

# EC Declaration of Conformity

Doc.No:	Certificate	FI15/07013-1	Revision:	03
	Q&S 2017- CE-03		Effective:	2019.11.11
			Page:	Page 1 of 1

Manufacturer:	Whose Single Authorized Representative
Dong Guan Q & S Electronic Manufacturing Company Ltd <i>Address:</i> Yin Shan District, Fu Gang Village, Xiang Mang West Road, Qing Xi Town, Dong Guan City, P.R.China	MedNet GmbH <i>Address:</i> Borkstrasse 10, 48163 Muenster, Germany

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

Products : Daylight therapy lamp

Model Ref: TL-100 #BEG005

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



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



Alex

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 Dong Guan, 2019.11.28  
 City, Date