DECLARATION OF CONFORMITY

TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

MANUFACTURER: Changzhou BioLight Medical Devices Co., Ltd.
Block C, Building 7, Israel Centre, No.123 Hexiang Road, Wujin District,
213149,Changzhou, Jiangsu Province,PEOPLE'S REPUBLIC OF CHINA

MEDICAL DEVICE: Allergic Rhinitis Phototherapy Device (Phototherapeutic Medical Devices)
Product model: BioNette
UMDNS Code: 17516

CLASSIFICATION -ANNEX IX: CLASS IIa， RULE 9.

CONFORMITY ASSESSMENT ROUTE: Annex II.3

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;

ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

WE ARE EXCLUSIVELY RESPONSIBLE FOR THIS DOC

(NOTE: IT IS SUGGESTED THAT THIS LIST STATE THE STANDARDS' FULL NAME AND DATE OF ISSUE AND INCLUDES ALL AMENDMENTS. A CROSS REFERENCE TO THIS STANDARDS LIST FROM THE ESSENTIAL REQUIREMENTS CHECKLIST MINIMISES DOCUMENT CHANGES IN THE EVENT OF STANDARDS RE-ISSUE OR AMENDMENT).

Notified Body: TÜV SÜD Products Service GmbH, Ridlestrasse.65, 80339, Munchen, Germany

NB Identification number: 0123

(EC) CERTIFICATE(S): G10864860008 REV.00

EC REP

EUROPEAN REPRESENTATIVE: Shanghai International Holding Corp.GmbH (Europe)
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Tel:+49-40-2513175 Fax:+49-40-255726

START OF CE-MARKING: 2016-05-10

PLACE, DATE OF DECLARATION: CHANGZHOU, NOV.1ST,2021

SIGNATURE: Wayne Jiang

NAME: WAYNE JIANG
POSITION: General Manager