

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

UK Responsible Person

Emergo Consulting (UK) Ltd
c/o Cr360 - UL International, Compass House, Vision
Park Histon
Cambridge CB24 9BZ
England, United Kingdom
MHRA Reference Number: 22395

Product Name

Withings ScanWatch 2 companion app

Model

HWA-CPN

EMDN Code

Z12040182

Basic UDI-DI

3700546708695WS

Risk Classification

Class IIa, rule 3.3

Description/Intended purpose

Withings ScanWatch 2 companion app is a software accessory of the Withings ScanWatch 2. It is part of the Withings App.

Withings ScanWatch 2 companion app allows the installation of the watch, activates its medical features, and displays the results of performed measurements.

Medical Device Regulation (MDR) 2017/745: We, Withings, declare under our sole responsibility that the device subject to this declaration is in conformity with the standards mentioned below and meets the general safety and performance requirements specified in Annex I.

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

- EN ISO 13485:2016/AC:2018/A11:2021
 - EN ISO 14971:2019/A11:2021
 - EN ISO 15223-1:2021
 - EN ISO 20417:2021
 - EN 62304:2006/A1:2015
 - EN 62366-1:2015/A1:2020
 - EN 82304-1:2017
 - EN ISO 14155:2020
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Thus,  1282 is placed on the product

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

Signed on behalf of Withings, in Issy-les-Moulineaux,

Name: Xavier Debreuil

Function: Product Director

Signed by Xavier Debreuil



Xavier Debreuil

I approve this document
28-Apr-2025 | 18:59 CEST

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