

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

Registration No.: HD 60126154 0001

Report No.: 15096242 001

Manufacturer: Weifang KM Electronics Co., Ltd.
No. 7999, Health East Street
High-tech District
Weifang City
261205 Shandong
China

Products: Dermatological Diode Laser Systems

Expiry Date: 2023-01-28

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: 2018-01-29

Date: 2018-01-29



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.

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
Weifang KM Electronics Co., Ltd.
No. 7999, Health East Street
High-tech District
Weifang City
261205 Shandong
China

has established and applies a quality management system for medical devices
for the following scope:

**Design and Development, Manufacture and Distribution of
Diode Laser Treatment Systems**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-01-29
Certificate Registration No.: SX 60126155 0001
An audit was performed. Report No.: 15096242 001
This Certificate is valid until: 2021-01-28

Certification Body



Date 2018-01-29



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail cert-validity@de.tuv.com <http://www.tuv.com/safety>

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Weifang KM Electronics Co., Ltd.
No. 7999, Health East Street
High-tech District
Weifang City
261205 Shandong
China

has established and applies a quality management system
for the following scope:

Design and Development, Manufacture and Distribution of
Diode Laser Treatment Systems
(This certificate information can be searched on CNCA
official website <http://www.cnca.gov.cn>)

Proof has been furnished that the requirements specified in

EN ISO 9001:2008

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-01-29
Certificate Registration No.: SY 60126156 0001
An audit was performed. Report No.: 15096242 001
This Certificate is valid until: 2018-09-14

Certification Body

Date 2018-01-29



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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