

EC DECLARATION OF CONFORMITY

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

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

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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# G1 086486 0008 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>
Phototherapeutic Medical Devices	BioNette	IIa
Phototherapeutic Medical Devices	BioBeam 940	IIa
Phototherapeutic Medical Devices	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 02nd, 2020.

Full Name: Wayne Jiang

Position: General Manager

Date: 02-January-2020

Signature: *Wayne Jiang*

