



Notified Body No 1023  
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.  
Zlín, Czech Republic – [www.itczlin.cz](http://www.itczlin.cz)

# EC CERTIFICATE

## No. 13 0218 QS/NB

Issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 (Collection of Laws), certifies that the product – medical device of Class IIa and IIb:

### Intense Pulsed Light Photorejuvenation Systems

Models: EROSE-YA, EROSE-YC, EROSE-YB1, EROSE-YB2, EROSE-YB3, EROSE-YB6, EROSE-YB8, HM-IPL-B1, HM-IPL-B2, HM-IPL-B3, HM-IPL-B6, HM-IPL-B8

### Laser treatment system

Models: HM-LB, HM-LB100, HM-LB200, HM-LB300, HM-LT, HM-LT100, HM-LT200, HM-LT300

manufactured by company

**Weifang Huamei Electronics Co., Ltd.**  
**454# Yuanfei Road, Weifang China**

is manufactured under conditions fulfilling the quality system requirements of Annex II, Section 3.2 of the Directive 93/42/EEC, as amended.

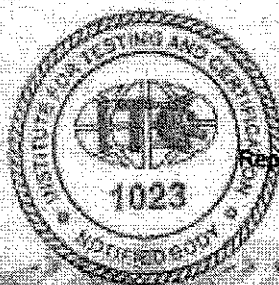
The Notified Body No. 1023 has performed an audit of the above products quality system covering the design, manufacture and final inspection of the certified products. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex II, Sections 3.3 and 5 of the Directive 93/42/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Report No. 803801905/2013, which is enclosed to this Certificate

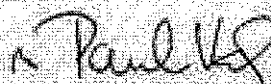
#### Conditions of this Certificate use and related information:

1. It applies only to the quality system maintained in the manufacture of above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested.
2. The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the 16<sup>th</sup> March 2018 at the latest.
3. The Certificate validity is conditioned by positive results of surveillance audits.
4. After fulfilling the relevant EU legislation, the manufacturer shall affix to each medical device, of the above referenced models, the CE-marking followed by the number of this Notified Body according to this example:



Issued in Zlín, on 19<sup>th</sup> March, 2013



  
RNDr. Radomír Čavelek  
Representative of the Notified Body No. 1023



Notified Body No 1023  
**INSTITUTE FOR TESTING AND CERTIFICATION, Inc.**  
Zlin, Czech Republic - [www.itczlin.cz](http://www.itczlin.cz)

# EC CERTIFICATE

## No. 10 0690 QS/NB/a

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 (Collection of Laws), certifies that the medical devices of Class IIa:

### **IPL Treatment System (with RF Function)**

**Models: HM-ELIGHT-B1, HM-ELIGHT-B2, HM-ELIGHT-B3, HM-ELIGHT-B6, HM-ELIGHT-B8, ELIGHT-YA, ELIGHT-YC, ELIGHT-YB1, ELIGHT-YB2, ELIGHT-YB3, ELIGHT-YB6, ELIGHT-YB8,**

### **RF Beauty System**

**Models: HM-RF-A100, HM-RF-A200, HM-RF-A300, HM-RF-B100, HM-RF-B200, HM-RF-B300,**

manufactured by company

**Weifang Huamei Electronics Co., Ltd.**  
**454# Yuanfei Road, Weifang China**

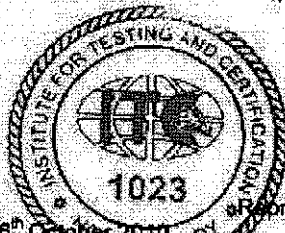
is manufactured under conditions fulfilling the quality system requirements of Annex II, Section 3.2 of the Directive 93/42/EEC, as amended.

The Notified Body No. 1023 has performed an audit of the above products quality system covering the design, manufacture and final inspection of the certified products. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex II, Sections 3.3 and 5 of the Directive 93/42/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Report No. 803600989/2010, which is enclosed to this Certificate.

*This Certificate is issued under the following conditions:*

- 1. It applies only to the quality system maintained in the manufacture of above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested.*
- 2. The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the 18<sup>th</sup> August 2015 at the latest.*
- 3. The Certificate validity is conditioned by positive results of surveillance audits.*
- 4. After fulfilling the relevant EU legislation, the manufacturer shall affix to each medical device, of the above referenced models, the CE-marking followed by the number of the Notified Body according to this example:*

**CE 1023**



*R. Paul Voj*  
**RNDr. Radomír Čevelík**

Issued in Zlin, on 20<sup>th</sup> August 2010  
Replaced by issue version a) dated 26<sup>th</sup> October 2010  
(Replaces withdrawn Certificate No. 10 0690 QS/NB/a issued on 20<sup>th</sup> August 2010)