

# 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 Core**  
**Brand name: Withings**  
**Model: WPM04**

**Risk Classification:** *Ila (rule 10)*

is in conformity with the relevant European Union harmonization Legislation:

<b>Directive</b>	93/42/CEE as amended by 2007/47/EC – Annex I and the certified quality system per Annex II, excluding (4) (Medical device)
<b>Directive</b>	2014/53/EU (RED)
<b>Directive</b>	2014/30/EU (EMC)
<b>Directive</b>	2011/65/EU (RoHS) amended by the 2015/863/EU

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:

<b>Quality Management System</b>	EN ISO 13485:2016 EN ISO 14971:2012
<b>Medical Electrical Equipment</b>	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

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## EMC

EN 60601-1-11:2010, 2015  
EN 60601-1 :1995 + A2 :2009  
EN 1060-3 :1997 + A2 :2009  
EN 81060-2-30 :2010,2013  
IEC 62304:2006  
IEC 62366-1:2015  
EN 15223-1 :2016  
ANSI/AAMI EC 57:2012


## 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,  **1282** is placed on the product

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

Name: Xavier Debreuil  
Position: Product Director

