Certificate

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

TÜVRheinland

Registration No.: HD 60145599 0001
Report No.: 15087436 013

Manufacturer:
Shanghai Apolo Medical
Technology Co., Ltd.
Room 301-310, Building 11
No. 388, Yindu Road, Xuhui District
200231 Shanghai
P.R. China

Products: Medical Devices
(see attachment for products included)
Replaces Approval, Registration No.: HD 60140612 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-03-31
Date: 2020-03-31

Notified Body
Jason Pan

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC certificate 93/42/EEC

Certificate

TÜVRheinland

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2058336-1

Organization:
Shanghai Apolo Medical Technology Co., Ltd.
Room 301-310, Building 11,
No. 388, Yindu Road, Xuhui District,
200231 Shanghai
P.R. China

Scope: Design and Development, Manufacture and Distribution of Diode Laser Therapy Devices, Intense Pulsed Light Skin Surface Treatment Systems, Dermatological Frequency-doubled (Nd:YAG) Solid-state Laser Systems, Multi-modality Skin Surface Treatment Systems, Skin Photodynamic Therapy Systems, Dermatological Dye Laser Systems, Multiple Surgical CO2 Laser Systems

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 244361207-200
Effective date: 2021-12-29
Expiry date: 2024-12-28
Issue date: 2021-12-12

Dipl.-Ing. W. Hsu
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

1 / 1

EN ISO 13485

Business Stream Products
Certification Department

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TÜV Rheinland LGA Products GmbH • 51105 Köln

Shanghai Apolo Medical Technology Co., Ltd.
Building 11, Lane 1566, Nanle Road, Songjiang District,
201613 Shanghai,
P.R. China

Contact
Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com
Date April 25, 2024

Notified Body Confirmation Letter
Reference. : 326006571

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Shanghai Apolo Medical Technology Co., Ltd.
Building 11, Lane 1566, Nanle Road, Songjiang District,
201613 Shanghai,
P.R. China
SRN Number (if available): CN-MF-000002904

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by March 20, 2023 for the relevant devices.

TÜV Rheinland
LGA Products GmbH

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Germany

Headquarter

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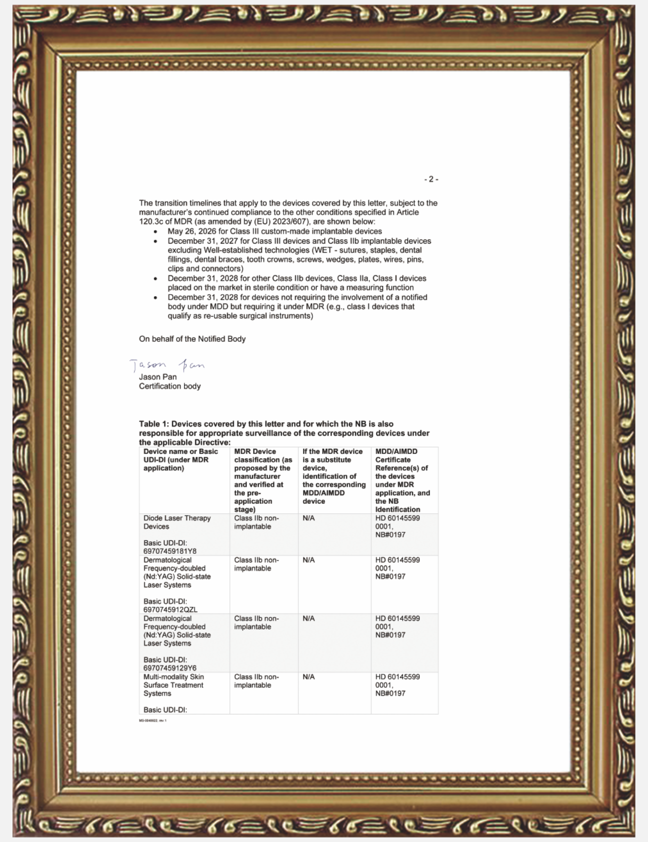


