WITHINGS

EC 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: Sleep Apnea Detector

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 Software	EN 60601-1-6 :2010 EN 62304 :2006/AC :2008 EN ISO 15223-1:2016 IEC 60601-1-11:2015 IEC 60601-1-2: 2015 EN 60601-1 : 2006/A1 :2013 EN 1041 :2008 EN ISO 14155:2011/AC:2011 EN 62366:2008

WITHINGS

The conformity assessment procedure referred to in Directive 93/42/CEE 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