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:

Brand name: Withings
Model: ECG Monitor

Risk Classification: IIa (rule 10)

is in conformity with the relevant Union harmonization Legislation:

Directive	93/42/EEC as amended by 2007/47/EC – Annex I and the certified quality system per Annex II, excluding (4) (Medical device)

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 14971:2019
Medical Software	EN 60601-1-6:2010 EN 62304:2006 EN 15223-1:2016 ANSI/AAMI/IEC 60601-2-47:2012 IEC 60601-1-11:2015 IEC 60601-1-2: 2015 EN 60601-1 : 2006 EN 1041:2008

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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, CE 1282 is placed on the instruction for use of the software.

Signed on behalf of Withings, in Issy-les-Moulineaux, May 11, 2022.

Name: Xavier Debreuil
Position: Product director