WITHINGS

EU DECLARATION OF CONFORMITY

Manufacturer	**Notified Body**
Withings 2 rue Maurice Hartmann 92130 Issy Les Moulineaux France SRN: FR-MF-000009505	Ente Certificazione Macchine Via Ca Bella 243 40053 Valsamoggia, Castello di Serravalle Italy Notified body number: 1282

Swiss Authorized Representative	**UK Responsible Person**
MedEnvoy Switzerland Gotthardstrasse 28 6302 Zug Switzerland CH RN: CHRN-AR-20000310	Emergo Consulting (UK) Ltd c/o Cr360 - UL International, Compass House, Vision Park Histon Cambridge CB24 9BZ England, United Kingdom MHRA Reference Number: 22395

Device Range Name	Withings ScanWatch 2
Withings ScanWatch 2 Series	38mm 42mm Rosegold Nova 42mm
Model	HWA10
Catalogue Number	hwa10-38-black-silver hwa10-38-white-silver hwa10-42-black-silver hwa10-42-white-silver hwa10-38-white-rosegold hwa10-38-blue-rosegold hwa10-42-blue-div2 hwa10-42-green-div2 hwa10-42-black-div2
Supplies	Charging cable Charging dock
EMDN Code	Z12040199

Basic UDI-DI	3700546708286W5
Risk Classification	Class IIa, rules 10 & 11
Intended purpose	Withings ScanWatch 2 is a medical device composed of software and the dedicated hardware of a reusable wrist applied device, which incorporates a single-lead electrocardiograph (ECG) and a reflectance photoplethysmograph (PPG). It is intended for intermittent measurements. Withings ScanWatch 2 measures, transfers, records, and displays lead I of an ECG. It calculates the heart rate and detects the presence of AF or sinus rhythm on a classifiable ECG waveform. Withings ScanWatch 2 measures, transfers, records and displays pulse rate to identify episodes of irregular heart rhythm suggestive of AF and provides a notification to the user. It can be used to supplement a clinician's decision to screen for possible AF. Withings ScanWatch 2 is indicated for over-the-counter (OTC) use in adults. Withings ScanWatch 2 is not recommended for users with other known arrhythmias.

We, Withings, declare under our sole responsibility that the above-named product conforms to the essential requirements of the following Directives:

Applied European Directives

Medical Device Regulation (MDR): 2017/745

Radio Equipment Directive (RED): 2014/53/EU

Waste Electrical and Electronic Equipment (WEEE): 2012/19/EU

RoHS: 2011/65/EU amended by 2015/863/EU

Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH): 1907/2006

Medical Device Regulation: We 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 14155:2020
- EN ISO 14971:2019/A11:2021
- EN ISO 15223-1:2021
- EN ISO 20417:2021
- EN ISO 10993-1:2020
- EN ISO 10993-5:2009
- EN ISO 10993-10:2013
- EN ISO 10993-18:2020
- EN ISO 10993-23:2021
- EN 60601-1:2006/A2:2021
- EN 60601-1-2:2015/A1:2021
- IEC 60601-1-6:2010/A2:2021
- EN 60601-1-11:2015/A1:2021
- EN 60601-2-47:2015
- EN 62304:2006/A1:2015
- ISO 17664-2:2021
- EN 62366-1:2015/A1:2020
- EN 62471:2008
- EN 60529:1991/A2:2013/AC:2019-02

Waste Electrical and Electronic Equipment Directive: The devices subject to the directive 2012/19/EU are marked with the logo from Annex IX and Withings supplies recycling information.

Radio Equipment Directive: The conformity assessment procedure as detailed in Annex III has been followed and performed.

Health & Safety (Article 3.1(a))

- EN IEC 62368-1: 2020/A11:2020
- EN 62479: 2010
- EN 50663

EMC (Article 3.1(b))

- EN 301 489-1 V2.2.3 (2019-11)
- EN 301 489-17 V3.2.4 (2020-09)
- EN 55035: 2017/A11:2020
- EN 55032: 2015/A1:2020

RF Spectrum (Article 3.2)

- EN 300 328 V2.2.2 (2019-07)

RoHS Directive: The device complies with the below-mentioned standards and meets the requirements specified in Article 4 of the 2011/65/EU Directive amended by 2015/863/EU.
List of RoHS restricted substances acceptation limits values tolerated and verification methods to ensure compliance with:

- EN IEC 63000:2018

Substances and Acceptance Limits	**Verification Methods**
- N/A	- EN 62321-3-1: 2014 - EN 62321-3-2: 2014
- Mercury (0,1%)	- EN 62321-4: 2013+A1:2017
- Cadmium (0,01%) - Lead (0,1%)	- EN 62321-5: 2014
- PBBs (0,1%) - PBDEs (0,1%)	- EN 62321-6: 2015
- Hexavalent chromium (0,1%)	- EN 62321-7-1: 2015 - EN 62321-7-2: 2017
- Phthalates (DEHP, BBP, DBP, DIBP) (0,1%)	- EN 62321-8:2017

REACH Directive: The product referenced above, as well as any articles[1] contained within the product, DO NOT CONTAIN any of the 247 REACH SVHCs as updated by ECHA on January 21, 2025 (http://echa.europa.eu/candidate-list-table) in concentrations above than 1000 PPM.

Additional Compliance:

Lithium-ion Battery: EN 62133-2 2017/A1:2021

Thus, CE 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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[1] An Article is any item within a part or component of the product which during production is given a special shape, surface or design that determines its function to a greater degree than its chemical composition. An example of articles within an electronic component would be the leads of a through-hole capacitor. For more information, please refer to Example 21 of the EU Chemicals Agency "Guidance for Requirements on Substances in Articles" (https://echa.europa.eu/documents/10162/23036412/articles_en.pdf/cc2e3f93-8391-4944-88e4-efed5fb5112c)

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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.

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- EN 62304:2006/A1:2015
- EN 62366-1:2015/A1:2020
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Signed by Xavier Debreuil
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