EC Certificate

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

Registration No.: HD 60145283 0001

Report No.: 50272755 002

Manufacturer:

Zhuolu Jontelaser Manufacturing
Technology Co., Ltd.
No.31, Sanguanmiao Alley, Zhuolu Town
Zhangjiakou
075600 Hebei
P.R. China

Products:

Dermatological Diode Laser Systems
Dermatological Carbon Dioxide Laser Systems

(see attachment for additional site included)

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: 2020-02-17

Date: 2020-02-17

Notified Body

TÜV Rheinland LGA Products GmbH

Jason Pan

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.

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

Attachment to Certificate
Registration No.: HD 60145283 0001
Report No.: 50272755 002

Manufacturer:
Zhuolu Jontelaser Manufacturing Technology Co., Ltd.
No.31, Sanguanmiao Alley, Zhuolu Town
Zhangjiakou
075600 Hebei
P.R. China

Site included:
Hebei Jontelaser Electronic Technology Co., Ltd.
YanLu Village East,Zhuolang Road,Development Zone,Zhuozhou City, 072750,Hebei Province,China

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2020-02-17

Jason Pan

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