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	P1 P12 P15 P18 P22

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. We are exclusively responsible for this DoC. 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 attached list of standards for which documented evidence of compliance can be provided.

Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany
Identification number:	0123
(EC) Certificate(s):	G10499570033 Rev.02
Expire date of the Certificate:	2024-05-26
Start of CE marking:	2021-02-22
Place, Date of Issue:	Zhuhai, China, 2022-04-15

Signature Jin liang

Name Jin Liang

Position Chief Engineer

Attached list:

Standards for P1/P12/P15/P18/P22 patient monitor

Standards for General Requirement

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 basic safety and essential performance.
2	General, EMC	IEC 60601-1-2:2014	Medical electrical equipment --Part 1-2: General requirements for basic safety and essential performance-- Collateral standard: Electromagnetic disturbances—Requirements and tests
3	General, Usability	IEC 60601-1-6:2010+A1:2013	Medical electrical equipment --Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
4	General, Software	IEC 62304:2006+A1:2015	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	Risk management	EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
7	Biological evaluation	ISO 10993-1:2009	Biological evaluation of medical devices — Part 1:Evaluation and testing within a risk management process
8		ISO 10993-5:2009	Biological evaluation of medical devices—Part 5: Tests for in vitro cytotoxicity
9		ISO 10993-10:2010	Biological evaluation of medical devices--Part 10:Tests for irritation and skin sensitization
10	Labeling	ISO 15223-1:2016	Medical devices-Symbols to be used with medical device labels, labeling and information to be supplied--Part 1: General requirements

11	Usability engineering	IEC 62366-1:2015	Medical devices—Part 1: Application of usability engineering to medical devices

Standards for multi-parameters patient monitor

Item	Scope	Number of standard	Name of standard
1	Particular, multifunction monitor	IEC 80601-2-49:2018	Medical electrical equipment -- Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors
2	Particular, ECG	IEC 60601-2-27:2011	Medical electrical equipment -- Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
3	Particular, NIBP	IEC 80601-2-30:2018	Medical electrical equipment -- Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
4	Particular, NIBP	ISO 81060-2:2013	Non-invasive sphygmomanometers —Part 2: Clinical validation of automated measurement type
7	Particular, SpO2	ISO 80601-2-61:2017	Medical electrical equipment --Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
8	Particular, TEMP	ISO 80601-2-56:2017+A1:2018	Medical electrical equipment --Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
9	Particular, IBP	IEC 60601-2-34:2011	Medical electrical equipment --Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment
10	Particular, CO2/AG	ISO 80601-2-55:2018	Medical electrical equipment –Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
11	Particular, ECG	IEC 60601-2-25:2011	Medical electrical equipment – Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
12	Particular, EEG/BIS	IEC 60601-2-26: 2012	Medical electrical equipment – Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs

13	Particular, NMT	IEC 60601-2-10: 2012+A1: 2016	Medical electrical equipment – Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators.