QARDIO

CE

EU DECLARATION OF CONFORMITY

We, Qardio Netherlands B.V., Van Hogendorpstraat 93, Amsterdam, 1051 BK, The Netherlands, declare under our sole responsibility of the manufacturer that the product:

Product Name: **QardioBase**

Model: **B100**

Brand Name: **Qardio**

is in conformity with the relevant harmonization legislation:

Directive 2004/108/EC relating to electromagnetic compatibility (EMC Directive) AND Directive 2014/53/EU FOR COUNCIL DIRECTIVE (Radio Equipment Directive) & 93/42/EEC (Medical devices (MDD Directive)) AND 2011/65/EU FOR the ELECTRONIC EQUIPMENT (RoHS Directive) ; Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Directive).

Thus, CE is placed on the product.

Standard(s) to which Conformity is Declared:

- EN 60601-1:2006/A1:2013 & IEC 60601-1:2005/A1:2012: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- EN 300 328 v1.9.1:2015: Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive
- EN 301 489 –1 v1.9.2:2011: Electromagnetic compatibility and Radio Spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
- EN 301 489-17 v2.2.1:2012: Electromagnetic compatibility and Radio Spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment; Part 17: Specific conditions for Broadband Data Transmission Systems
- EN 55022:2010+AC:2011: Information technology equipment – Radio disturbance characteristics – Limits and methods of measurement CISPR 22:2008 (Modified)
- EN 62304:2006/AC:2008: Medical device software – Software life cycle processes
- EN 60601-1-2:2007/AC:2010 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- EN 60601-1-6:2010(Third Edition)+A1:2013: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

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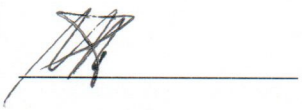
- EN 62366:2007(First Edition)+A1:2014: Medical devices - Application of usability engineering to medical devices
- EN ISO 10993-1:2009/AC:2010: Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
- EN ISO 10993-5:2009: Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- EN ISO 10993-10:2010: Biological evaluation of medical devices. Tests for irritation and skin sensitization

This declaration of conformity is valid from October 2, 2015.

Signed on behalf of Qardio Netherlands B.V., in Amsterdam, December 19, 2017:

Signature:



Marco Peluso, CEO