



SEC International a.s., Hradičná 15, 821 09 Bratislava, Slovakia  
Notified Body No. 2250

## EC CERTIFICATE

No. 2016-MDD/QS-037

Issued in compliance with the Council Directive 93/42/EEC as amended by 2007/47/EC, which is implemented by the Slovak Government Decree No. 540/2006 Coll. as amended by 216/2013 Coll. certifies that the medical device of Class II,

**Medical Multifunction Laser Device**  
**Model: LASEST**

Manufactured by company

**LLC "LasMedTech"**

**Regd. Address: Building 1, Novinsky Boulevard 5, Moscow 121098, Russian Federation**  
**Production Site: Building 1, Kievskaya St. 25, Moscow 121151, Russian Federation**

is manufactured under conditions fulfilling the quality system requirements of Annex II, excluding (4), of the Directive 93/42/EEC as amended by 2007/47/EC.

The Notified Body No. 2250 has performed an audit of the above device quality system. The full quality assurance system has been assessed and found that it meets the requirements above. The quality system is subject to continuous surveillance according to Annex II, Sections 3.3, and 5, of the Directive 93/42/EEC as amended by 2007/47/EC. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. 310015, and the Final protocol No. 3102150016 that is enclosed to this certificate.

The certificate is issued under the following conditions:

It applies only to the quality system maintained in the manufacture of the above referenced model of medical device and it does not substitute the design or type-examination procedures, if requested. The certificate remains valid until the manufacturing conditions or the quality system are changed but until December 21st, 2021 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfillment of relevant legal and other requirements by manufacturer.



Dr. Katarina Srdobová  
Responsible for all on behalf of NB 2250

In Bratislava, on December 22nd, 2016