SZUTEST

EC CERTIFICATE

According to Annex II of the Directive 93/42/EEC on Medical Devices

Full Quality Assurance System

Certificate Number: 2195-MED-401428301

Manufacturer:	**Jeisys Medical Inc.** #307, 308, 401 Daeryung Techno Town 8th, 96, Gamasan-ro, Geumcheon-gu, Seoul, Korea
Product(s):	**(1) Focused Ultrasound Stimulator Use System and Electrosurgical Unit** **(2) Therapeutical Laser Unit** **(3) Electrosurgical Unit**
Model(s):	**(1) ULTRAcel, ULTRAcel Q+** **(2) Hilthera 4.0** **(3) INTRAgen**
Reference Report No:	**2195-MED-1409006, 2195-MED-1410014, MM0273-P001-R01, MM0273-P001-R02, MM0273-P002-R01, MM0273-P002-R02**

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s).

This EC certificate is valid till 2019-10-09.

Issue Date:	2014-10-10
Revision No.:	03 Rev.
Revision Date:	2017-11-02

Rukiye BALKAN
Deputy General Manager

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.
Szutest Plaza Nato Yolu Cad. Çam Sok. No:7 Ümraniye 34775 İSTANBUL / TÜRKİYE
Szutest.com.tr