EC Certificate Production Quality Assurance System: Certificate
CN16/20895

The management system of

Hubei YJT Technology Co., Ltd.

Room 1~8, 8F, Block7, Guannan Fuxing Pharmaceutical Park,
No. 62 Optical Valley Ave, East Lake High-tech Development Zone,
Wuhan, Hubei Province, P.R.China

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

For the following products

The scope of registration appears on page 2 of this certificate

This certificate is valid from 16 August 2018 until 26 July 2023
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 08 March 2021
Issue 2. Certified since 15 July 2016

Certification is based on reports numbered CN/WUH 4984

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
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SGS CE 13 0311 M2

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中华人民共和国
PEOPLE’S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号： 鄂武汉食药监械出 20240187
Certificate NO.： 鄂武汉食药监械出 20240187

产品名称： 激光生发仪
Product(s): Hair growth device

规格型号： YJT-01
Model: YJT-01

产品注册或备案凭证号： 鄂械注准 20232094522
Registration certificate(s): 鄂械注准 20232094522

生产企业： 湖北益健堂科技股份有限公司
Manufacturer： Hubei YJT Technology Co., Ltd

生产企业住所： 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)
Address of manufacturer: Room 1-4, Floor 8, Building 7, Guannan Fuxing Pharmacel Park, No.58, Optics Valley Avenue, East Lake High-tech Development Zone, Wuhan ， China (Free Trade Zone,wuhan area)

生产许可或备案凭证号： 鄂药监械生产许 20221191 号
Manufacturing License(s): 鄂药监械生产许 20221191 号

兹证明上述产品已准许在中国生产和销售。
This is to certify that the above products have been registered to be manufactured and sold in China.

证明有效日期至： 2026-09-25
This certification valid until: 2026-09-25

备注： /
Remark： /

湖北省药品监督管理局
2024-09-26

U.S. FOOD & DRUG ADMINISTRATION

October 24, 2023

Hubei YJT Technology Co.,Ltd
% Gamma Zhang
RA Manager
Shenzhen Tacro Medical technology services Co., Ltd.
Suite 405, Bldg. A Nanfeng, No.4093 Liuxian Blvd., Nanshan Dist.
Shenzhen, Guangdong 510000
China

Re: K232356
Trade/Device Name: Laser Cap, Model: Hat-01
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: August 7, 2023
Received: August 7, 2023

Dear Gamma Zhang:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of

U.S. FOOD & DRUG ADMINISTRATION

May 23, 2023

Hubei YJT Technology Co.,Ltd
% Gamma Zhang
RA Manager
Tacro Guangzhou Branch
Rm. 501, No.55 West Tiyu Rd., Tianhe Dist., Guangzhou
Guangdong
Guangzhou, Guangdong 510000
China

Re: K230134
Trade/Device Name: Laser Therapy Hair Growth Comb, Model: Lasercomb-001 & Lasercomb-002
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: April 7, 2023
Received: April 7, 2023

Dear Gamma Zhang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate CN23/00005469

The management system of

Hubei YJT Technology Co., Ltd.

Unified Social Credit Code: 91420100771357198Q

Business Registration Address: Room 1~4, 8F, Block7, Guannan Fuxing Pharmaceutical Park, No. 58 Optical Valley Ave, East Lake High-tech Development Zone, Wuhan, Hubei Province, P.R. China (Free Trade Zone, Wuhan Area)

Business Operation Address: Room 1~4, 8F, Block7, Guannan Fuxing Pharmaceutical Park, No. 58 Optical Valley Ave, East Lake High-tech Development Zone, Wuhan, Hubei Province, P.R. China (Free Trade Zone, Wuhan Area)

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

Design and Manufacturing 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 Concentrator, Hair growth device and Nail cleaning laser device

This certificate is valid from 15 October 2023 until 14 October 2026 and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 15 October 2023
Certified activities performed by additional sites are listed on subsequent pages.

Authorised by
Jonathan Hall
Global Head - Certification Services

SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
t +44 (0)151 350-6666 - www.sgs.com

The certification information can be verified on the web site of Certification and Accreditation Administration of the People's Republic of China www.cnca.gov.cn

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