- 2 -

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body

Jason Pan
Jason Pan
Certification body

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Diode Laser Therapy Devices Basic UDI-DI: 69707459181Y8	Class IIb non-implantable	N/A	HD 60145599 0001, NB#0197
Dermatological Frequency-doubled (Nd:YAG) Solid-state Laser Systems Basic UDI-DI: 6970745912QZL	Class IIb non-implantable	N/A	HD 60145599 0001, NB#0197
Dermatological Frequency-doubled (Nd:YAG) Solid-state Laser Systems Basic UDI-DI: 69707459129Y6	Class IIb non-implantable	N/A	HD 60145599 0001, NB#0197
Multi-modality Skin Surface Treatment Systems Basic UDI-DI:	Class IIb non-implantable	N/A	HD 60145599 0001, NB#0197

Extension confirmation letter by TUV Rheinland

Certificate

Certificate

TÜVRheinland

Certificate No.: MD 2058336-1-1
Manufacturer: **Shanghai Apolo Medical Technology Co., Ltd.**
Building 11, Lane 1566, Nanle Road, Songjiang District,
201613 Shanghai
P.R. China
REPs Facility ID: F007106
Certification criteria:
ISO 13485:2016
Australia Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure
Brazil RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021, RDC ANVISA n. 67/2009
Canada Medical Devices Regulations – Part 1 – SOR 98/282
Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act (as applicable)
United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D
Scope: Design and Development, Manufacture and Distribution of Diode Laser Therapy Devices, Intense Pulsed Light Skin Surface Treatment Systems, Dermatological Frequency-doubled (Nd:YAG) Solid-state Laser Systems, Multi-modality Skin Surface Treatment Systems,Skin Photodynamic Therapy Systems, Dermatological Dye Laser Systems, Multiple Surgical CO2 Laser Systems, Ultrasonic Skin Contouring Systems

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.: 244308845-200
Issue Date: 2024-04-15
Effective Date: 2024-04-15
Expiry Date: 2027-04-14

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: Samuel Qin
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com or calling 1-888-743-4652.

Page 1 of 1

TUV Rheinland of North America, Inc., 400 Beaver Brook Road, Boxborough, MA 01719, USA
Tel: (925) 249-9123, Fax: (925) 249-9124

MDSAP

FDA U.S. FOOD & DRUG ADMINISTRATION

January 28, 2022

Shanghai Apolo Medical Technology Co., Ltd.
Felix Li
RA Supervisor
Room 301-310, Building 11, No.388, Yindu Road, Xuhui District
Shanghai, Shanghai 200231
China

Re: K203395
Trade/Device Name: Platform treatment system
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: ONF, GEX
Dated: October 21, 2021
Received: November 1, 2021

Dear Felix Li:

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.

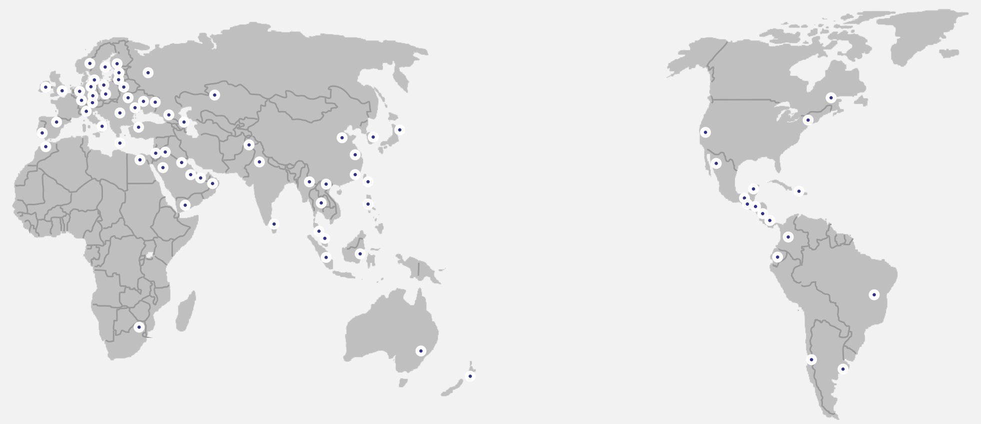
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

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

FDA K203395 HS-900

Sales Network

Today, we deliver our innovative products and services to over 80 countries worldwide through our network of 115 partners. With our extensive international presence, we are proud to offer you our products and solutions right to your doorstep.



