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	Electrocardiograph
GMDN Code	16231
Model Code	E65

Classification: Class II a , 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:	2016-11-10
Place, Date of Issue:	Zhuhai, China. 2022-04-15

Signature Jin liang

Name Jin Liang

Position Chief Engineer

APPENDIX

Standards for E65 Electrocardiograph

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