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

Medical Device	Withings Body Scan	Withings Body Comp
Models	wbs08	wbs12
CND Code	Z12062404 - ELECTRODERMIC SIGNAL BIOFEEDBACK SYSTEMS	
Basic UDI DI	3700546707957WS	
Risk Classification (according to 2017/745 annex VIII)	Class IIa, rule 4 and 10	

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

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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, *23/12/2022*.

Name: Xavier Debreuil
Function: Product Director
Signature: