

# WITHINGS

## CE DECLARATION OF CONFORMITY

We,  
Withings  
2, rue Maurice Hartmann,  
92130 Issy-les-Moulineaux – France

Declare under our sole responsibility of the manufacturer, that the product:

**Brand name: Withings**  
**Model: Scan Monitor**

The Scan Monitor is used with the ScanWatch which has four variants:

- ScanWatch 38mm
- ScanWatch 42mm
- ScanWatch Horizon (Alternative name : ScanWatch Diver)
- ScanWatch RoseGold

**Manufacturer:**

Withings  
2, rue Maurice Hartmann,  
92130 Issy-les-Moulineaux – France

**Risk Classification :** IIa (rule 10)

**Quality Management System Certificate: PGH-2019-002**

is in conformity with the relevant Union harmonization Legislation:

<b>Directive</b>	93/42/EEC as amended by 2007/47/EC – Annex I and the certified quality system per Annex II, excluding (4) (Medical device)
<b>Quality Management System</b>	EN ISO 13485:2016 EN ISO 14971:2012
<b>Medical Standard</b>	EN 60601-2-47 :2001 ISO 80601-2-61 :2017 EN 62304 :2006/AC :2008 EN ISO 15223-1:2016

# WITHINGS

## Safety Standards

EN ISO 14155:2011/AC:2011

EN 62366:2008


ISO 10993-5:2009

ISO 10993-10:2010

IEC 62133-2:2017

IEC 62471: 2006

The conformity assessment procedure referred to in Directive 93/42/EEC as amended by the 2007/47/EC has been performed by the notified body Ente Certificazione Macchine, Via Ca Bella 243, 40053 Valsamoggia, Castello di Serravalle, Italy.

Thus,  1282 is placed on the instruction for use of the software.

Signed on behalf of Withings, in Issy-les-Moulineaux, *March 7<sup>th</sup>, 2022*

Name: Xavier Debreuil  
Position: Product Director

