

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 Model	WBS08	WBS12	WBS13
Trade Name	Withings Body Scan	Withings Body Comp	Withings Body Smart
Catalog number	WBS08-White-All-Inter WBS08-Black-All-Inter	WBS12-White-All-Inter WBS12-Black-All-Inter	WBS13-White-All-Inter WBS13-Black-All-Inter
EMDN Code	Z12062404 - ELECTRODERMIC SIGNAL BIOFEEDBACK SYSTEMS		
Basic UDI DI	3700546707957WS		
Risk Classification (according to 2017/745 annex VIII)	Class IIa, rule 4 and 10		
Intended purpose	Withings Smart Scales are intended to detect and follow-up peripheral autonomic neuropathies in an adult population by performing measurements on the feet, on intact skin or in the presence of damaged skin, such as, but not limited to, blisters, callosities or wounds. Additionally, they provide the following features without medical purposes: measure weight, calculate Body Mass Index (BMI), measure body composition, measure pulse rate, measure pulse wave velocity, and estimate vascular age.		
Supplied Accessories	Charging Cable	N/A	N/A

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We, Withings, declare under our sole responsibility that the above-named products conform 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
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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.

- ISO 13485:2016 (EN ISO 13485:2016/AC:2008/A11:2021)
 - ISO 14155:2020 (EN ISO 14155:2020)
 - ISO 14971:2019 (EN ISO 14971:2019/A11:2021)
 - ISO 10993-1:2018 (EN ISO 10993-1:2020)
 - ISO 15223-1:2021 (EN ISO 15223-1:2021)
 - IEC 60601-1:2005/A2:2020 (EN 60601-1:2006/A2:2021)
 - IEC 60601-1-2:2014/A1:2020 (EN 60601-1-2:2015/A1:2021)
 - EN 55011:2016/A11:2020 class B
 - IEC 60601-1-6:2010/A2:2020 (EN 60601-1-6:2010/A2:2021)
 - IEC 60601-1-11:2015/A1:2020 (EN 60601-1-11:2015/A1:2021)
 - IEC 62304:2006/A1:2015 (EN 62304:2006/A1:2015)
 - IEC 62366-1:2015/A1:2020 (EN 62366-1:2015/A1:2020)
 - ISO 20417:2021 (EN ISO 20417:2021)
 - IEC 62133-2:2017/A1:2021 (EN 62133-2:2017/A1:2021) (Only wbs08)
 - IEC 60601-2-47:2012 (EN 60601-2-47:2015) (Only wbs08)
 - IEC 60529:1989/A1:1999/A2:2013 (EN 60529:1991/AC:2016-12; EN 60529/A2:2013/AC:2019-02)
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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))

- IEC 62368-1:2018/C1:2020 (EN IEC 62368-1:2020/A11:2020)

EMC (Article3.1(b))

- EN 301 489-1 V2.2.3

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- EN 301 489-17 V3.2.4
- EN 55032:2015/A1:2020, Class B (only wbs12 - wbs13)
- EN 55035:2017/A1:2020 (only wbs12 - wbs13)

RF Spectrum(Article3.2)

- EN 300 328 V2.2.2
- IEC 62311:2019 (EN IEC 62311:2020 / EN 50665:2017)

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	- IEC 62321-1:2013 - IEC 62321-2:2013 - IEC 62321-3:2013
- Mercury (0,1%)	- EN 62321-4: 2013+A1:2017
- Cadmium (0,01%) - Lead (0,1%)	- IEC 62321-5: 2013
- PBBs (0,1%) - PBDEs (0,1%)	- EN 62321-6: 2015
- Hexavalent chromium (0,1%)	- EN 62321-7-1: 2015
- Phthalates (DEHP, BBP, DBP, DIBP) (0,1%)	- EN 62321-8:2017

Additional Compliance:

Lithium-ion Battery:IEC 62133-2:2017/A1:2021 (EN 62133-2:2017/A1:2021) (only wbs08)

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: Aline Criton
Function: Chief Clinical and Regulatory Affairs Officer

Signé par Aline Criton



J'approuve ce document
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