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

Shanghai International Holding Corp GmbH (Europe)

Representative

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.

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

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

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

Jin living

Place, Date of Issue:

Zhuhai, China, 2023-04-11

Signature

Jin Liang

Position

Name

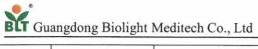
Chief Engineer

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 equipmentPart 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 equipmentPart 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 equipmentPart 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 devicesPart 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 suppliedPart 1: General requirements



11	Usability	IEC 62366-1:2015	Medical devices—Part 1: Application of
11.	engineering	IEC 02300-1.2013	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 equipmentPart 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 equipmentPart 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 equipmentPart 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