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:

Medical Device Name : Sleep Apnea Detector

Sleep Apnea Detector is a medical device software intended for use with Withings Sleep Analyzer (wsm02)

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

Risk Classification : IIa (rule 10)

GMDN Code: 64939 - Sleep disorder interpretive software, patient-use

Quality Management System Certificate: PGH-2019-002

complies with the European regulation and standards identified below:

Directive	93/42/EEC as amended by 2007/47/EC – Annex I and the certified quality system per Annex II, excluding (4)
Quality Management System	EN ISO 13485:2016 EN ISO 14971 :2019
Medical Software	EN 60601-1-6 :2010 EN 62304 :2006/AC :2008 EN ISO 15223-1:2016 EN 60601-1-11:2015 (IEC 60601-1-11:2015) EN 60601-1-2:2015

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EN 60601-1 : 2006/A1 :2013
EN 1041 :2008
EN ISO 14155:2011/AC:2011
EN 62366:2008

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 5th, 2022.

Name: Xavier Debreuil
Position: Product Director