3EC International

**3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia**
SKTC-113 and Notified Body No. 2265

# EC CERTIFICATE

## No. 2011-MDD-032

issued in compliance with the Council Directive 93/42/EEC as amended 2007/47/EC, which is implemented by the Slovak Government Decree No. 582/2008 (Collection of Laws), certifies that the medical device of Class IIa,

**Surgical Blade, Ophthalmic Micro Surgical Blade, Ophthalmic Cannula, Ophthalmic Micro Surgical Instruments, Ophthalmic Kit**

(For detailed specification refer to Annex; pages 1-16)

manufactured by company

**SURGI EDGE (India)**

*Office:* 305, Vedant, Nr Ganesh Plaza, Navrangpura, Ahmedabad - 380 009, Gujarat - INDIA

*Factory:* 12/Shri Hari Industrial Estate, Behind Fire station, Odhav, Ahmedabad 382 415, Gujarat - INDIA

**is manufactured under conditions fulfilling the quality system requirements of Annex II, Section 3.2, of the Directive 93/42/EEC as amended 2007/47/EC.**

The Notified Body No. 2265 has performed an audit of the above device 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 as amended 2007/47/EC. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Final protocol No. 310028/2011 that is enclosed to this certificate.

*This 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 November 30th, 2021 at the latest. The certificate validity is conditional upon positive results of surveillance audits. After receiving of the complementary EC Design-Examination Certificate related to the above referenced model, and fulfilling the relevant EU legislation requirements, the manufacturer shall affix to each medical device of the above referenced model, the CE marking followed by the number of the Notified Body.*

At Bratislava, on December 1st, 2016

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

Dr. Katarína Srdošová
*Responsible to act on behalf of NB 2265*