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

Manufacturer: Shenzhen Luckcome Technology Inc., Ltd.
201, 2F, NO.1 ZhongJian Industrial Building，NO.18 Yanshan Road, SheKou, Nanshan District, Shenzhen. Guangdong, China

European Representative: MEQUIPEX
Feldstrasse 39, 4813 Altmuenster Austria

Product: Fetal/Maternal Monitor

MODEL： L8、L8A、L8E、L8F、L8M、L8ME、L8P、eFM-60

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): 6016GB410141217

Start of CE-marking: 17 December, 2014

Place, Date of Issue: 5 June, 2016

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 15223-1:2012
3	Term, symbol and information of medical device— information of medical device manufacturer offering	EN 1041:2008
4	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance	EN 60601-1:2006 / AC:2010
5	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2:2007
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	Clinical thermometers - Part 4: Performance of electrical thermometers for continuous measurement	EN 12470-4:2000+A1:2009
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 61157:2007
11	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	EN ISO 10993-1:2009
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 10993-10-2010
14	Medical device software - Software life-cycle processes	EN 62304:2006
15	Packaging-Pictorial marking for handling of goods	ISO 780 :1997
16	Sterilization of medical devices Information to be provided by the manufacturer for the processing of resterilizable medical devices	ISO 17664:2004
17	Standard Test Method to Determine Efficacy of Disinfection Processes for Reusable Medical Devices (Simulated Use Test)	ASTM E 1837 – 96 (Reapproved 2002)
18	Non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers	EN 1060-4:2004
19	Medical electrical equipment -- Part 2-30: Particular	IEC 80601-2-30:2009

	requirements for basic safety and essential performance of automated non-invasive sphygmomanometers	
20	Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment	ISO 80601-2-61:2011
21	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 60601-1-8:2006
22	Medical electrical equipment -- Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment	EN 60601-2-49:2001