WITHINGS

EU DECLARATION OF CONFORMITY

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

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

Product name: BPM Connect Brand name: Withings Model: WPM05

Risk Classification: Ila (rule 10)

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) amended by the 2015/863/EU

Directive 1907/2006 (REACH)

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 60601-1 :1995 + A2 :2009 EN 1060-3 :1997 + A2 :2009 EN 81060-2-30 :2010,2013

EN 15223-1 :2016 IEC 62304:2006 IEC 62366-1:2015

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)

WITHINGS

RF spectrum use

EN 300 328 v2.1.1

Biocompatibility

ISO 10993-1:2009

The conformity assessment procedure referred to in Directive 93/42/EEC as amended by the 2007/47/EC has been verified by Ente Certificazione Macchine, Via Ca Bella 243, 40053 Valsamoggia, Castello di Serravalle, Italy.

Thus, **C E** 1282 is placed on the product

Signed on behalf of Withings, in Issy-les-Moulineaux, September 27, 2021.

Name: Xavier Debreuil Position: Product director