Declaration of Conformity

CE 2195

according to the Medical Devices Directive 93/42/EEC as amended by Directive 2007/47/EC

Manufacturer:	Jeisys Medical Inc.
Address	307, 308, 401 Daeryung Techno Town 8th, 96, Gamasan-ro, Geumcheon-gu, Seoul, Korea
European Representative:	Emergo Europe
Address	Emergo Europe, Prinsessegracht 20, 2514 AP, The Hague, The Netherlands
Product :	Therapeutical Laser Unit
Brand name:	Hilthera 4.0
Classification :	Class IIb by Rule 9 of Annex IX, Council Directive 93/42/EEC
GMDN Code:	35940 Laser, Nd:YAG

The product identified above complies with the essential requirements of the above EC Directives by meeting the following standards:

EN 60601-1:2006, EN 60601-1-2:2007,
IEC 60601-2-22:2007,
EN ISO 14971:2012
EN 1041:2008, EN ISO 15223-1:2016
EN ISO 13485:2012,
MEDDEV 2.12/2 Rev.2
MEDDEV 2.7/1 Rev.3
MEDDEV 2.12/1 Rev.8
EN 62304:2006, ISO 7010:2011
IEC 62348/TR Ed. 1.0
IECEE OD-2044-Ed.1.0
EN60601-1-6:2010, EN 62366:2008
IEC 60825-1, EN ISO 10993-1:2009
EN ISO 10993-5:2009,
EN ISO 10993-10:2013

This Declaration of Conformity is based on the EC Directives 93/42/EEC, Annex II (Excluding Section 4) under the supervision of Notified body, SZUTEST (NB No. 2195).

Notified body: Szutest Teknik Kontrol ve Belgelendirme Hizmetleri Tic. Ltd. Şti.
Szutest Plaza Yukarı Dudullu Mh. Nato Yolu Cd. Çam Sk. No:7 Ümraniye – İstanbul Turkey

EC Certificate No.: ***Issue date: 2014.10.10 / Valid until:2019.10.09***

2195-MED-401428301

Dong-Hwan Kang, President

Place: Seoul, Korea **Date:** Sep 04, 2017