

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

Device Range Name

Withings BeamO

Model

SCT02

Catalog Number

SCT02-02
SCT02-03

Supplies

Charging cable
Headphone Adaptor

EMDN Code

Z1203020299

Basic UDI DI

3700546709937X2

Risk Classification

Class IIa, rules 10 & 11

Intended purpose

Withings BeamO is a non-sterile, contactless, reusable clinical thermometer intended for the intermittent determination of human body temperature over the temporal artery as the measurement site on people of all ages.

Withings BeamO is also an electronic stethoscope that enables the recording and transmission of heart and lung auscultation sound data. Withings BeamO is intended to be used by professional users in a clinical environment or by lay users in a non-clinical environment on people of all ages.

Withings BeamO measures, transfers, records, and displays lead I of an ECG. It calculates the heart rate and detects the presence of atrial fibrillation or sinus rhythm on a classifiable ECG waveform.

Withings BeamO is also intended for the spot-checking of functional oxygen saturation of arterial hemoglobin (blood oxygen, or SpO2) and pulse rate (PR). It is indicated for use with individuals 18 years and older.

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

Medical Device Regulation: We declare under our sole responsibility that the devices subject to this declaration are in conformity with the standards mentioned below and meet the requirements specified in Annex I.

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.

- 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
- EN 60601-1-6: 2010/A2:2021
- EN 60601-1-11: 2015/A1:2021
- EN 60601-2-47: 2015
- EN 62304:2006/A1:2015

- EN 62366-1:2015/A1:2020
- EN 62471: 2008
- EN ISO 80601-2-56 : 2017/A1 : 2020
- EN ISO 80601-2-61:2019
- ISO 17664-2:2021

Waste Electrical and Electronic Equipment Directive: The device subject to the directive 2012/19/EU is 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(Article3.1(a))

- EN 50566:2017
- EN 62209-2:2010
- EN 62471:2008

EMC (Article3.1(b))

- ESTI EN 301 489-1 V2.2.3 (2019-11)
- ESTI EN 301 489-17 V3.2.4 (2020-09)
- ESTI EN 301 489-52 V1.2.1 (2021-11)

RF Spectrum(Article3.2)

- ESTI 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 acceptance limits values tolerated and verification methods to ensure compliance:

- 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

Additional Compliance:

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

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
07-Apr-2025 | 15:59 CEST

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Product Name

Withings BeamO companion app

Model

SCT-CPN

EMDN Code

Z1203020282 MULTI-PARAMETER MONITORS -
SOFTWARE ACCESSORIES

Basic UDI-DI

3700546710407UC

Risk Classification

Class IIa, rule 3.3

Description/Intended purpose

Withings BeamO companion app is a software accessory of the Withings BeamO range. It is part of the Withings App.

Withings BeamO companion app allows the device installation 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

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- 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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Name: Xavier Debreuil

Function: Product Director

Signed by Xavier Debreuil

 *Xavier Debreuil* | I approve this document
07-Apr-2025 | 15:58 CEST

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