APPROVAL

EC Directive 93/42/EEC Annex II, Article 3
Full Quality Assurance System
Medical Devices

Registration No.: HD 60028063 0001

Report No.: 16700744 004

Manufacturer:
Beijing Honkon Technologies
Co., Ltd.
No.3 Building, No.11 Yard,
Kangding Street, BDA

100176 Beijing
China

Scope:
Design and Development, Manufacture of Laser Therapy Systems and Photo Therapy Systems

Replaces Approval, Registration No.: HD 60016545 0001

Date of Expiry: 03.01.2012

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Notified Body

Date 25.01.2010

Dipl.-Ing. D. Meier

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. 0197 to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE

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Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Beijing Honkon Technologies Co., Ltd.
No.3 Building, No.11 Yard, Kangding Street, BDA

100176 Beijing
China

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

Design and Development, Manufacture and Distribution of Laser Therapy Systems and Photo Therapy Systems

Proof has been furnished that the requirements specified in

EN ISO 13485:2003 + AC:2007

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

Certificate Registration No.: SX 60028064 0001

An audit was performed. Report No.: 16700744 004

This Certificate is valid until: 03.01.2012

Akkreditiert durch
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-ZQ-995.00.01-46

Certification Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 25.01.2010

Dipl.-Ing. D. Meier

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TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Beijing Honkon Technologies Co., Ltd.
No.3 Building, No.11 Yard, Kangding Street, BDA

100176 Beijing
China

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

Design and Development, Manufacture and Distribution of Laser Therapy Systems and Photo Therapy Systems

Proof has been furnished that the requirements specified in

EN ISO 9001:2008

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

Certificate Registration No.: SY 60028065 0001

An audit was performed. Report No.: 16700744 004

This Certificate is valid until: 03.01.2012

Certification Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date 25.01.2010

Dipl.-Ing. D. Meier

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