Declaration of Conformity

Manufacturer	Guangdong Biolight Meditech Co., Ltd
Address	No.2 Innovation First Road, Technical Innovation Coast, Hi-tech Zone, Zhuhai, P.R. China
European Representative	Shanghai international Holding Corp GmbH (Europe) Eiffestrasse 80, 20537 Hamburg Germany
Product	Patient Monitor
GMDN Code	33586
Model Code	M860 (SN: M-088-E-00001～M-088-E-99999)

Classification: Class II b , rule 10 of Annex IX of the MDD 93/42/EEC

Conformity Assessment Route: Annex II.3 of the MDD 93/42/EEC

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC concerning medical devices (MDD 93/42/EEC).

Standard applied:

See the appendix.

Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany
Identification number:	0123
(EC) Certificate(s):	G1150949957026
Expire date of the Certificate:	Mar.19, 2020
Start of CE marking:	Nov.9, 2016
Place, Date of Issue:	Zhuhai, China, Nov.9, 2016

Signature Jin Liang

Name Jin Liang

Position Chief Engineer

APPENDIX

Item	Scope	Number of standard	Name of standard
1.	General, Safety	IEC 60601-1: 2005 + A1: 2012	Medical electrical equipment -- Part 1: General requirements for safety
2.	General, EMC	IEC 60601-1-2:2007	Medical electrical equipment --Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
3.	General, Usability	IEC 60601-1-6: 2010	Medical electrical equipment --Part 1-6: General requirements for safety and essential performance - Collateral Standard: Usability
4.	General, Software	IEC 62304:2006	Medical device software – Software life cycle processes
5.	General, Alarm	IEC 60601-1-8:2006+A1:2012	Medical electrical equipment --Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
6.	Information Supplied by the Manufacturer	EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
7.	Risk management	EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices
8.	Biological evaluation	EN ISO 10993-1: 2009	Biological evaluation of medical devices—Part 1： Evaluation and testing
9.	Biological evaluation	ISO 10993-5: 2009	Biological evaluation of medical devices—Part 5： Tests for in vitro cytotoxicity.
10.	Biological evaluation	EN ISO 10993-10: 2010	Biological evaluation of medical devices—Part 10： Tests for irritation and skin sensitization.
11.	Labeling	ISO15223-1:2012	Symbols for use in the labeling of medical devices
12.	Clinical Investigation	ISO 14155: 2011	Clinical investigation of medical devices for human subjects - Good clinical practice

13.	Particular, multifunction monitor	IEC 60601-2-49:2011	Medical electrical equipment -- Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment
14.	Particular, NIBP	IEC 80601-2-30:2009 +A1:2013	Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
15.	Non-invasive sphygmomanometers	ISO 81060-2-2009	Non-invasive sphygmomanometers—Part 2: Clinical validation of automated measurement type
16.	Particular, SpO2	ISO80601-2-61:2011	Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use