



Product Service

认证证书

Q5 122071 0001 Rev. 00

证书持有者：

湖北益健堂科技股份有限公司

中华人民共和国武汉东湖新技术开发区光谷大道58号关南福星医药园
7幢8层1-4号房（自贸区武汉片区）430074

认证标志：



认证范围：

设计，开发，生产和分销：

**半导体激光治疗仪，低频脉冲治疗仪，疼痛治疗仪，
LED治疗仪，高电位治疗仪，毫米波治疗仪，
制氧机，生发仪，指甲清洁激光设备**

认证机构TÜV SÜD产品服务有限公司证明上述公司已经建立并运行了满足所列标准要求的质量管理体系。

TÜV 南德集团检测、认证、审定与核查准则所有适用要求也须得到遵守。详情及证书有效期请见

www.tuvsud.com/ps-cert?q=cert:Q5 122071 0001 Rev. 00 0001 Rev. 00

报告号：

SH23219701

生效期：

2024-04-23

有效期：

2027-04-22

Christoph Dicks

发证日期， 2024-04-23

Head of Certification/Notified Body

认证证书

Q5 122071 0001 Rev. 00

认证标准：

ISO 13485:2016

(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)

医疗器械 - 质量管理体系 - 用于法规的要求

生产场地：

湖北益健堂科技股份有限公司

中华人民共和国武汉东湖新技术开发区光谷大道58号关南福星医药园7幢8层
1-4号房（自贸区武汉片区）430074

设计、开发和分销：

半导体激光治疗仪，低频脉冲治疗仪，疼痛治疗仪，LED治疗仪，
高电位治疗仪，毫米波治疗仪，制氧机，生发仪，
指甲清洁激光设备

湖北泽生康医疗科技有限公司

中华人民共和国湖北省鄂州市葛店开发区东湖路68号 436032

生产：

半导体激光治疗仪，低频脉冲治疗仪，疼痛治疗仪，LED治疗仪，
高电位治疗仪，毫米波治疗仪，制氧机，生发仪，
指甲清洁激光设备



Product Service

Certificate

No. Q5 122071 0001 Rev. 00

Holder of Certificate: **Hubei YJT Technology Co.,Ltd.**

Room 1-4, 8F, Block 7
Guannan Fuxing Pharmacel Park
No.58, Optics Valley Avenue
East Lake High-tech Development Zone
(Free Trade Zone, Wuhan area)
430074 Wuhan
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

Design, Development, Production and Distribution of Semiconductor Laser Treatment Instruments, Low-Frequency Pulse Treatment Instruments, Pain-relief Device, LED Treatment Instrument, High Electrical Potential Therapeutic Apparatus, Millimeter Waves Therapy Equipment, Oxygen Concentrators, Hair growth device, Nail cleaning laser device

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 122071 0001 Rev. 00

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Date, 2024-04-23

Christoph Dicks

Head of Certification/Notified Body

Certificate

No. Q5 122071 0001 Rev. 00

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **Hubei YJT Technology Co.,Ltd.**
Room 1-4, 8F, Block 7, Guannan Fuxing Pharmacei Park, No.58,
Optics Valley Avenue, East Lake High-tech Development Zone,
(Free Trade Zone, Wuhan area), 430074 Wuhan, PEOPLE'S
REPUBLIC OF CHINA

Design, Development and Distribution of Semiconductor Laser
Treatment Instruments, Low-Frequency Pulse Treatment
Instruments, Pain-relief Device, LED Treatment Instrument, High
Electrical Potential Thearapeutic Apparatus, Millimeter Waves
Therapy Equipment, Oxygen Concentrators, Hair growth device,
Nail cleaning laser device

Hubei ZSK Medical Technology Co.,Ltd.
No.68, Donghu Road, Gedian Development Zone, 436032 Ezhou
City, Hubei Province, PEOPLE'S REPUBLIC OF CHINA

Production of Semiconductor Laser Treatment Instruments, Low-
Frequency Pulse Treatment Instruments, Pain-relief Device, LED
Treatment Instrument, High Electrical Potential Thearapeutic
Apparatus, Millimeter Waves Therapy Equipment, Oxygen
Concentrators, Hair growth device, Nail cleaning laser device

Certificate

No. Q5 122071 0001 Rev. 00

Holder of Certificate: Hubei YJT Technology Co.,Ltd.

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East Lake High-tech Development Zone
(Free Trade Zone, Wuhan area)
430074 Wuhan
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



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