

# 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

Date 25.01.2010

Certification Body



Dipl.-Ing. D. Meier

**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

**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

Date 25.01.2010

Certification Body



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**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.

**Date** 25.01.2010

Notified Body



**TÜVRheinland**  
LGA Products GmbH  
Zentralstelle


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**

<b>Product Description Form</b>	 <b>TÜVRheinland®</b> Precisely Right.
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**93/42/EEC** ☒  
 Please list only class I (sterile or with measuring function), class IIa, IIb, III

**90/385/EEC** ☐

**98/79/EC** ☐  
 Please list only  
 List A/List B/self-testing device

**Note: If needed, please use additional sheets for additional information!**


<b>Only if applicable: Date of "Application for conformity Assessment Procedure" for EC Type-Examination or EC Design-Examination</b>	N.A.
<b>Date of "Application for conformity Assessment Procedure" for Quality Management Systems</b> (according to MDD, Annex II, V, VI; AIMD, Annex 2 or IVDD, Annex IV or VII) <b>or EC Verification</b>	2009. 8. 1

<b>EC Certificate Registration No.</b> Please enter certificate registration number from TRPS, if available	<b>HD 60016545 0001</b>
<b>Legal Manufacturer</b> Please enter complete name and address of the legal manufacturer for this product	<b>Beijing Honkon Technologies Co., Ltd.</b> <b>No.3 Building, No.11 Yard, Kangding Street, BDA, 100176, Beijing , P.R.China</b>

<b>Product group</b>	<b>Photo Therapy Systems</b>
<b>UMDNS Number</b> For In-vitro-Diagnostics the EDMS-Classification shall be used if possible	13-037
<b>Short Name of product:</b>	IPL (Intense Pulsed Light Photo rejuvenation)
<b>Product Name(s)</b> <b>List of Sizes/Models/Article No</b>	Intense Pulsed Light Photo rejuvenation YILIYA-GG+, YILIYA-GG-, YILIYA-GA-, YILIYA-GB-, YILIYA-GC-, YILIYA-GD-, YILIYA-GD+, YILIYA-GE-, YILIYA-GM80E
<b>Classification Rule</b> According to Annex IX, MDD or the classification according to the IVDD (List A/List B/self-testing device)	Class IIa, Rule 9, Annex IX, MDD

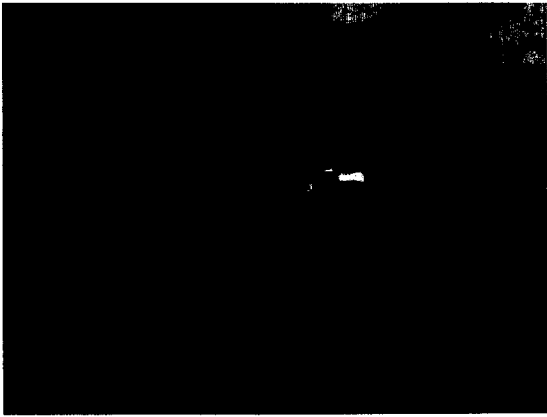
<b>OEM Product</b>	no <input checked="" type="checkbox"/>	Applicable certificate attached <input type="checkbox"/> OEM Contract dated
	yes <input type="checkbox"/>	


**Product Description Form for product**

<b>Product Description Form</b>	 <b>TÜVRheinland®</b> Precisely Right.
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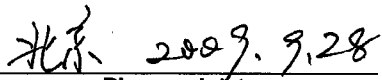
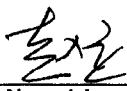
**Note: If needed, please use additional sheets for additional information!**

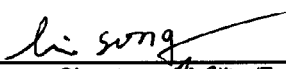
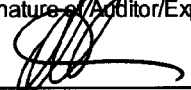
<b>Manufacturing facilities</b> <small>Please enter name and address of all manufacturing facilities involved(also for final packaging, labeling and final testing), as well as OEM manufacturing facilities</small>	<b>Facility of research and development</b> <small>Please enter complete name and address of the places of research and development for this product</small>	<b>Sterilization facility and sterilization method</b> <small>Please enter complete name and address of the sterilization facilities and the sterilization method for this product</small>
<b>Beijing Honkon Technologies Co., Ltd.</b> No.3 Building, No.11 Yard, Kangding Street, BDA, 100176, Beijing , P.R.China	<b>Beijing Honkon Technologies Co., Ltd.</b> No.3 Building, No.11 Yard, Kangding Street, BDA, 100176, Beijing , P.R.China	<b>N.A.</b>


