

# 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:** Solarmax LED160+80, Solarmax LED160, Solarmax LED80  
**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 : Seong Young il**