Apolo

ISO 13485

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Shanghai Apolo Medical Technology Co.,Ltd.

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CE CE0197 TGA NMPA

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ANVISA

U.S.FDA(510K)

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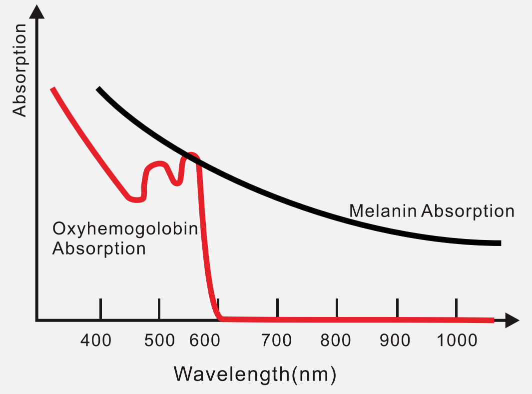
1064nm Long pulse Nd:YAG laser (Hair Removal)

The latest innovation in laser hair removal is the use of a long-pulse Nd:YAG laser at 1064 nm, which safely passes through the epidermis to the underlying layers. Hair follicles are eliminated by a process known as selective photothermolysis, meaning the hair can be treated without harming the surrounding skin. The 1064 nm wavelength targets the follicular germ cells in the hair shaft and bulb. Once the melanin absorbs this energy, the hair can then be destroyed. Applications include hair removal, vascular lesions, and leg veins.



1064/532nm Q-Switched Nd:YAG Laser (Pigmented Lesions)

Tthe special wavelengths of the Q-switched Nd:YAG laser can penetrate the skin based on the principle of “selective photothermolysis.” The instrument uses laser energy to break chromophores into pieces which can be naturally absorbed by the body, in order to achieve the purpose of freckle removal. The 1064nm wavelength shatters and removes black and blue pigments, while the 532nm wavelength targets red, pink, purple, and brown pigments in tattoos or other pigmented lesions without damaging normal tissue. Applications include tattoo removal, pigmented epidermal and dermal lesions, and vascular lesion removal

1540nm Er:Glass Fractional Laser (Non-ablative)

The Er:Glass laser system emits a 1540 nm erbium-glass laser beam and splits it into a number of microscopic beams, producing tiny dots (fractional treatment zones) within the selected target skin area and leaving the surrounding skin unaffected. The heat generated by the laser penetrates deep into the fractionally damaged area.

This allows the skin to heal much faster than if the whole area were treated. During the skin’s self-resurfacing, a large amount of collagen is produced to rejuvenate the skin; eventually, the skin looks healthy and young. Applications include skin resurfacing, melasma, wrinkles, post-inflammatory hyperpigmentation, and surgical & acne scar removal.


10x10pixel 18x18pixel

1540nm Er:Glass Fractional Laser (Microbeam)

Application

1550/1927nm Fiber Laser

Skin rejuvenation, Skin resurfacing, Wrinkle reduction, Skin toning and tightening, Stretch mark improvement, Acne scar correction, Stimulated hair growth.

1064/532nm EO Q-S Nd:YAG Laser (Microbeam)

Precise ablation of skin tissue, stimulate collagen regeneration and skin resurfacing.

Microlens tip: 7x7pixel, 10x10 pixel, Collimating lens, Array lens, Long pulse lens

1064nm Long Pulse Nd:YAG Laser

Permanent Hair Removal for all skin types, leg Veins and telangiectasi, Vascular lesion, wrinkle Removal

2940nm Er:YAG Fractional Laser (Microbeam)

Precise ablation of skin tissue, stimulate collagen regeneration and skin resurfacing.

Microlens tip: 7x7pixel, 9x9 pixel, Beam expander tip: Φ6mm,Φ9mm, Zoom lens tip：Φ1~3.5mm

1540nm Er:Glass Fractional Laser (Microbeam)

Penetrates the dermis to stimulate collagen regeneration, achieve skin lifting, wrinkle removing and rejuvenating.
Microlens tip: 10x10 pixel, 18x18 pixel

1064/532nm EO Q-Switched Nd:YAG Laser

For unwanted tattoos, pigmented lesions (brown spots, age spots, etc.), vascular lesions, spider veins, toenail fungus, non-ablative skin rejuvenation (carbon peeling)

Diode laser

Permanent hair removal, Whole body and facial skin rejuvenation.
Laser output: 1600W
Spot size: 12x20mm, 12x14mm/12x30mm

IPL

Skin care and rejuvenation, permanent hair removal, vascular treatment, dispel epidermal pigmentation, spots and freckles, acne removal, skin lifting and firming.

HS-900

2940nm Er:YAG Fractional Laser (Ablative)

The 2940nm Er:YAG laser was chosen for its high ablation efficiency. Because of high absorption by the target chromophore (water) at the 2940nm wavelength, the skin is quickly heated and instantly ablated with minimal thermal damage. The treatment features a shallow exposure depth; therefore, the affected area can heal almost immediately. Applications include skin resurfacing, melasma, wrinkles and fine lines, and wart and nevus removal.

Microbeam Array Technology will emit energy uniformly distributed laser dot matrix, which effectively remove pigments without damaging surrounding tissues.


7x7pixel 9x9pixel

Microbeam tip(10x10mm)

Beam expander
(ϕ6mm)

Beam expander
(ϕ9mm)

Zoom lens
(ϕ1mm~3.5mm)

Multi-function light-based device

A simple and affordable approach to a wide variety of cosmetic and aesthetic procedures, with fewer risks and superior outcomes. The versatile platform provides a wide range of applications without investing in multiple laser systems. With the Apolomed platform, different technologies can be purchased and incorporated at different times, offering versatility and convenience to customers.

U.S.FDA 510K
K203395

TUV Rheinland
CERTIFIED

CE0197

1550+1927nm Laser

The 1927nm laser is mainly suitable for superficial skin problems. Laser has minimal damage to the skin with a short recovery time. When used in combination with 1550nm laser, it can achieve full layer treatment for different skin layers (superficial pigments and deep wrinkles/scars).

Shapes adjust buttons on all applicators, making easy & friendly operation during treatment.
The doctor can easily switch and view the shape of the treatment graph from the handpiece OLED.

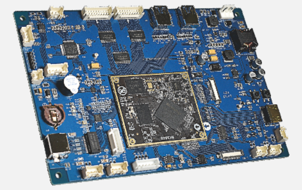
Multiple Advantages

- Interlock design ensures a safe treatment environment.
- Friendly one-finger touch screen with Standard and Professional modes.
- Modular design for convenient maintenance.

Advanced Medical Power Supply (IGBT)

- The working frequency of the IGBT power supply can reach several hundred kHz, and its response time is on the order of tens of nanoseconds.
- IGBT modules offer high integration, smaller size, and lighter weight.
- IGBT power conversion efficiency is higher, with lower power loss and heat generation.

Advanced operating system



- ARM-A13 CPU, Android O/S 11, 2K HD screen.
- Supports 16 languages and features a color touch screen interface.
- Easily adjustable treatment parameters ensure simple and precise operation.

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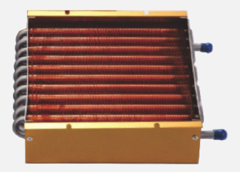
Advanced Cooling System Components

The powerful built-in heat dissipation device improves the machine’s heat dissipation efficiency, ensuring a stable working state and extending the machine’s service life.


TEC water-tank cooling system


Advanced radiator system


Compressor (optional)