

EU DECLARATION OF CONFORMITY

Manufacturer

Withings
2 rue Maurice Hartmann
92130 Issy Les Moulineaux
France

SRN: FR-MF-000009505

Notified Body

Ente Certificazione Macchine
Via Ca Bella 243
40053 Valsamoggia, Castello di Serravalle
Italy

Notified body number: 1282

Medical Device	Withings ECG Monitor
Model	wbsecg
CND Code	Z12050392 - ELECTROCARDIOGRAPHS - MEDICAL DEVICE SOFTWARE
Basic UDI DI	3700546708084VP
Risk Classification (according to 2017/745 annex VIII)	Class IIa, rule 11

Applied European Regulations & Standards

2017/745 (MDR)

- ISO 13485:2016 (EN ISO 13485:2016/AC:2008/A11:2021)
- EN ISO 14155:2020
- ISO 14971:2019 (EN ISO 14971:2019/A11:2021)
- EN ISO 15223-1:2021
- EN ISO 20417:2021
- IEC 60601-1-2:2014/A1:2020 (EN 60601-1-2:2015/A1:2021)¹
- IEC 60601-2-47:2012 (EN 60601-2-47:2015)¹
- IEC 62304:2006/A1:2015 (EN 62304:2006/A1:2015)
- IEC 62366-1:2015/A1:2020 (EN 62366-1:2015/A1:2020)

We hereby declare under our sole responsibility that :

- wbsecg, Withings ECG Monitor

complies with the above-mentioned standards and meets the requirements specified in:

- Annex I of the 2017/745 Medical Device Regulation,

¹ - wbsecg is activated with wbs08 (Withings Body Scan)

WITHINGS

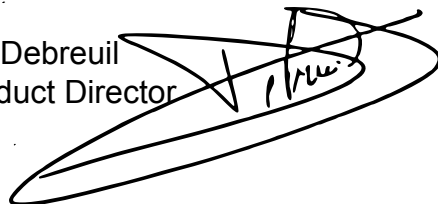
The conformity assessment of the quality management system and the technical documentation according to Annex IX, Chapters I and III of the 2017/745 medical device regulation has been performed by the Notified Body mentioned above.

EC Certificate No: ECM22MDR001 – Expiry date : 22/12/2027

Signed on behalf of Withings, in Issy-les-Moulineaux, 23/12/2022.

Thus, **CE 1282** is available on the product's electronic label.

Name: Xavier Debreuil
Function: Product Director
Signature:

A handwritten signature in black ink, appearing to read 'X. Debreuil', is written over a large, loopy oval scribble.