Declaration of Conformity to Council Directive 93/42 EEC (Including Directive 2007/47/EEC) Concerning Medical Devices

Manufacturer: Shenzhen Luckcome Technology Inc., Ltd.
Floor 6A, 6th Building, Tongfuyu Industrial Park，Nanshan District, Shenzhen, Guangdong, China, 518055

European Representative: Shanghai International Holding Corp. GmbH (Europe)
Add: Eiffestrasse 80, 20537 Hamburg，Germany

Product: Fetal/Maternal Monitor

Model： L8E、L8F、L8M-M、L8M6-M、L8M9-M

Classification: II a (Rule 10 of Annex IX, MDD)

Conformity assessment route: Annex II excluding (4)

We, the manufacturer, herewith declare under our sole responsibility that the stated medical devices meet the transposition into national law, the provisions of Council Directive 93/42/EEC of 14 June, 1993, concerning medical devices; including the amendments by Council Directive 2007/47/EEC. All supporting documentation is retained at the premises of the manufacturer.
The validity period of this declaration of conformity is limited by the issuing of a revised declaration of conformity after change of the product and/or by the expiration date of the related Annex II certificate issued by the notified body.

Standards applied: Applied Standards List (attached) for which documented evidence of compliance can be provided.

Notified Body: MEDCERT GmbH
Pilatuspool 2, D-20355 Hamburg, Germany

Identification Number: CE 0482

(EC) Certificate(s): 6016GB410190923

Start of CE-marking: 18 October, 2016

Place, Date of Issue: 27 September, 2019

Signature: Name：Huang Ping
Position：General Manager

List of Harmonized standard

No.	Standard Name	Reference No.
1	Medical device risk management to medical devices application	EN ISO 14971:2012
2	Symbol for the label of medical devices	EN ISO 15223-1:2016
3	Term, symbol and information of medical device— information of medical device manufacturer offering	EN 1041:2008+A1:2013
4	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance	EN 60601-1:2006 / A1:2013
5	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2:2015
6	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	EN 60601-1-6:2010
7	Medical electrical equipment Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment	EN 60601-2-37:2008
8	Medical electrical equipment -- Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement	EN ISO 80601-2-56:2017
9	Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems	EN 1060-3:1997+A2:2009
10	Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment	IEC 61157:2013
11	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	EN ISO 10993-1:2009/AC:2010
12	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	EN ISO 10993-5:2009
13	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization	EN ISO 10993-10:2013
14	Medical device software - Software life-cycle processes	EN 62304:2006+A1:2015
15	Packaging-Pictorial marking for handling of goods	ISO 780 :2015
16	Standard Test Method to Determine Efficacy of Disinfection Processes for Reusable Medical Devices (Simulated Use Test)	ASTM E 1837 – 96 (Reapproved 2002)
17	Non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers	EN 1060-4:2004

18	Medical electrical equipment -- Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers	IEC 80601-2-30:2018
19	Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment	ISO 80601-2-61:2017
20	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	IEC 60601-1-8:2012
21	Medical electrical equipment -- Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment	EN 60601-2-49:2015
22	Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment	EN 60601-2-27:2006/AC:2006
23	Medical devices - Application of usability engineering to medical devices	EN 62366:2008
24	Clinical evaluation: a guide for manufacturers and notified bodies under directives 93/42 and 90/385	MEDDEV 2.7/1 rev.4
25	Guidance document - Market surveillance - Guidelines on a Medical Devices Vigilance System	MEDDEV 2.12/1 rev.8