Declaration of Conformity

Manufacturer	Guangdong Biolight Meditech Co., Ltd.
Address	No.2 Innovation First Road, Technical Innovation Coast, Hi-tech Zone, Zhuhai 519085, Guangdong, P.R. China
SRN	CN-MF-000006333
European Representative	Shanghai International Holding Corp GmbH (Europe) Eiffestraße 80, 20537 Hamburg Germany
Product name	Patient Monitor
Model Number	M10, M12
Basic UDI-DI	M10: 69325623100033V M12: 69325623100194C
Intended purpose	The patient monitors are intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters of patients.

Classification (MDR, Annex VIII): Class IIb, rule 10

Conformity Assessment Route: Annex IX chapter I + chapter III of MDR

We herewith declare that this EU declaration conformity is issued under the sole responsibility of the manufacturer. The product mentioned above is in conformity with the Medical Device Regulation (EU 2017/745). All supporting documentations are retained under the premises of the manufacturer.

CS or Harmonized standards:

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):	G10 049957 0037 Rev.00
Expire date of the Certificate:	2028-04-10
Start of CE marking:	2023-04-11
Place, Date of Issue:	Zhuhai, China, 2023-04-11

Signature Jin Liang

Name Jin Liang

Position Chief Engineer

Attached list:

Standards for M10/M12 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	ISO 14971:2019	Medical devices - Application of risk management to medical devices
7.	Biological evaluation	ISO 10993-1:2018	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 81060-2:2018	Non-invasive sphygmomanometers —Part 2: Clinical validation of automated measurement type
5.	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
6.	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
7.	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
8.	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
9.	Particular, ECG	IEC 60601-2-25:2011	Medical electrical equipment – Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs