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 Zertifizierungsstelle TÜVRheinland®

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.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
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:

- Diode Laser Therapy Devices
- Dermatological Frequency-doubled (Nd:YAG) Solid-state Laser Systems
- Multi-modality Skin Surface Treatment Systems
- Skin Photodynamic Therapy Systems
- Dermatological Dye Laser Systems
- Intense Pulsed Light Skin Surface Treatment Systems
- Multiple Surgical CO2 Laser Systems

Notified Body

Jason Pan

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Date: 2020-03-31