

Declaration of Conformity



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

Manufacturer : Handok Medical Instrument Corp.

Address : 27, Paryasandan-ro 3beon-gil, Jinjeop-eup, Namyangju-si, Gyeonggi-do,
#472-868 Republic of Korea

European Representative : CALMED INVEST Kft.

Address : 1182 Budapest, Fiume utca 3., Budapest, Hungary

Product : Operating light

Model name : HM801, HM802, HM804

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.

Handok Medical Instrument Corp.

President : Kim Ki Soo

27, Paryasandan-ro 3beon-gil, jinjeop-eup,
Namyangju-si, Gyeonggi-do, 472-868, Korea

Handok Medical Instrument Corp.

President K I M K I S O O



Issuing Date : June 23th 2017

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European Representative : CALMED INVEST Kft.

Address : 1182 Budapest, Fiume utca 3., Budapest, Hungary

Product : Operating light

Model name : LED T7050, LED T70, LED T5050, LED T50,
LED G7050, LED G70, LED G5050, LED G50

Classification : Class I by Rule 12 of Annex IX, Medical Device Directive 93/42/EEC as
amended by 2007/47/EC

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Directives by meeting the following standards:

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