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	Withings Body Scan	Withings Body Comp
Models	wbs08	wbs12
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.	

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2017/745 (MDR)	– 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) – 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
2014/53/EU (RED) 2014/30/EU (EMC)	– EN 300 328 V2.2.2 – EN 301 489-1 V2.2.3 – EN 301 489-17 V3.2.4 – IEC 62311:2019 (EN IEC 62311:2020 / EN 50665:2017)
2011/65/EU amended by 2015/863/EU (RoHS)	– IEC 62321-5:2013 (EN 62321-5:2014) – IEC 62321-4:2013/A1:2017 (EN 62321-4:2014/A1:2017) – IEC 62321-7-1:2015 (EN 62321-7-1:2015) – IEC 62321-6:2015 (EN 62321-6:2015) – IEC 62321-8:2017 (EN 62321-8:2017) – IEC 63000:2016 (EN IEC 63000:2018)
1907/2006 (REACH)	– ISO 12472:2003 (EN 12472:2020)
2014/35/EU (LVD)	– IEC 62368-1:2018/C1:2020 (EN IEC 62368-1:2020/A11:2020)

We hereby declare under our sole responsibility that :

- wbs08, Withings Body Scan
- wbs12, Withings Body Comp

comply with the above-mentioned standards and meet the requirements specified in:

- Annex I of the 2017/745 Medical Device Regulation,

- Article 3 of the 2014/53/EU Directive (RED),
- Annex I of the 2014/30/EU Directive (EMC),
- Article 4 of the 2011/65/EU Directive amended by 2016/863/EU (RoHS).

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.

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

Thus, CE 1282 is placed on the product

Signed on behalf of Withings, in Issy-les-Moulineaux, 23*/01/2023*.

Name:Xavier Debreuil
Function: Product Director
Signature: