NOTIFIED BODY No. 1023
Institute for Testing and Certification, Inc., Zlín, Czech Republic

EC CERTIFICATE

NO. 09 0820 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 IIb:

Nd:YAG Q-Switched Laser Treatment System

Models: XO-100 ,XO-200 and XO-300

manufactured by company

Shanghai Bester Medical Technology Co., Ltd.

No.366, Xingzhan Road, Qibao Town, Minhang District, Shanghai City, 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. 803600298B/2008, 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* ***December 27, 2012*** *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 Zlín, on 28th December 2009

INSTITUTE FOR TESTING AND CERTIFICATION * 1023 * NOTIFIED BODY

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