



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

EC CERTIFICATE

No. 06 0351 QS/NB

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

808nm diode laser
model LAR150

placed on the market by company

LUXLASER

22 rue de l'industrie, 8399 Windhof, Luxembourg

are 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. The quality system has been assessed, approved and is a subject of the 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. 803600351/2006, which is an integral part of this Certificate.

This Certificate is issued under 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 14th August 2013 at the latest.*
3. *The Certificate validity is conditioned by positive results of surveillance audits.*
4. *The manufacturer shall affix to each medical device of the above referenced type the conformity mark CE followed by number of Notified Body according to an example:*

CE 1023

Issued in Zlín, on 8th June 2010



A handwritten signature in blue ink, appearing to read 'R. Čevelík'.

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