

中国国际贸易促进委员会
中国国际商会



China Council for the Promotion of International Trade
China Chamber of International Commerce

证明书
CERTIFICATE



号码 No. 251100B0/048383

兹证明：所附文件的影印件与原件相符。

THIS IS TO CERTIFY THAT: the annexed photostated copy of
DOCUMENT is in conformity with the original.



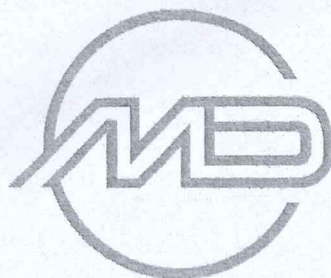
China Council for the Promotion
of International Trade



授权签字:

Authorized
Signature: Gao Lichao

日期: 2025年08月26日
(Date: Aug. 26, 2025)



证书编号: 04725Q10000259

医疗器械 质量管理体系认证证书

兹证明

河南翔宇医疗设备股份有限公司

(统一社会信用代码: 914105277474012089)

住 所: 河南省安阳市内黄县帝誉大道中段

生产地址: 河南省安阳市内黄县帝誉大道中段; 内黄县平安路西段 (康复设备产业园内)
(委托生产地址)

质量管理体系符合:

GB/T 42061-2022 idt ISO 13485:2016

体系覆盖:

见附件

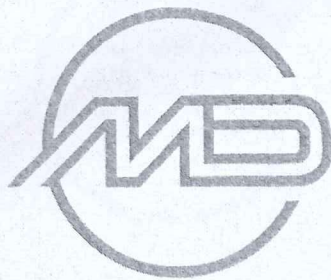
颁证日期: 2025 年 06 月 13 日

有效期至: 2028 年 06 月 12 日

总经理:

北京国医械华光认证有限公司





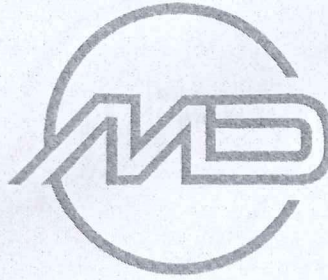
证书编号: 04725Q10000259

附件:

多功能牵引床、颈椎牵引机、颈腰椎治疗多功能牵引床、中药熏蒸治疗机、熏蒸治疗机、远红外理疗床、下肢关节康复器、疼痛光疗仪、低频交变磁场治疗机、电脑中频治疗仪、电针治疗仪、温热电针综合治疗仪、生物陶瓷热敷袋、极超短波治疗机、多体位医用诊疗床、经皮神经电刺激仪、低频脉冲痉挛肌治疗仪、立体动态干扰电治疗仪、减重步态康复平台、空气波压力治疗仪、神经肌肉低频电刺激仪、体外冲击波治疗仪、低频电磁脉冲治疗仪、磁振热治疗仪、低频脉冲磁场治疗机、下肢反馈康复训练系统、腕关节被动活动仪、指关节训练器、上肢关节康复器、多关节主被动训练仪、四肢联动康复训练仪、认知障碍康复评估训练系统、语言障碍康复评估训练系统、平衡功能训练及评估系统、高压低频脉冲治疗仪、吞咽神经和肌肉电刺激仪、离子导入仪、超声波治疗仪、电脑恒温电蜡疗仪、上肢反馈康复训练系统、康复床、红外偏振光治疗仪、短波治疗仪、肌电生物反馈刺激仪、热垫磁疗仪、脉冲磁治疗仪、盆底肌训练仪、紫外线治疗仪、手关节持续被动活动仪、红光治疗仪、低频交变磁场治疗仪、低频脉冲刺激仪、中频脊柱物理治疗系统、踝关节训练器、红外光灸疗机、多功能转运床、经颅磁刺激器、医用电动诊疗床、脊柱减压牵引床、红外频谱热辐射治疗仪、生物反馈助力电刺激仪、减重平衡评估训练系统、脊柱微创减压治疗牵引系统、超短波治疗仪、医用红外热像仪、低频产后康复治疗仪、可穿戴式中频治疗仪、低温冲击镇痛仪、电脑恒温电蜡疗仪、中医艾灸治疗机、深层肌肉刺激仪、红光艾灸仪、肌电生物反馈训练系统、综合物理治疗系统、压电式冲击波治疗仪、督脉熏蒸治疗机、低温冲击镇痛仪、间歇充气加压防治系统、妇科熏蒸治疗机、低周波治疗仪、神经康复肌电生物反馈治疗系统、肌电生物反馈刺激仪、充气式医用升温仪、深层肌肉振动治疗仪、手功能热电治疗仪、便携式低温冲击镇痛仪、气压手功能康复仪、激光低频交变磁场治疗机、上下肢主被动协同康复训练系统、多功能综合电疗系统、多功能清创仪、直立床、垂直振动医用康复训练仪、手功能康复训练仪、电动病床、定向透药治疗仪、红外热辐射治疗仪、超声电导定向透药仪、呼吸训练低频电治疗仪、上下肢主被动康复训练仪、超声治疗仪、全胸振荡排痰机、中频干扰电治疗仪、医用电动病床、电磁刺激治疗仪、等速肌力评估康复训练仪、加压冷热敷治疗仪的设计开发、生产和服务；深层肌肉振动治疗仪的设计开发、生产（注册人制度委托生产）和服务；生物反馈助力电刺激仪的受托生产。

