EC Declaration of Conformity

Doc.No:	Certificate	FI15/07013-1	Revision:	03
	Q&S 2017- CE-03		Effective:	2019.11.11
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Manufacturer:	**Whose Single Authorized Representative**
Dong Guan Q & S Electronic Manufacturing Company Ltd *Address*:Yin Shan District, Fu Gang Village, Xiang Mang West Road, Qing Xi Town, Dong Guan City, P.R.China	MedNet GmbH *Address*:_Borkstrasse 10, 48163 Muenster, Germany

We,the manufacturer,herewith declare at our sole responsibility that the products

Products : Daylight therapy lamp

Model Ref:TL-70 (#BEG006) & TL-50 (#BEG007)

Meet the provisions of EU Directive 2011/65/EU of 8 June 2011 amended by Commission Delegated Directive (EU) 2015/863 of 31 March 2015 on the restriction of the use of certain Hazardous substances in electrical and electric equipment.

The medical device has been assigned to Class IIa according to Annex IX Rule 9 of the CONCIL DIRECTIVE 93/42/EEC amended by 2007/47/EC. It bears the mark

CE 0598

The product concerned has been manufactured under a quality management system according to Annex V of CONCIL DIRECTIVE 93/42/EEC amended by 2007/47/EC.

Compliance of the designated product with the CONCIL DIRECTIVE 93/42/EEC amended by 2007/47/EC has been assessed and certified by the Notified Body

SGS FIMKO OY
P.O. Box 30, 00211 HELSINKI, Finland

Following the procedure relating to the EC Declaration of Conformity set out in Annex V of **CONCIL DIRECTIVE 93/42/EEC amended by 2007/47/EC and in** Conformity to the following standards or other Normative documents:

EN 60601-1:2006 +A1:2013; EN 60601-1-2:2015; EN60601-1-6:2010+A1:2015 ;

EN 60601-2-57:2011 ; EN 60601-1-11:2015; EN 62304:2006 ; EN62366-1:2015;

EN ISO 10993-1:2009; EN ISO 10993-5:2009; ISO 10993-10:2010; EN ISO 10993-12:2012

The above mentioned declaration of conformity is exclusively under the responsibility of
DONG GUAN Q&S ELECTRONIC MANUFACTURING CO.,LTD

Management Representative
Alex Chong, Regulatory Affair Director

Dong Guan,2019.12.12
City,Date

Form No:R14A020-01