DECLARATION OF CONFORMITY
TO COUNCIL DIRECTIVE 93/42/EEC Amended by 2007/47/EC
OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES

MANUFACTURER:

Shenzhen Jamr Technology Co., Ltd

2ND FLOOR, A-BUILDING, NO.2 GUIYUAN ROAD, GUIHUA COMMUNITY, GUANLAN TOWN, LONGHUA NEW DISTRICT, SHENZHEN, CHINA

MEDICAL DEVICE: Blood Pressure Monitor

MODEL NUMBER: W02 /W03/ B02 / B05 / B06T / B07 / B15 / B02T / B51 / B22 / B26/ B66T / B63 / BN1W / B56 / B07S / B22S/C01/C02/C03/C04/C05/F01

CLASSIFICATION - *ANNEX IX, RULE 10*: *CLASS IIA*

CONFORMITY ASSESSMENT ROUTE: *ANNEX V*

WE, THE MANUFACTURER, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC Amended by 2007/47/EC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES; INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EC. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

STANDARDS APPLIED: *SEE ATTACHED LIST OF (HARMONISED - EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED.*

NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, D-80339 M NCHEN, GERMANY

IDENTIFICATION NUMBER 0123

(EC) CERTIFICATE(S): *EC CERTIFICATE(S) NUMBER(S) :G2 090084 0007 REV.00*

EC REP

EUROPEAN REPRESENTATIVE: SHANGHAI INTERNATIONAL HOLDING CORP. GMBH (EUROPE);
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START OF CE-MARKING: *2014-05-07*

PLACE, DATE OF DECLARATION: SHENZHEN *518001, 2020-06-03*

SIGNATURE:

NAME: FUSHEGN LUO

POSITION: Management representative

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Harmonized Standards List

Product title
Blood Pressure Monitor

No	File No.	Edition	File name
1	EN ISO13485	2016	Medical Devices - Quality Management Systems-Requirement for Regulatory Purposes
2	MDD 93/42/EEC (amended by 2007_47_EC)	2007	Medical Device Directive
3	ISO14971	2019	Medical devices - Application of risk management to medical devices
4	IEC 60601-1-2005/Amd 1-2012	2012	Medical electrical equipment-Part1: General requirements for safety and essential performance
5	IEC 60601-1-2	2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
6	ISO 10993-1	2009	Biological evaluation of medical device- Part1: Evaluation and testing
7	ISO 10993-5	2009	Biological evaluation of medical device- Part5: Tests for in vitro cytotoxicity
8	ISO 10993-10	2010	Biological evaluation of medical device- Part10: Tests for irritation and delayed-type hypersensitivity
9	IEC 80601-2-30	2013	Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers.
10	IEC 62366-1-2015/Cor 1-2016 EN 62366-1-2015+AC-2015	2016	IEC 62366-2007: Medical Devices - Application of Usability Engineering to Medical Devices
11	EN1041+A1-2013	2013	Information supplied by the manufacture of medical devices
12	MEDDEV2.7.1 Rev.4	2016	Evaluation of clinical data: A guide for manufacturers and notified bodies
13	IEC 62304-2006/Amd 1-2015 EN 62304-2006+A1-2015	2015	Medical device software-Software life cycle processes
14	IEC 60601-1-11-2015	2015+ CORR. 1:2011	Medical electrical equipment-Part1-11: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

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15	IISO 14155-2011/Cor 1-2011	2011	Clinical investigation of medical devices for human subjects-Good clinical practice
16	EN ISO 15223-1-2017	2017	Medical device-- Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General requirements
17	EN ISO 81060-1:2012	2012	Non-invasive sphygmomanometers - part 1: test methods and requirements for non-automatic measurement types
18	ISO 81060-2 : 2018	2018	specifies the requirements and methods for the clinical investigation

PLACE, DATE OF DECLARATION: SHENZHEN *518001，2020-06-03*

SIGNATURE:

NAME: FUSHEGN LUO

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