

Outside In (Cambridge) Ltd
3 The Links, Trafalgar Way, Bar Hill
Cambridge UK CB23 8UD

tel : +44 (0)1954 780500
fax : +44 (0)1954 780510

e : info@lumie.com
www.lumie.com



Lumie is a registered trademark of Outside In (Cambridge) Ltd. Registered in England & Wales, 2647359

EU DECLARATION OF CONFORMITY

It is hereby declared that the products listed below, are Class I medical devices, and conform to the applicable requirements of the following Directives:

- Directive 93/42/EEC concerning medical devices (as amended by Directive 2007/47/EC).
- Directive 2011/65/EU concerning the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Lumie Dawn Simulator with Aromatherapy

Lumie Bodyclock Iris 500

The full list of standards upon which the presumption of conformity is based is given in the Technical File Master Document for this product.

The principal standards are:

- EN 60601-1:2006 + A12:2014 Medical Electrical Equipment Safety and applicable collateral and international standards.
- EN 50581:2012 Technical Documentation requirements for the assessment of electrical and electronic products with respect to the restriction of hazardous substances.

This Declaration of Conformity is issued under the sole responsibility of Outside In (Cambridge) Ltd, the product manufacturer.

Technical Manager: 

Effective Date: 12.05.2015