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 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

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 acceptation 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, 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
24-Apr-2025 | 19:08 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
- 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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