

# Withings

Société Anonyme au capital de 3 243 071 euros

Siège social : 2, rue Maurice Hartmann – 92130 ISSY LES MOULINEAUX - FRANCE

N° de SIRET : 504 787 565 RCS NANTERRE

Tél : +33 1 41 46 04 60

Fax : +33 1 41 46 04 56



## EC - DECLARATION OF CONFORMITY

*This declaration consists of 2 pages*

**Medical Device(s):** Withings Thermo

**Model(s):** SCT01

**Trademark:** Withings

**Manufacturer:** Ya Horng Electronic Co., Ltd.

**Manufacturing Site(s):**

(1) Ya Horng (Dongguan) Electronic Co., Ltd.

188 Industrial District, Ping Shan Administrative District, Tang Shia Town, Dongguan, Guangdong, China

(2) Atten Electronic (Dongguan) Co., Ltd.

188 Industrial District, Ping Shan Administrative District, Tang Shia Town, Dongguan, Guangdong, China

**Risk Classification:** IIa

**Quality Management System Certificate:**

Certificate No. 7971-2016-CE-RGC-NA revision 0.0, issued by DNV BUSINESS ASSURANCE, Notified Body No.: 0434, Expiration date: 21 July 2021

**We, Withings, 2 rue Maurice Hartmann, 92130 Issy-les-Moulineaux, declare under our sole responsibility that the product to which this declaration relates is in conformity with the essential requirements and other relevant requirements of the R&TTE Directive**

(1999/5/EC & 2014/53/EU), of the Council Directive on the harmonization of the Laws of the Member States concerning Medical Devices Directive 93/42/EEC of 14 June 1993 concerning medical devices as amended by Directive 2007/47/EC - Annex I for the evaluation regarding Class IIa product safety aspects, and Council Directive 2011/65/UE on restriction of the use of certain hazardous substances in electrical and electronic equipment. The product is in conformity with the following standards and/or other normative documents:

EN ISO 13485:2003/AC:2009

EN ISO 14971:2012

EN 60601-1-11: 2010

ISO 80601-2-56:2009 (First Edition), for use in conjunction with IEC 60601-1:2005 (Third Edition)

ASTM 1965:1998

EN 12470-5:2003

EN 60601-1-2:2007

EN 60601-1-2:2007 (EN 55011:2009+A1:2010)

EN ISO 15223-1:2012

IEC 60601-1:2005+CORR.1(2006)+CORR.2(2007)

EN 60601-1:2006 + AC:2010 + A1:2013

IEC 62304:2006/AC:2008

IEC 60601-1-6:2010

IEC62366:2008

IEC10993-1, -5, -10

EN 301 489-1 V1.9.2 (2011-09)

EN 301 489-17 V2.2.1 (2012-09)

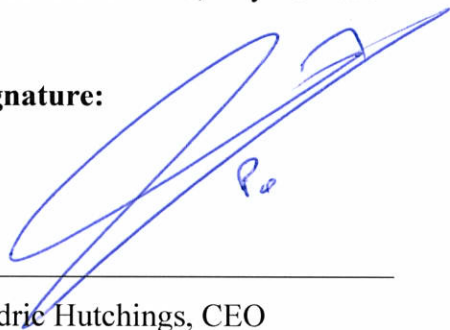
EN 300 328 V1.9.1 (2015-02)

**This declaration of conformity is valid from July 21, 2016.**

**Authorised Signatory:** Cedric Hutchings, CEO

**Place/ Date:** Paris, July 28 2016

**Signature:**



Cedric Hutchings, CEO