withings

EU DECLARATION OF CONFORMITY

We,
Withings SA
2, rue Maurice Hartmann,
92130 Issy-les-Moulineaux – France

Declare under our sole responsibility of the manufacturer, that the product:

Product name: BPM Core
Brand name: Withings
Model: WPM04

Risk Classification: IIa

is in conformity with the relevant Union harmonization Legislation:

Directive	93/42/CEE as amended by 2007/47/EC – Annex I and the certified quality system per Annex II, excluding (4) (Medical device)
Directive	2014/53/EU (RED)
Directive	2011/65/EU (RoHS)

The conformity with the essential requirements of the 93/42/CEE has been demonstrated against the following standards:

Quality Management System	EN ISO 13485:2016 EN ISO 14971:2012
Medical Electrical Equipment	EN 60601-1-11:2010, 2015 EN 6060-1 :1995 + A2 :2009 EN 1060-3 :1997 + A2 :2009 EN 81060-2-30 :2010,2013 EN 15223-1 :2016 ANSI/AAMI EC 57:2012
EMC	EN 60601-1-2-2015 (EN 55011 :2016) EN 301 489-1 V2.1.1 (2017-02) + EN 301 489-17 V3.1.1 (2017-02)
RF spectrum use	EN 300 328 v2.1.1

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Biocompatibility ISO 10993-1:2009

The conformity assessment procedure referred to in Directive 93/42/CEE has been by Ente Certificazione Macchine, Via Ca Bella 243, 40053 Valsamoggia, Castello di Serravalle, Italy.

Thus, CE is placed on the product

Signed on behalf of Withings SA, in Issy-les-Moulineaux, July 5th, 2019.

Name: Xavier Debreuil
Position: Product director