限公司

统一社会信用代码: 91440300MA5H927D7B

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设计和开发、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、麻醉机和附件、呼吸机、空压机、为窥镜摄像系统、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、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、输液泵、注射泵、营养泵、输液监护管理系统)

深圳迈瑞生物医疗电子股份有限公司光明工厂

统一社会信用代码: 914403003426616186

注册地址: 深圳市光明区玉塘街道南环大道 1203 号

经营地址: 中国广东省深圳市光明区玉塘街道南环大道 1203 号

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、麻醉机和附件、呼吸机、空压机、为窥镜摄像系统、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、液式细胞仪、(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、液式细胞仪用试剂、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)

设计: 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、液式细胞仪、(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、液式细胞仪用试剂、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



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第 3 页共 4 页

环境管理体系认证证书

主证书编号: CN17/31686

此为证书 CN17/31686 译本, 续

深圳迈瑞生物医疗电子股份有限公司

SGS

ISO 14001:2015

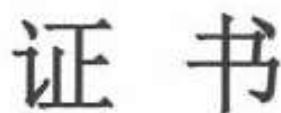
深圳迈瑞科技有限公司
统一社会信用代码: 914403007634515478
注册地址: 深圳市光明区玉塘街道南环大道 1203 号 2 号楼 6 楼
经营地址: 中国深圳市光明区玉塘街道南环大道 1203 号 2 号楼 8 楼
生产: 输液泵, 注射泵, 营养泵, 输液监护管理系统



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第 4 页共 4 页



浙江优亿医疗器械股份有限公司

中国浙江省台州市仙居县白塔镇仙居县经济开发区白塔区块优亿路8号
邮政编码: 317300

在以下适用范围
建立和实施了环境管理体系

视频内窥镜产品（包括可视喉镜、可视软性喉镜、可视硬性喉镜、视频耳镜、视频鼻镜、视频喉镜）及配件、肺活量计、一次性使用喉镜片、一次性使用全包裹镜片、一次性使用喉罩气道导管、一次性使用可视喉罩气道导管、一次性使用气管插管、一次性使用可视气管插管、一次性使用无菌腹腔镜穿刺器、一次性单孔腹腔镜穿刺器、一次性使用内窥镜套管、一次性使用支气管封堵器、一次性医用水凝胶眼贴的研发、生产和销售。

通过审核, 订单编号: 7482341292

证明该体系满足

ISO 14001:2015

的要求。

本证书的有效期限从**2021年12月25日至2024年12月24日**。

证书注册号: 12 104 61964 TMS

Head of Certification Body
蔡元星, 2021年12月20日



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www.tuvsud.com/de-certificate-validity-check

TUV®



Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH
certifies that

Zhejiang UE Medical Corp.
No. 8, Youyi Road, Baita Economic Development Zone,
Baita Town, Xianju County,
Taizhou City, Zhejiang Province, P.R. China
Post Code: 317300

has established and applies
an Environmental Management System for

**Design, Production and Sales for the Video Endoscope Products
(include Video Laryngoscopes, Flexible Videoscope, Video Stylets,
Video Otoscope, Video Nasoscope) and Accessories, Vital Capacity Meter,
Laryngoscope Blade for Single Use, Disposable Medical Laryngeal Masks,
Disposable Tracheal Intubation, Disposable Laparoscopic Puncture Device,
Disposable Endoscopic Cannula, Disposable Bronchial Occluder,
Disposable Medical Hydrogel Eye Patch**

An audit was performed, Order No. 7482341292.

Proof has been furnished that the requirements according to

ISO 14001:2015

are fulfilled.

The certificate is valid from 2021-12-25 until 2024-12-24

Certificate Registration No.: 12 104 61964 TMS

Peri Vell

Head of Certification Body
Munich, 2021-12-20



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www.tuvsud.com/de/certificate-validity-check

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认证证书

苏州好博医疗器械股份有限公司

统一社会信用代码: 91320585569107240F

注册地址: 江苏省太仓市浏河镇紫藤路8号

生产/经营地址: 江苏省太仓市浏河镇紫藤路8号

环境管理体系

符合标准: **GB/T 24001-2016/ISO 14001:2015**

认证范围: 医疗器械组装与销售(资质许可范围内)

初次注册日期: 2022-01-06

发放/改版日期: 2022-01-06

注册编号: KC112F6030E

失效日期: 2025-01-05



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。

以贴在证书上的合格标签表明通过监督审核。

开成认证公司(CNCA-R-2016-215, 地址: 上海市杨浦区宁国路313弄7号602室)依据国家认证认可监督管理委员会准则及上海开成认证有限公司认证规则规定, 发放此证书

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

证书有效状态可登录 (www.shkcrz.com) 查询。



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CERTIFICATION



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签发人

上海开成认证有限公司

中国上海市杨浦区宁国路313弄7号602