

# EC DECLARATION OF CONFORMITY

Manufacturer: *Changzhou Biolight Medical Devices Co., Ltd.*

Israel Centre, No.123 He Xiang Road, Wujin District  
Changzhou 213149, China

**0123**

Appointed Notified Body: TÜV SÜD Product Service GmbH Zertifizierstellen (NB # 0123) for the requirements of MDD 93/42/EEC Annex II

No of certificate: TUV SUD No# Q5 086486 0007 Rev.00

Products: **Phototherapeutic Medical Devices** placed the products in the European market, declare that our products conform and meet the Medical Device Directive 93/42 EEC & MDD2007/47 including essential requirements set out in Annex I

<u>Product:</u>	<u>Model:</u>	<u>Class:</u>
<b>Phototherapeutic Medical Devices</b>	BioNette	IIa
<b>Phototherapeutic Medical Devices</b>	BioBeam 940	IIa
<b>Phototherapeutic Medical Devices</b>	BioBeam 660	IIa

The object of the declaration described above is also in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Conforming to Production Standards:

- ❖ ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes
- ❖ MDD 93/42EEC & MDD 2007/47 Medical Devices Directive93/42/EC amended by Directive 2007/47/EC
- ❖ EN60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- ❖ EN60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

Appointed EU Authorized Representative: Within those requirements we prepared the required technical documentation, put into place corrective action and vigilance procedures and have appointed Shanghai International Holding Corp. GmbH (Europe) Tel: +49-40-2513175 Fax: +49-40-255726 , to act as our Authorized Representative in the European Community.

***Date of issuing this certificate: January 02<sup>nd</sup>, 2020.***

Full Name: Wayne Jiang

Position: General Manager

Date: 02-January-2020

Signature: *Wayne Jiang*

