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: Scan Monitor

The Scan Monitor is used with the ScanWatch which has several variants:

- ScanWatch 38mm
- ScanWatch 42mm
- ScanWatch Horizon (Alternative name: ScanWatch Diver)
- ScanWatch Nova
- ScanWatch RoseGold

Manufacturer:
Withings
2, rue Maurice Hartmann,
92130 Issy-les-Moulineaux – France

Risk Classification : IIa (rule 10)

Quality Management System Certificate: PGH-2019-002

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)
Quality Management System	EN ISO 13485:2016 EN ISO 14971:2012
Medical Standard	EN 60601-2-47 :2001

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Safety Standards	ISO 80601-2-61 :2017 EN 62304 :2006/AC :2008 EN ISO 15223-1:2016 EN ISO 14155:2011/AC:2011 EN 62366:2008 ISO 10993-5:2009 ISO 10993-10:2010 IEC 62133-2:2017 IEC 62471: 2006

The conformity assessment procedure referred to in Directive 93/42/EEC as amended by the 2007/47/EC has been performed by the notified body 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

Name: Xavier Debreuil
Position: Product Director

DocuSigned by Xavier Debreuil
Xavier Debreuil
J'approuve ce document
04-Dec-2023 | 22:53 CET
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