北京国医械华光认证有限公司





Registration No. 04725Q10000259

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that:

Sunnyou Medical Co., Ltd.

Registered address: Middle Section of Diku Road, Neihuang County, Anyang City, Henan Province, 456300, China

Manufacturing address: Middle Section of Diku Road, Neihuang County, Anyang City, Henan Province, 456300, China

Operates a Quality Management System which complies with the requirements of:
GB/T 42061-2022 idt ISO 13485:2016

For the following scope:

See the Attached

Date of issue: June 13, 2025

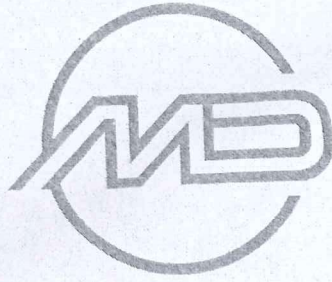
Date of expiry: June 12, 2028

General manager:

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



Note: This certificate will not be continuously valid until the organization has been approved in the annual surveillance audit. The certificate information is available on the website of the certification and accreditation administration of the People's Republic of China (<http://www.cnca.gov.cn>) or the website of CMD (<http://www.cmdc.com.cn>). Address: 5th floor of Zhong Lian building, No. jia88, An Ding Nian Wai street, Dongcheng district, Beijing, 100011, P.R. China Telephone: 010-62351993



Registration No. 04725Q10000259

Attachment:

Design, development, production and service of Multifunctional Traction Table, Cervical Traction Chair, Multifunctional Traction Table for Lumbar and Cervical, TCM Steam Therapy Device, Steam Therapy Device, Far Infrared Massage Bed, Lower Limb CPM, Light Therapy Device, Low Frequency Magnetic Field Therapy Device, Medium Frequency Electrotherapy Device, Electroacupuncture Therapy Device, Warm Electroacupuncture Therapy Device, Bioceramics Hot Pack, Microwave Therapy Device, Treatment Table, T.E.N.S. Hufschmidt Therapy Device, Interferential Current Therapy Device, Gait Training Device, Air Compression Therapy Device, Neuromuscular Electrical Stimulation Device, Extracorporeal Shock Wave Therapy Device, Low Frequency Electromagnetic Pulse Therapy Device, Magnetic Vibration and Heating Therapy Device, Low Frequency Pulse Magnetic Therapy Device, **Lower Limb Rehabilitation System**, Wrist CPM, Finger CPM, Upper Limb CPM, Passive and Active Exerciser, Recumbent Cross Trainer, Cognitive Disorder Rehabilitation Assessment Training System, Language Disorder Rehabilitation Assessment Training System, Balance Training and Evaluation System, High Voltage Low Frequency Pulse Therapy Device, Swallowing Nerve and Muscle Electrical Stimulator, Iontophoresis Device, Ultrasound Therapy Device, Paraffin Wax Therapy Device, Upper Limb Rehabilitation System, Rehabilitation Table, Infrared Polarized Light Therapy Device, Shortwave Therapy Device, EMG Biofeedback Stimulation Device, Hot Magnetotherapy Device, Pulse Magnetic Therapy Device, Pelvic Floor Muscle Training Device, Ultraviolet Radiation Therapy Device, Hand Continuous Passive Motion Device, Red Light Therapy Device, Magnetic Therapy Device, Low Frequency Pulse Stimulator, Spine Stimulator, Ankle Exercise Device, Infrared Light Moxibustion Therapy Device, Multifunctional Nursing Bed, TMS System, PT Training Table, Spinal Decompression Traction Table, Spectrum Therapy Device, Biofeedback Electrical Stimulator, Gait Training Balance Assessment System, Spinal Decompression Traction System, Ultra Shortwave Therapy Device, Medical Infrared Thermal Imager, Low Frequency Postpartum Rehabilitation Device, Wearable Medium Frequency Electrotherapy Device, Cryotherapy Device, Paraffin Wax Therapy Device, TCM Moxibustion Therapy Device, Deep Muscle Stimulator, Red Light Moxibustion Device, EMG Biofeedback Training System, Integrated Physiotherapy System, Focused Shockwave Therapy System, Du Channel Steam Therapy Device, Cryotherapy Device, Intermittent Pneumatic Compression Device, Gynecology Steam Therapy Device, Low Frequency Electrotherapy Device, Neurorehabilitation EMG Biofeedback Treatment System, EMG Biofeedback Stimulation Device, Pneumatic Medical Warming Unit, Deep Muscle Vibration Therapy Device, Hand Electrical Stimulator, Portable Cryogenic Analgesia Device, Pneumatic Hand Rehabilitation Device, High Energy Inductive Therapy System, Active and Passive Rehabilitation Training System for Upper and Lower Limbs, Multifunctional Electrotherapy System, Multifunctional Debridement Device, Tilt Table, Sonic Wave Vibration Therapy System, Hand Rehabilitation Device, Electrical Hospital Bed, Oriented Drug Penetration Therapy Device, Infrared Radiation Therapy Device, Ultrasonic Drug Delivery Device, Breathing Training Low Frequency Electrotherapy Device, Passive and Active Exerciser for Upper and Lower Limbs, Ultrasound Therapy Device, Oscillatory Expectoration Device, MF Interferential Current Therapy Device, Electrical Hospital Bed, Electromagnetic Stimulation Therapy Device, Isokinetic Muscle Strength Assessment Rehabilitation Training Device, Hot and Cold Compression Therapy Device.

Design, development, production (commissioned production by the registrant system) and service of Deep Muscle Vibration Therapy Device.

Commissioned production of Biofeedback Electrical Stimulator.

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



Note: This certificate will not be continuously valid until the organization has been approved in the annual surveillance audit. The certificate information is available on the website of the certification and accreditation administration of the People's Republic of China (<http://www.cnca.gov.cn>) or the website of CMD (<http://www.cmdc.com.cn>). Address: 5th floor of Zhong Lian building, No. jia88, An Ding Men Wai street, Dongcheng district, Beijing, 100011, P.R. China Telephone: 010-62351993

认字第250000387839号



兹证明前面文书上中国国际贸易促进委员会印章和授权签字人高丽超的签字属实。




中华人民共和国外交部
 领事司一等秘书
 二〇二五年八月二十八日

韩斌


 04820496





ĐẠI SỨ QUÁN NƯỚC CHXHCN VIỆT NAM TẠI CHND TRUNG HOA
 Embassy of the S.R. of Viet Nam in the P.R. of China

CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

1. Quốc gia : VIỆT NAM Country: Viet Nam
 Giấy tờ, tài liệu này/ This public document

2. do Ông(Bà) Han binh ký
 has been signed by


3. với chức danh/ acting in the capacity of
bí thư thư Nhất

4. và con dấu của Vụ Lãnh sự, Bộ Ngoại giao Trung Quốc/bears
 the seal/stamp of Consular Dept of MOFA of the P.R. of China
 được chứng nhận/hợp pháp hóa lãnh sự/ Certified

5. tại Bắc Kinh/at Beijing 6. Ngày/the 29/8 /2025

7. Cơ quan cấp: Đại sứ quán nước CHXHCN Việt Nam tại CHND
 Trung Hoa/By the Embassy of the S.R. of Viet Nam in the P.R. of China

8. Số/No 26116 /2025
 KT. Đại sứ /For the Ambassador
 Công sứ/Minister


 Ninh Thành Công

