YA HORNG ELECTRONIC CO.,LTD.
TEL：886-6-5932201~8 FAX：886-6-5930030 www.yahorng.com
No.35, Shalun, Anding District, Tainan City. Taiwan. R.O.C.

EC Declaration of Conformity

according to the Medical Device Directive(MDD) 93/42/EEC

For the following equipment:

Product Name:
Smart temporal thermometer

Model Designation / Brand Name:
SCT01 / WITHINGS

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

Manufacturer Address:
Manufacturer: No.35, Shalun, Anding Dist., Tainan City 745, Taiwan
Facory: Room 201, Building #9, No.84 Gaoyu SouthRoad, Tangxia Town, Dong Guan,Guangdong, China

Notified body Name:
DNV Product Assurance AS

Notified body Address:
Veritasveien 1
1363 Høvik
Country : Norway

Intended purpose:
The device is intended for use in measuring temperature in adult population, children and babies population. This device is not suitable for children born before term.
Withings Thermo (SCT01) is intended for the intermittent monitoring of human body temperature at home. Always consult your doctor.
Self-diagnosis of measurement results and self-treatment are dangerous.
Pregnant women should consult a doctor before using the thermometer.
Please consult your doctor when there is a temperature rise on:
- Neonates and babies under 3 months
- Patients over 60 year old
- Immunocompromised patients
- Bedridden patients

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- Transplanted patients

Please consult your doctor if other symptoms (vomiting , diarrhea, pain, shivering, stiff neck....) occur even if there is no fever.

This device is a precision thermometer measuring equipment liable to be understood by lay user but it still should be handled with care.

GMDN Code:
17888 Thermometer, infrared, skin

EMDN/CND Code:
V03010199 THERMOMETERS - OTHERS

Classification:
Class IIa MDD 93/42/EEC Annex IX, Rule 10

Declared under the sole responsibility of the manufacture above mentioned.

It 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 Presafe AS(notified body number – 2460). For the evaluation regarding the Class IIa product safety aspects, the following harmonized standards are applied:

- 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
- IEC 60601-1: 2005/A1:2012 ; EN 60601-1:2015 : Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11:2010 ; EN 60601-1-11: 2010: 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 v2.2.2 :2019: Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive
- EN 301 489 –1 v2.1.1 : 2017 : Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
- EN 301 489-17 v3.1.1 :2017 : Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard

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for radio equipment; Part 17: Specific conditions for Broadband Data Transmission Systems

- IEC 60601-1-2:2014 ; EN 60601-1-2:2015 : Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- 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
- ISO 10993-10: 2010 : Biological evaluation of medical devices. Tests for irritation and skin sensitization
- IEC 60601-1-6:2010 ; EN 60601-1-6:2010 : Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62366:2007 ; EN 62366:2008 : Medical devices - Application of usability engineering to medical devices
- EN ISO 15223-1:2016 : Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- IEC 62304:2006 ; EN 62304:2006/AC:2008 : Medical device software – Software life cycle processes
- ISO 80601-2-56:2017/AMD 1:2018: Medical electrical equipment -- Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
- EN12470-5:2003 : Clinical thermometers. Performance of infra-red ear thermometers (with maximum device)
- ASTM E1965-98(2016) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature
- 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. The Certificate of Compliance includes Directive 2015/863 published in 2015 by the EU (often referred as RoHS 3) and Directive 2017/2102/EU published by the EU November 17, 2015.
- 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 thermometer is responsible for this declaration:

Kahl Handelsvertretung

(Company name of the authorized representative)

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Isarstr. 33 40699 Erkrath Germany

(Company address of the authorized representative)

Person responsible of the manufacturer for making this declaration:

Jerry Hsu	**General Manager**
(Name ,Surname)	(Position/Title)

Ya Horng	2023. APR. 24	
(Manufacturer name)	(Date)	(Legal Signature)