

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)
Product Eiffestraße 80, 20537 Hamburg Germany
UMDNS Code Ultrasonic Doppler Fetal Heartbeat Detector
Model Code 11696
WF100(SN: W-11-Year-week-00001~W-11-Year-week-99999),
WF200 (SN: W-10-Year-week-00001~W-10-Year-week-99999).

Classification: Class II a , rule 10 of Annex IX of the MDD 93/42/EEC

Conformity Assessment Route: Annex II without chapter 4 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:

All applicable harmonized Standard (see the Appendix)

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany

Identification number: 0123

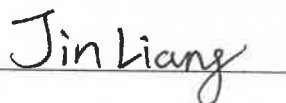
(EC) Certificate(s): G10499570033 Rev.02

Expire date of the Certificate: 2024-05-26

Start of CE marking: 2016-11-09

Place, Date of Issue: Zhuhai, China. 2021-3-10

Signature



Name Jin Liang

Position Chief Engineer

Appendix:

Standards for WF100 & WF200 Ultrasonic Doppler Fetal Heartbeat Detector

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		IEC 62366-1:2015	Medical devices—Part 1: Application of usability engineering to medical devices
5	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
6	General, Software	IEC 62304:2006+A1:2015	Medical device software – Software life cycle processes
7	Particular, requirements	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
8	Particular requirements	BS EN 61266:1995	Ultrasonics - Hand-held probe Doppler foetal heartbeat detectors - Performance requirements and methods of measurement and reporting
9	Risk management	EN ISO 14971:2012	Medical devices- Application of risk management to medical devices
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	Biological evaluation	ISO 10993-1: 2009	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
12		ISO 10993-5: 2009	Biological evaluation of medical devices—Part 5: Tests for in vitro cytotoxicity
13		ISO 10993-10: 2010	Biological evaluation of medical devices--Part 10: Tests for irritation and skin sensitization

