

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 14971:2012

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, September 27, 2021.

Name: Xavier Debreuil
Position: Product director

A handwritten signature in black ink, appearing to read 'X. Debreuil', enclosed within a large, loopy oval scribble.