



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

# EC CERTIFICATE

No. 13 0656 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:

## Laser System

models: SL-TRV01, SL-TRV02, SL-TRP01, SL-TRP02, SL-TRP03  
SL-HRV01, SL-HRV02, SL-HRV03, SL-HRV04  
SL-COV01, SL-COV02, SL-COP01, SL-ERV01, SL-ERV02

manufactured by company

## Beijing Neugol Sci-Tech Co., Ltd.

Zuoanyiyuan 4#, Zuoanmennei Street, Chongwen District, Beijing, China

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

The Notified Body No. 1023 has performed an audit of the above products quality system. 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. 803800930B/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 2<sup>nd</sup> August, 2020 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 3<sup>rd</sup> August 2015



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