

WITHINGS

CE 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 Pro
Brand name: Withings
Model: WPM06

Risk Classification: IIa (rule 10)

is in conformity with the relevant European 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)
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The conformity with the essential requirements of the 93/42/EEC as amended by the 2007/47/EC has been demonstrated against the following standards:

Quality Management System	EN ISO 13485:2016 EN ISO 14971:2012
Medical Electrical Equipment	IEC 60601-1:2005/A1:2012 IEC 60601-1-2:2014 IEC 60601-1-6:2010 IEC 60601-1-11:2015 IEC 62304:2015 IEC 62366-1:2015 IEC 62133-2:2017 IEC 80601-2-30:2018 EN ISO 15223-1:2016

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Biocompatibility

ISO 10993-1:2009/AC:2010

ISO 10993-5:2009

ISO 10993-10:2010

The conformity assessment procedure referred to in the Directive 93/42/CEE 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,  **1282** is placed on the product.

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

Name: Xavier Debreuil
Position: Product director

