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# QS1 17 08 86486 006

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

Product:	**Model:**	**Class:**
Phototherapeutic Medical Devices	BioNette	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 13485:2012 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: May 31, 2018.

CHANGZHOU BIOLIGHT MEDICAL DEVICES CO., LTD. 常州赛瑞乐医疗器械有限公司 320411940894

Full Name: Wayne Jiang Position: General Manager

Date: 31-May-2018 Signature: Wayne Jiang