

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	Fetal Monitor
GMDN Code	43958
Model Code	F90 F50

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 the appendix.

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: 2013-11-18

Place, Date of Issue: Zhuhai, China. 2022-09-20

Signature



Name Jin Liang

Position Chief Engineer

APPENDIX

Standards for F90 & F50 Fetal Monitor

Item	Scope	Number of standard	Name of standard
1.	General, Software	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.	Usability	IEC 62366-1:2015	Medical devices—Part 1: Application of usability engineering to medical devices
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.	General, Software	IEC 62304:2006+A1:2015	Medical device software – Software life cycle processes
7.	General, Risk	EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
8.	Biological evaluation	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	ISO 10993-10:2010	Biological evaluation of medical devices--Part 10:Tests for irritation and skin sensitization
11.	General, Symbols	ISO 15223-1:2016	Medical devices-Symbols to be used with medical device labels, labeling and information to be supplied--Part 1: General requirements
12.	Particular, Ultrasonic monitoring equipment	BS EN 60601-2-37: 2008	Medical electrical equipment- Part 2-37:Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
13.	Particular, multifunction monitor	IEC 60601-2-49:2011	Medical electrical equipment -- Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
14.	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
15.	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
16.	Particular, NIBP	ISO 80601-2:2013	Non-invasive sphygmomanometers —Part 2: Clinical validation of automated measurement type
17.	Particular, SpO2	ISO 80601-2-61:2011	Medical electrical equipment --Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
18.	Particular, TEMP	ISO 80601-2-56:2009	Medical electrical equipment --Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement