

Declaration of Conformity



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

Manufacturer: Elpis Medical Co., Ltd.
Address 16, Saam-gil, Dongnae-myeon, Chuncheon-si, Gangwon-do, Korea
European Representative: CALMED INVEST Kft.
Address 1182 Budapest, Fiume utca 3., Budapest, Hungary
Product : Operating light
Model name: LED SL88A , LED SL99A
Classification : Class I by Rule 12 of Annex IX, Medical Device Directive 93/42/EEC as amended by 2007/47/EC

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

EN ISO 15223-1:2012 EN 980:2008
EN ISO 13485:2012 EN 1041:2008
EN ISO 14971:2012 EN 60601-1-2:2007
MEDDEV 2.12-1Rev.8 MEDDEV 2.7.1 Rev.3
MEDDEV 2.12.2 Rev2

This Declaration of Conformity is based on the EC Directives 93/42/EEC as amended by 2007/47/EC.

Elpis Medical Co., Ltd.
President : Hwang jae cheon