

EU DECLARATION OF CONFORMITY

Manufacturer

Withings
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92130 Issy Les Moulineaux
France

Notified Body

Ente Certificazione Macchine
Via Ca Bella 243
40053 Valsamoggia, Castello di Serravalle
Italy
Notified body number: 1282

Swiss Authorized Representative

MedEnvoy Switzerland
Gotthardstrasse 28
6302 Zug
Switzerland
CH RN: CHRN-AR-20000310

Product Name

Withings BPM Connect

Model

WPM05

Supplied Accessories

Charging Cable

Risk Classification

Class IIa, rule 10

Intended purpose

The BPM Connect is a digital monitor intended for use in measuring blood pressure and heart rate. The device is intended to be used in a human adult population with an arm circumference of 9 inches to 17 inches (22 cm to 42 cm).

We, Withings, declare under our sole responsibility that the above-named product conforms to the essential requirements of the following Directives:

Applied European Directives

Medical Device Directive (MDD): 93/42/EEC

Radio Equipment Directive (RED): 2014/53/EU

Waste Electrical and Electronic Equipment (WEEE): 2012/19/EU

RoHS: 2011/65/EU amended by 2015/863/EU

Medical Device Directive: We declare under our sole responsibility that the devices subject to this declaration are in conformity with the standards mentioned below and meet the requirements specified in Annex I.

- ISO 13485:2016 (EN ISO 13485:2016/AC:2008/A11:2021)
 - ISO 14155:2020 (EN ISO 14155:2020)
 - ISO 14971:2019 (EN ISO 14971:2019/A11:2021)
 - ISO 10993-1:2018 (EN ISO 10993-1:2020)
 - ISO 15223-1:2021 (EN ISO 15223-1:2021)
 - EN 60601-1:2015
 - EN 60601-1-2:2015 (EN 55011 :2016)
 - EN 1060-3:1997/A1:2005/ A2:2009
 - IEC 60601-1-6:2010/A1:2013(EN 60601-1-6:2010)
 - EN 60601-1-11:2015
 - IEC 80601-2-30: 2018 (EN 80601-2-30:2019)
 - IEC 62304:2006/A1:2015 (EN 62304:2006/A1:2015)
 - IEC 62366-1:2015/A1:2020 (EN 62366-1:2015/A1:2020)
 - ISO 20417:2021 (EN ISO 20417:2021)
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Radio Equipment Directive: The conformity assessment procedure as detailed in Annex III has been followed and performed.

Health&Safety(Article3.1(a))

- EN 62209-2:2010

EMC (Article3.1(b))

- EN 301 489-1 V2.1.1
- EN 301 489-17 V3.1.1
- EN 5011:2009/A1:2010

RF Spectrum(Article3.2)

- EN 300 328 V2.1.1
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Waste Electrical and Electronic Equipment Directive: The device subject to the directive 2012/19/EU is marked with the logo from Annex IX and Withings supplies recycling information.

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RoHS Directive: The device complies with the below-mentioned standards and meets the requirements specified in Article 4 of the 2011/65/EU Directive amended by 2015/863/EU. List of RoHS restricted substances acceptance limits values tolerated and verification methods to ensure compliance:

- EN IEC 63000:2018

Substances and Acceptance Limits	Verification Methods
- N/A	- IEC 62321-1:2013 - IEC 62321-2:2013 - IEC 62321-3:2013
- Mercury (0,1%)	- IEC 62321-4:2013+A1:2017
- Cadmium (0,01%) - Lead (0,1%)	- IEC 62321-5:2013
- PBBs (0,1%) - PBDEs (0,1%)	- IEC 62321-6:2015
- Hexavalent chromium (0,1%)	- IEC 62321-7-1:2015
- Phthalates (DEHP, BBP, DBP, DIBP) (0,1%)	- IEC 62321-8:2017

Additional Compliance::

Lithium-ion Battery: IEC 62133-2:2017

Thus,  1282 is placed on the product

Signed on behalf of Withings, in Issy-les-Moulineaux,

Name: Xavier Debreuil

Function: Product Director

DocuSigned by Xavier Debreuil
 *Xavier Debreuil* | J'approuve ce document
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