WITHINGS

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

Swiss Authorized Representative

MedEnvoy Switzerland
Gotthardstrasse 28
6302 Zug
Switzerland

CH RN: CHRN-AR-20000310

Medical Device	Withings ECG Monitor
Model	wbsecg
EMDN Code	Z12050392 - ELECTROCARDIOGRAPHS - MEDICAL DEVICE SOFTWARE
Basic UDI DI	3700546708084VP
Risk Classification (according to 2017/745 annex VIII)	Class IIa, rule 11
Intended purpose	The Withings ECG Monitor is a software-only device intended for use with the Withings Body Scan (wbs08) to create, record, store, transfer and display lead-II and lead-III of a two-channel electrocardiogram (ECG). It derives and displays leads I, aVR, aVF and aVL. The Withings ECG Monitor determines the presence of atrial fibrillation (AFib), sinus rhythm, and high heart rate (no signs of AFib but a sinus rhythm with heart rate between 100-150 bpm) on a classifiable waveform. The Withings ECG Monitor is not recommended for users with other known arrhythmias.

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	The Withings ECG Monitor is intended for over-the-counter (OTC) use. The ECG data displayed by the Withings ECG Monitor is intended for informational use only. The user is not intended to interpret or take clinical action based on the device output without consultation of a qualified healthcare professional. The ECG waveform is meant to supplement rhythm classification for the purposes of discriminating AFib from sinus rhythm and is not intended to replace traditional methods of diagnosis or treatment. The Withings ECG Monitor is intended for use by an adult population.

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)

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

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,

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

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Signed on behalf of Withings, in Issy-les-Moulineaux, *23/01/2023*.

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

Name: Xavier Debreuil
Function: Product Director
Signature: