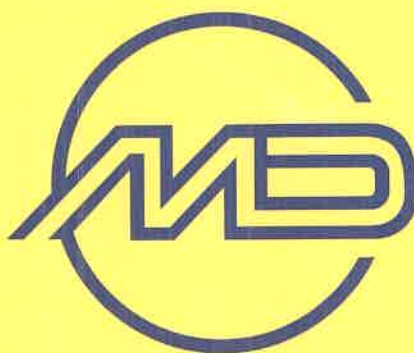




证书编号: 04726Q00341R901

质量管理体系认证证书

兹证明

徐州市科诺医学仪器设备有限公司

(统一社会信用代码: 91320301608015657C)

住 所: 徐州经济开发区科诺大厦(金山桥大厦西隔壁)

生产地址: 徐州经济开发区科诺大厦(金山桥大厦西隔壁); 江苏省徐州市鼓楼区经济技术开发区金山桥开发区工业4区(徐州经济技术开发区金桥路25号)一楼102室

质量管理体系符合:

GB/T 19001-2016 / ISO 9001:2015 《质量管理体系 要求》

体系覆盖:

多参数床边监护仪、阴道镜数码成像系统、紫外线光疗仪、LED光谱治疗仪、医用放大镜、半导体激光治疗仪、光动力治疗仪、皮肤毛发观察仪、鼻腔冲洗与激光治疗仪、弱视综合治疗仪、电动压力喷雾洗鼻器、医用电子体温计、在体反射式共聚焦显微镜、X射线放射治疗系统、回弹式眼压计、盆底肌治疗仪、伍德灯(仅供出口)、毛发生长系统(仅供出口)的设计开发、生产和服务。

磁刺激仪的受托生产。

颁证日期: 2026年07月07日

有效期至: 2029年07月06日

总经理:

北京国医械华光认证有限公司



国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C047-M

注: 获证组织需定期接受监督审核并经审核合格, 此证书方继续有效。本证书信息可在国家认证认可监督管理委员会官方网站 (<http://www.cnca.gov.cn>) 或北京国医械华光认证有限公司网站 (<http://www.cmdc.com.cn>) 上查询。 地址: 北京市东城区安定门外大街甲88号中联大厦第5层 邮编: 100011 电话: 010-62351993



Registration No. 04726Q00341R901

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM

This is to certify that:

Xuzhou Kernel Medical Equipment Co., Ltd.

Registered address: **Kernel Mansion, Economic Development District, Xuzhou City, Jiangsu Province, China**

Manufacturing address 1: **Kernel Mansion, Economic Development District, Xuzhou City, Jiangsu Province, China**

Manufacturing address 2: **(For Superficial X-ray Radiation Therapy System): Room 102, 1st Floor, Industrial Zone 4 (No. 25 Jinqiao Road), Economic and Technological Development District, Xuzhou City, Jiangsu Province, China**

Operates a Quality Management System which complies with the requirements of:

GB/T 19001-2016 / ISO 9001:2015

Quality management systems-Requirements

For the following scope:

The Design Development, Production and Service of Multi-parameter Patient Monitor, Colposcope System, UV Phototherapy, LED Light Therapy Device, Medical Magnifying Lens, Rhinitis Laser Therapy Device, Photodynamic Therapy Device, Skin and Hair Analysis Device, Nasal Irrigation and Laser Therapy Device, Amblyopia Synthetical Therapy Device, Nasal Irrigation Therapy Device, Electronic Thermometer, In Vivo Reflectance Confocal Microscopy, Superficial X-ray Radiation Therapy System, Rebound Tonometer, Pelvic Floor Muscle Rehabilitation Therapy Device, Wood's Lamp, Hair Growth System.

Contract Manufacturing of Pelvic Floor Magnetic Therapy Device.

Date of issue: **July 07, 2026**

Date of expiry: **July 06, 2029**

General manager:

**BEIJING HUA GUANG CERTIFICATION
OF MEDICAL DEVICES CO., LTD.**



**管理体系
MANAGEMENT SYSTEM
CNAS C047-M**

Note: Only certified organizations have received regular supervision audits and resulted in compliance, the certificates would remain valid. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (<http://www.cnca.gov.cn>) or CMD (<http://www.cmdc.com.cn>). Address: 5th floor of Zhong Lian building, No. A88, An Ding Men Wai street, Dongcheng district, Beijing, 100011, P.R. China Telephone: 010-62351993



证书编号: 04726M00341R900

医疗器械 质量管理体系认证证书

兹证明

徐州市科诺医学仪器设备有限公司

(统一社会信用代码: 91320301608015657C)

住 所: 徐州经济开发区科诺大厦(金山桥大厦西隔壁)

生产地址: 徐州经济开发区科诺大厦(金山桥大厦西隔壁); 江苏省徐州市鼓楼区经济
技术开发区金山桥开发区工业4区(徐州经济技术开发区金桥路25号)一楼102室

质量管理体系符合:

GB/T 42061-2022 / ISO 13485:2016

《医疗器械 质量管理体系 用于法规的要求》

体系覆盖:

多参数床边监护仪、阴道镜数码成像系统、紫外线光疗仪、LED光谱治疗仪、医用放
大镜、半导体激光治疗仪、光动力治疗仪、皮肤毛发观察仪、鼻腔冲洗与激光治疗仪、弱
视综合治疗仪、电动压力喷雾洗鼻器、医用电子体温计、在体反射式共聚焦显微镜、X射
线放射治疗系统、回弹式眼压计、盆底肌治疗仪、伍德灯(仅供出口)、毛发生长系统(仅
供出口)的设计开发、生产和服务。

磁刺激仪的受托生产。

颁证日期: 2026年07月07日

有效期至: 2029年07月06日

总经理:

北京国医械华光认证有限公司



注: 认证组织需通过年度监督审核后, 此证书方为持续有效。 本证书信息可在国家认证认可监督管理委员会官方网站(<http://www.cnca.gov.cn>)或北京国医械华光认证有限
公司网站(<http://www.cmdc.com.cn>)上查询。 地址: 北京市东城区安定门外大街甲88号中联大厦第5层 邮编: 100011 电话: 010-62351993



Registration No. 04726M00341R900

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that:

Xuzhou Kernel Medical Equipment Co., Ltd.

Registered address: **Kernel Mansion, Economic Development District, Xuzhou City, Jiangsu Province, China**

Manufacturing address 1: **Kernel Mansion, Economic Development District, Xuzhou City, Jiangsu Province, China**

Manufacturing address 2: **(For Superficial X-ray Radiation Therapy System): Room 102, 1st Floor, Industrial Zone 4 (No. 25 Jinqiao Road), Economic and Technological Development District, Xuzhou City, Jiangsu Province, China**

Operates a Quality Management System which complies with the requirements of:

GB/T 42061-2022 / ISO 13485:2016

Medical devices-Quality management systems-Requirements for regulatory purposes

For the following scope:

The Design Development, Production and Service of Multi-parameter Patient Monitor, Colposcope System, UV Phototherapy, LED Light Therapy Device, Medical Magnifying Lens, Rhinitis Laser Therapy Device, Photodynamic Therapy Device, Skin and Hair Analysis Device, Nasal Irrigation and Laser Therapy Device, Amblyopia Synthetical Therapy Device, Nasal Irrigation Therapy Device, Electronic Thermometer, In Vivo Reflectance Confocal Microscopy, Superficial X-ray Radiation Therapy System, Rebound Tonometer, Pelvic Floor Muscle Rehabilitation Therapy Device, Wood's Lamp, Hair Growth System.

Contract Manufacturing of Pelvic Floor Magnetic Therapy Device.

Date of issue: **July 07, 2026**

Date of expiry: **July 06, 2029**

General manager: 

**BEIJING HUA GUANG CERTIFICATION
OF MEDICAL DEVICES CO., LTD.**



Note: Only certified organizations have received regular supervision audits and resulted in compliance, the certificates would remain valid. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (<http://www.cnca.gov.cn>) or CMD (<http://www.cmdc.com.cn>). Address: 5th floor of Zhong Lian building, No. A88, An Ding Men Wai street, Dongcheng district, Beijing, 100011, P.R. China Telephone: 010-62351993