<b>Intended use</b> <small>Please attach additionally the instruction for use</small>	YILIYA-G Skin Rejuvenator is used for the purpose of treatment because it can eliminate freckle and senile plaque, tighten skin, minimize slight wrinkle, blockade superficial telangiectasia and restrain growth of hair for a long term.
<b>Product description</b> <small>Drawings, photo documentation, excerpt out of brochure attached</small>	

<b>Product Description Form</b>	 <b>TÜVRheinland®</b> Precisely Right.
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<b>All standards applied</b>  Please list all standards used (per product) or add a separate signed standard list per product	EN 980: 2008 EN 1041:2008 EN ISO 14971:2007 EN 60601-1:1990+ A1+ A2 EN 60601-1-2:2007 EN 60601-1-4:1996+ A1 EN 60601-1-6:2007 EN ISO 10993-1:2003 EN ISO 10993-5:1999 EN ISO 10993-10:2002+A1:2006
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 Place and date	 Name/signature of the Company's Representative
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Section for TRPS use only			
<b>Verified by</b>			
Auditor/Expert	<u>LIU SONG</u> Name	<u>2009-9-28</u> Date	 Signature of Auditor/Expert
Certification Department	<u>D. Nie</u> Name	<u>2010-01-05</u> Date	 Signature of Certifier

<b>Product Description Form</b>	 <b>TÜVRheinland®</b> Precisely Right.
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**93/42/EEC** ☒  
 Please list only class I (sterile or with measuring function), class IIa, IIb, III

**90/385/EEC** ☐

**98/79/EC** ☐  
 Please list only  
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**Note: If needed, please use additional sheets for additional information!**

<b>Only if applicable: Date of "Application for conformity Assessment Procedure" for EC Type-Examination or EC Design-Examination</b>	N.A.
<b>Date of "Application for conformity Assessment Procedure" for Quality Management Systems</b> (according to MDD, Annex II, V, VI; AIMD, Annex 2 or IVDD, Annex IV or VII) <b>or EC Verification</b>	2009. 8. 1

<b>EC Certificate Registration No.</b> Please enter certificate registration number from TRPS, if available	HD 60016545 0001
<b>Legal Manufacturer</b> Please enter complete name and address of the legal manufacturer for this product	Beijing Honkon Technologies Co., Ltd. No.3 Building, No.11 Yard, Kangding Street, BDA, 100176, Beijing , P.R.China

<b>Product group</b>	Laser Therapy Systems
<b>UMDNS Number</b> For In-vitro-Diagnostics the EDMS-Classification shall be used if possible	16-943
<b>Short Name of product:</b>	
<b>Product Name(s)</b> <b>List of Sizes/Models/Article No</b>	ND:YAG Laser System YILIYA-MVE+, YILIYA-MVG, YILIYA-MV4500, YILIYA-MV6000, YILIYA-MV6, YILIYA-MV8, YILIYA-MV9, YILIYA-MV12, ✓  Er:Glass Laser Scanner Therapy Device YILIYA-1550A (new product) ✓  CO <sub>2</sub> Laser Scanner Therapy Device YILIYA-10600A (new product) ✓
<b>Classification Rule</b> According to Annex IX, MDD or the classification according to the IVDD (List A/List B/self-testing device)	Class IIb, Rule 9, Annex IX,MDD

<b>OEM Product</b>	no <input checked="" type="checkbox"/>	
	yes <input type="checkbox"/>	Applicable certificate attached <input type="checkbox"/> OEM Contract dated

## Product Description Form



### Product Description Form for product

**Note: If needed, please use additional sheets for additional information!**

Manufacturing facilities	Facility of research and development	Sterilization facility and sterilization method
Please enter name and address of all manufacturing facilities involved(also for final packaging, labeling and final testing), as well as OEM manufacturing facilities	Please enter complete name and address of the places of research and development for this product	Please enter complete name and address of the sterilization facilities and the sterilization method for this product
<b>Beijing Honkon Technologies Co., Ltd.</b> No.3 Building, No.11 Yard, Kangding Street, BDA, 100176, Beijing , P.R.China	<b>Beijing Honkon Technologies Co., Ltd.</b> No.3 Building, No.11 Yard, Kangding Street, BDA, 100176, Beijing , P.R.China	<b>N.A.</b>

Intended use	
Please attach additionally the instruction for use	<p><b>ND:YAG Laser System</b></p> <p>Skin Beautifier to eliminating pigment. The basics of applying laser to get rid of pigment results in the interaction between biological organism and pigment cells. Laser when effecting on human body will be in taken by the skin and pigment cells and will penetrate to certain depth. Skin and pigment cell have different intake modulus and penetrating depth of as per different length wave of laser. The longer the length wave, the minimum the intake modulus, thus bringing about deepen laser penetrating.</p> <p><b>CO2 Laser Scanner Therapy Device</b></p> <p>The ultra pulse CO<sub>2</sub> laser scanner therapy device scans a highly focused laser beam of high-energy and short pulse rapidly over certain spot sizes randomly. Due to its absorption by water in soft tissue, the fractional CO<sub>2</sub> laser incorporating the advanced technologies can immediate ablate discrete columns of tissue without charring, deposit heat and promote regeneration throughout the underlying layers of the skin, eliminating heat conduction to adjacent tissue. Also, random scanning technology ensures every spot have enough time to be cooled to avoid thermal damage. This device can be used in multiple specialties,such as Oral Surgery, Plastic Surgery, Dermatology.</p> <p><b>Er:Glass Laser Scanner Therapy Device</b></p> <p>The ultra pulse Er:Glass laser scanner therapy device scans a highly focused laser beam of high-energy short pulse rapidly over certain spot sizes randomly. Due to its much more absorption by water in soft tissue,resulting in much less thermal damage, the fractional Er:Glass laser incorporating the advanced technologies can immediate ablate discrete columns of tissue without charring, deposit heat and promote regeneration throughout the underlying layers of the skin, eliminating heat conduction to adjacent tissue. Also, random scanning technology ensures every spot have enough time to be cooled to avoid thermal damage. This device can be used in multiple specialties,such as Oral Surgery, Plastic Surgery, Dermatology.</p>



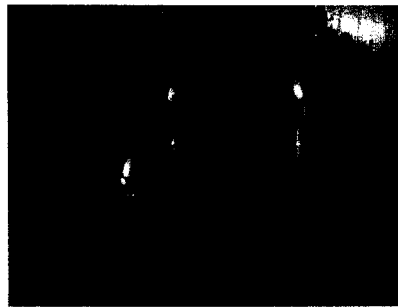
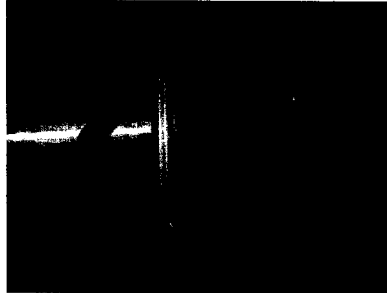
## Product Description Form



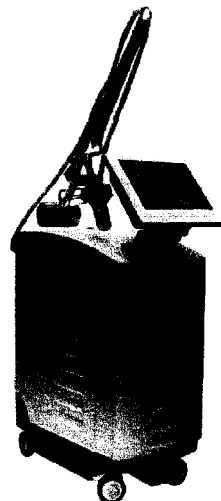
### Product description

Drawings, photo documentation, excerpt out of brochure attached

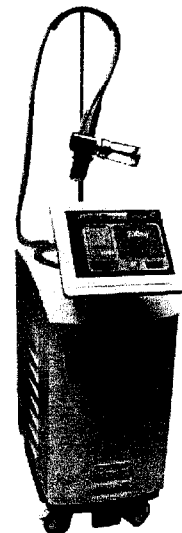
#### ND:YAG Laser System YILIYA-MV8



#### CO<sub>2</sub> Laser Scanner Therapy Device YILIYA-10600A



#### Er: Glass Laser Scanner Therapy Device YILIYA-1550A



**Product Description Form**



**TÜVRheinland®**  
Precisely Right.

**All standards applied**

Please list all standards used (per product)  
or add a separate signed standard list per  
product

EN 980:2008  
EN 1041:2008  
EN ISO 14971:2007  
EN 60601-1:1990+A1+A2  
EN 60601-1-2:2007  
EN 60601-1-4:1996+A1  
EN 60601-1-6:2007  
EN 60601-2-22:1996  
EN 60825-1:2007  
EN ISO 10993-1:2003

北京, 2009. 9. 28

Place and date

Name/signature of the Company's Representative

**Section for TRPS use only**

**Verified by**

Auditor/Expert

LIU SONG

Name

2009-9-28

Date

Signature of Auditor/Expert

Certification  
Department

D.1721

Name

2010-01-05

Date

Signature of Certifier