

Withings

Société anonyme au capital de 3 127 031 euros
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EC - DECLARATION OF CONFORMITY

This declaration consists of 2 pages

Medical Device(s): Wireless Blood Pressure Monitor

Model(s): BP-801

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. 93878-2011-CE-RGC-NA rev 5.0, issued by DNV BUSINESS ASSURANCE,
Notified Body No.: 0434, Expiration date: 06 April 2021

We, Withings, 2 rue Maurice Hartmann, 92130 Issy-les-Moulineaux, declare under our sole responsibility that this 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), Council Directive 93/42/EEC of 14 June 1993 concerning medical devices,

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:

IEC60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)

EN 60601-1: 2006+AC (2010) :

IEC/EN 60601-1-11 : 2010

IEC/EN 60601-1-11 : 2010

EN 1060-3: 1997 + A1: 2005

IEC 80601-2-30: 2009 (First Edition) for use in conjunction with IEC 60601-1:2005

EN 80601-2-30: 2010

ANSI/AAMI 80601-2-30: 2009

EN 301 489 –1 v1.9.2: 2011

EN 301 489 –17 V2.2.1: 2012

EN 60601-1-2:2007/AC:2010

ETSI EN 300 328 V1.8.1: 2012

EN1060-4: 2004

EN ISO 13485:2003 /AC: 2009

EN ISO 9001:2008/AC: 2009

EN ISO14971:2012

This declaration of conformity is valid from April 15, 2016.

Authorised Signatory: Cedric Hutchings, CEO

Place/ Date: Paris, April 15 2016

Signature:

p.a.


Cedric Hutchings, CEO