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	Pulse Oximeter
GMDN Code	45607
Model Code	M800

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:

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:	2010-03-25
Place, Date of Issue:	Zhuhai, China, 2022-04-15

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 basic safety and essential performance.
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
		IEC 62366:2007+A1:2014	Medical device - Application of usability engineering to medical devices
4.	General, Software	IEC 62304:2006	Medical device software – Software life cycle processes
5.	Risk management	EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices
6.	Biological evaluation	ISO 10993-1:2009	Biological evaluation of medical devices — Part 1:Evaluation and testing within a risk management process
7.		ISO 10993-5:2009	Biological evaluation of medical devices—Part 5: Tests for in vitro cytotoxicity
8.		ISO 10993-10:2010	Biological evaluation of medical devices--Part 10:Tests for irritation and skin sensitization
9.	General, Symbols	ISO15223-1:2012	Medical devices -Symbols to be used with medical device labels, labeling and information to be supplied-Part 1: General requirements
10.	Particular, SpO2	ISO80601-2-61:2011	Medical electrical equipment --Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
11.	General, home healthcare	IEC 60601-1-11:2015	Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance –Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment