Notified Body No 1023

**INSTITUTE FOR TESTING AND CERTIFICATION, Inc.**

South Korea, Seoul

# EC CERTIFICATE

## No. 09 0739 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 medical devices of Class IIa:

**Models: 801**, VarıaZ OPT

manufactured by company

**OPT LASER HAİR REMOVER SYSTEM**

**BORUIP MEDICAL EQUIPMENT CO., LTD.**

**T. Bati 299, 764 21 South Korea, Seoul**

is manufactured under conditions fulfilling the quality system requirements of Annex V, 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 V, Sections 3.3 and 4 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.803600652/2009, 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* **29th October 2014** *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

Issued in Zlin, on 30th October 2009

RNDr. Radomir Čevelík

Representative of the Notified Body No. 1023