

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

**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.

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 1/1, Rev. 0

**Attachment to  
Certificate**

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**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

**Date:** 2020-03-31

**Notified Body**

*Jason Pan*  
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Jason Pan

