# Declaration of Conformity

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| **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** | Ultrasonic Doppler Fetal Heartbeat Detector |
| **UMDNS Code** | 11696 |
| **Model Code** | WF100<br>WF200 |

**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)

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| **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. 2022-04-15 |

Signature Jin Liang

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 |

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| 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 |