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 2

Model: B200

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 +AC: 2014 & IEC 60601-1: 2005/A1: 2012: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- EN ISO 14971:2012 Medical devices – Application of risk management to medical devices
- ISO 13485:2016/NS-EN ISO 13485:2016: Medical devices. Quality management systems. Requirements for regulatory purposes
- IEC 60601-1-11:2015 (Second Edition) for use in conjunction with IEC 60601-1:2012 (Third Edition) +A1:2012 & EN 60601-1-11:2015 MEDICAL ELECTRICAL EQUIPMENT – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- EN 300 328 v2.1.1:2016: 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 v2.2.0: 2017-03: 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 v3.2.0:2017-03: Electromagnetic compatibility and Radio Spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment; Part 17: Specific conditions for Broadband Data Transmission Systems

- EN 55032:2015+AC:2016-07: Electromagnetic compatibility of multimedia equipment – Emission requirements CISPR 32: 2012
- EN 62304:2006/AC:2008: Medical device software – Software life cycle processes
- EN 60601-1-2:2015 & IEC 60601-1-2:2014: 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
- 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

CE SAR TEST:

- EN 50566:2013: Product standard to demonstrate compliance of radio frequency fields from handheld and body-mounted wireless communication devices used by the general public (30 MHz – 6 GHz)
- EN 62209-2:2010: Human exposure to radio frequency fields from hand-held and body-mounted wireless communication devices – Human models, instrumentation, and procedures – Part 2: Procedure to determine the specific absorption rate (SAR) for wireless communication devices used in close proximity to the human body (frequency range of 30 MHz to 6 GHz)
- EN 62479:2010: Assessment of the compliance of low-power electronic and electrical equipment with the basic restictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)

This declaration of conformity is valid from September 1, 2017.

Signed on behalf of Qardio Netherlands B.V., in Amsterdam, November 1, 2018:

Signature:

Marco Peluso, CEO