



尊敬的客户：

很高兴地通知您，经 SGS 审核员的评审，您所在组织的管理体系的运行符合相关标准要求。

现附上 SGS 管理与保证事业群颁发的电子版证书及纸质证书，请查收。

您可以通过扫描证书上的二维码来验明真伪，您也可以根据不同的使用需要，打印使用电子版证书。

通过 SGS 的认证，您可在信笺和宣传资料中使用 SGS 认证标志及相关认可委的认可标志，以彰显贵司在管理方面取得的成就。为了帮助您了解如何正确使用认证/认可标志，随函附上《SGS 体系认证标志使用规则简易说明》。如果您有任何关于标志使用方面的疑问，请联系您当地的 SGS 客户主任。

如您对我们的服务有任何的意见或建议，敬请发送邮件至 SGS 管理与保证服务事业群组织和服务卓越团队：：CNSGS.integrity@sgs.com。

借此机会，祝贺贵司通过认证，愿贵司未来不断取得成功，SGS 期待着与您长期合作！

Dear Valued Client,

Following the recent assessment by SGS auditors, we are pleased to inform you that the operation of your organization's management system conforms to the requirements of the relevant management system standard.

Please find the attached electronic and paper certificate issued by SGS Business Assurance. You can scan the QR code on the certificate to verify its authenticity, and you can also print and use the electronic version of the certificate according to different needs.

As a SGS certified organization, you are entitled to use the SGS certification marks and the relevant accreditation marks on your letterhead and promotional materials to highlight your organization's achievements in the management system. In order to help you understand how to use the certification/accreditation marks correctly, please find attached a copy of the "Explanation of SGS regulations governing the use of management system certification marks". If you have any questions regarding the use of the Mark, please contact your local SGS Account Executive.

If you have any comments or suggestions about our services, please email the Organizational and Service Excellence Team of SGS Business Assurance at CNSGS.integrity@sgs.com.

We would like to take this opportunity to congratulate you on your certification and wish your continued success in the future. SGS looks forward to working with your in the long term!

此致

Yours faithfully,

辛斌

David Xin

总经理

Senior Director

通标标准技术服务有限公司管理与保证服务事业群

Business Assurance, SGS-CSTC Standards Technical Services Co., Ltd.

此为证书 CN25/00002689 译本



下述组织

武汉迈瑞生物医疗科技有限公司

中国湖北省武汉市东湖新技术开发区高新大道 828 号 5 栋

的管理体系已经过审核，并被证明符合下述要求

ISO 13485:2016

EN ISO 13485:2016

所涉及的活动范围覆盖

重复性使用等离子手术电极、一次性使用等离子手术电极、电切外鞘、电切内鞘、闭孔器、工作手件、硬性光学内窥镜、超声高频集成手术设备、一次性使用超声软组织手术刀头、高频手术设备、一次性软性电子输尿管肾盂内窥镜成像导管和一次性使用电子膀胱肾盂成像导管、内窥镜摄像系统及内窥镜摄像头和医用内窥镜冷光源及导光束的设计、生产、服务和销售

该证书的有效期自 2025 年 04 月 24 日 至 2028 年 04 月 24 日 并须经过符合要求的监督审核保持有效

版本号 1. 初始注册日期 2025 年 04 月 24 日

在其它场所实施的认证活动在后续页面上列出

L. Moran

签署

Liz Moran
Business Manager

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此为证书 CN25/00002689 译本, 续

武汉迈瑞生物医疗科技有限公司



ISO 13485:2016

EN ISO 13485:2016

版本号 1

场所

武汉迈瑞生物医疗科技有限公司

中国湖北省武汉市东湖新技术开发区高新大道 828 号 5 栋

重复性使用等离子手术电极、一次性使用等离子手术电极、电切外鞘、电切内鞘、闭孔器、工作手件、硬性光学内窥镜、超声高频集成手术设备、一次性使用超声软组织手术刀头、高频手术设备、一次性软性电子输尿管肾盂内窥镜成像导管和一次性使用电子膀胱肾盂成像导管、内窥镜摄像系统及内窥镜摄像头和医用内窥镜冷光源及导光束的设计、服务和销售

武汉迈瑞生物医疗科技有限公司

中国湖北省武汉市东湖新技术开发区九龙南路 18 号 B 区

重复性使用等离子手术电极、一次性使用等离子手术电极、电切外鞘、电切内鞘、闭孔器、工作手件、硬性光学内窥镜、超声高频集成手术设备、一次性使用超声软组织手术刀头、高频手术设备、一次性软性电子输尿管肾盂内窥镜成像导管和一次性使用电子膀胱肾盂成像导管、内窥镜摄像系统及内窥镜摄像头和医用内窥镜冷光源及导光束的生产

仅供产品销售备案使用 (2026)



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Certificate CN25/00002689

The management system of

Wuhan Mindray Bio-Medical Scientific Co., Ltd.



Building 5, No.828, Gaoxin Avenue, East Lake High-Tech Development Zone, Wuhan, Hubei, 430206, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design, Manufacture, Service and Sales of Reusable Plasma Electrode, Disposable Plasma Electrode, Resectoscope Outer Sheaths, Resectoscope Inner Sheaths, Obturators, Working Elements, Rigid Endoscope, Ultrasonic Surgical & Electrosurgical Energy Platform, Ultrasonic Surgical Instrument, Electrosurgical Platform, Single-Use Ureteroscope and Single-Use Cysto-Nephroscope, Endoscope Camera System with Camera Head and Endoscope Light Source with Light Cable

This certificate is valid from 24 April 2025 until 24 April 2028 and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 24 April 2025

Certified activities performed by additional sites are listed on subsequent pages.

L. Moran

Authorised by

Liz Moran
Business Manager

SGS United Kingdom Ltd
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Certificate CN25/00002689, continued

Wuhan Mindray Bio-Medical Scientific Co., Ltd.



ISO 13485:2016

EN ISO 13485:2016

Issue 1

Sites

Wuhan Mindray Bio-Medical Scientific Co., Ltd.

Building 5, No.828, Gaoxin Avenue, East Lake High-Tech Development Zone, Wuhan, Hubei, 430206, P.R. China

Design, Service and Sales of Reusable Plasma Electrode, Disposable Plasma Electrode, Resectoscope Outer Sheaths, Resectoscope Inner Sheaths, Obturators, Working Elements, Rigid Endoscope, Ultrasonic Surgical & Electrosurgical Energy Platform, Ultrasonic Surgical Instrument, Electrosurgical Platform, Single-Use Ureteroscope and Single-Use Cysto-Nephroscope, Endoscope Camera System with Camera Head and Endoscope Light Source with Light Cable

Wuhan Mindray Bio-Medical Scientific Co., Ltd.

Zone B, No.18, Jiulong South Road, East Lake High-Tech Development Zone, Wuhan, Hubei, 430206, P.R. China

Manufacture of Reusable Plasma Electrode, Disposable Plasma Electrode, Resectoscope Outer Sheaths, Resectoscope Inner Sheaths, Obturators, Working Elements, Rigid Endoscope, Ultrasonic surgical & Electrosurgical Energy Platform, Ultrasonic Surgical Instrument, Electrosurgical Platform, Single-Use Ureteroscope and Single-Use Cysto-Nephroscope, Endoscope Camera System with Camera Head and Endoscope Light Source with Light Cable



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