

EC Declaration of Conformity

Manufacturer's Name **Sung Hwan E&B Co., Ltd.**
Manufacturer's Address #502, SK Techno Bldg, 16-4 Seongsu-dong 1-ga
Seongdong-gu, seoul, korea

EC Representative **CENTER Ltd.**
EC Representative Address Nagy Lajos Kiraly Road 10.
Budapest, 1148 HUNGARY

Product Name **High-Frequency Electrosurgical Unit**
Model **VIVACE**

Classification (MDD Annex IX)
High-Frequency Stimulator
- Class IIb according to the rule 9 Annex IX of MDD(EC Directive 93/42/EEC)
Conformity assessment route: Annex II.(excluding Section 4)of EC Directive 93/42/EEC
RoHS2 Directive 2011/65/EU

We here with declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained under of the manufacture.



Details of NB; SGS United Kingdom Ltd. System & Service Certification
22B Worle Parkway, Weston-super-Mare, BS22 6WA UK

Standards IEC60601-1:12005
IEC 60601-1-2:2007
IEC 60601-2-10:2009
ISO 10993-1:2009
IEC 60601-1-6:2010
IEC 60601-1-9:2007
IEC 62304:2006
IEC 62366:2007
EN ISO 14971:2012

Date

Signature

SUNG HWAN E&B CO.,LTD.


SUN YOUNG KANG / CEO 

S.Y, Kang / President
Sung Hwan E&B Co., Ltd