

EC Declaration of Conformity

F-QA-037 Rev.01 20160107



Globalcare Medical Technology CO., LTD.

7th Building, 39 Middle Industrial Main Road, European Industrial Zone,

Xiaolan Town, 528415 Zhongshan City, Guangdong Province,

PEOPLE'S REPUBLIC OF CHINA

Product Category:

Bright Light Therapy Lamp

Product Code:

608.05

Product Description:

TL30 Bright Light

Classification - Annex IX:

Class IIa, Rule 9

Conformity Assessment Route:

ANNEX V

We, the manufacturer, herewith declare that the stated medical devices meet the transposition into national law, the provisions of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices; including, at 21 march 2010, the amendments by Council Directive 2007/47/EEC.

All supporting documentation is retained at the premises of the manufacturer.

Globalcare Medical Technology CO., LTD. is exclusively responsible for this EC Declaration of Conformity.

Standards applied: see attached list

Notified Body:

TÜV SÜD Product service GmbH

Ridlerstr 65, D-80339 München, Germany

Identification Number

0123

(EC) Certificate(s):

G2 088855 0009

EC REP

European Representative:

Donawa Lifescience Consulting Srl

Piazza Albania, 10

00153 Rome

Italy

Place, Date of Declaration:

Zhongshan, 2018-09-03

Signature:

Name: Lambert Zhao

Position: General Manager