withings

Attestation of EC Conformity

Withings SA,
2 Rue Maurice Hartmann,
92130, Issy-les-Moulineaux, FRANCE
Hereby declares that the following product meets all applicable requirements to be sold within the European Market

Name of product: Blood Pressure Monitor
Brand Name: Withings
Model: BP-801

The EC Declaration of conformity is attached hereafter.

14 October 2019
Xavier Debreuil
Product Director

EC Declaration of Conformity

For the following equipment:

Blood Pressure Monitor

(Product Name)

BP-801 / WITHINGS

(Model Designation / Brand Name)

Manufacturer: Ya Horng Electronic Co.,Ltd.
Factory: Atten Electronic(Dongguan) Co., Ltd.
Factory: Ya Horng (Dongguan) Electronic Co., Ltd.

(Manufacturer Name)

Manufacturer: No.35, Shalun, Anding Dist., Tainan City 745, Taiwan
Facory: No.34 Gao Yu Nan Road. Tang Xia Town, Dong Guan, Guangdong, China.
Factory: No.34 Gao Yu Nan Road. Tang Xia Town, Dong Guan, Guangdong, China.

(Manufacturer Address)

is herewith confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning Medical Device Directive 93/42/EEC of 14 June 1993 concerning medical devices as amended by Directive 2007/47/EC– Annex I and the conformity assessment Annex II-exclusive section 4 to be certified by DNV GL Nemko Presafe AS (notify body number – 2460) For the evaluation regarding the Class IIa product safety aspects, the following harmonized standards are applied:

- ISO 13485:2016/NS-EN ISO 13485:2016:Medical devices. Quality management systems. Requirements for regulatory purposes
- EN ISO 14971:2012: Medical devices -- Application of risk management to medical devices
- IEC60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012) + CORR.1 (2014)/IEC 60601-1: 2012+ CORR.1 (2014), EN 60601-1: 2006 + A1: 2013+ A12: 2014 : Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- EN 1060-1: 1995 + A2: 2009 : Non-invasive sphygmomanometers. General requirements
- EN 1060-3: 1997 + A2: 2009: Non-invasive sphygmomanometers. Supplementary requirements for electro-mechanical blood pressure measuring systems
- EN 1060-4: 2004: Non-invasive sphygmomanometers. Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers
- EN 80601-2-30: 2013: Medical electrical equipment -- Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers
- EN 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
- ETSI EN 300 328 V2.1.1: 2016: Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU

- EN 301 489-1 v2.1.1: 2016 : ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU
- EN 301 489-17 V3.1.1: 2016 : ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
- EN 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
- EN 55011:2009/A1:2010 : Industrial, scientific and medical equipment– Radio-frequency disturbance characteristics Limits and methods of measurement
- EN ISO 10993-1:2009/AC:2010 : Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
- EN ISO 10993-5:2009:Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- EN ISO 10993-10:2010:Biological evaluation of medical devices.Tests for irritation and skin sensitization
- EN 60601-1-6:2010(Third Edition)+A1:2013 : Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- EN 62366:2008 : Medical devices - Application of usability engineering to medical devices
- EN ISO 15223-1:2012 : Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- EN 62304:2006/AC:2008 : Medical device software – Software life cycle processes
- Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment(RoHS)
- Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

The following manufacturer / importer or authorized representative established within the electrocardiograph is responsible for this declaration:

YA HORNG ELECTRONIC CO., LTD.

(Company Name)

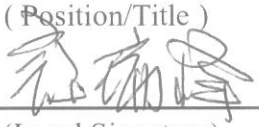
NO. 35, SHALUN, ANDING DIST., TAINAN CITY, TAIWAN, POSTAL CODE: 745

(Company Address)

Person responsible for making this declaration:

JERRY HSU — DIRECTOR OF HEALTH CARE DEPARTMENT

(Name,Surname) — (Position/Title)

TAINAN, TAIWAN — SEP. 3, 2018 — 

(Place) (Date) (Legal Signature)