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: QardioArm

Model: A100

Brand Name: Qardio

is in conformity with the relevant harmonization legislation:

Medical Device Directive 93/42/EEC of 14 June 1993 concerning medical devices as amended by Directive 2007/47/EC– Annex I and the conformity assessment Annex II-exclusive section 4 to be certified by DNV GL Nemko Presafe AS (notify body number – 2460).

Thus, CE is placed on the product.

Standard(s) to which Class IIa Conformity is Declared:

- EN ISO 13485:2016/NS-EN ISO 13485:2016: Medical devices. Quality management systems. Requirements for regulatory purposes
- EN ISO 14971:2012: Medical devices - Application of risk management to medical devices
- EN 60601-1:2005 + CORR. 1 (2006) + CORR. 2 (2007)/ EN 60601-1:2006 + AC (2010): Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- EN 1060-1: 1995 + A1: 2002: Non-invasive sphygmomanometers Part I: General requirements
- EN 1060-3:1997+ A1: 2005 (used in conjunction with EN 1060-1): Non-invasive sphygmomanometers. Supplementary requirements for electro-mechanical blood pressure measuring systems
- EN 1060-4:2004: Non-invasive sphygmomanometers. Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers
- EN 80601-2-30: 2010: Medical electrical equipment – Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers
- EN 60601-1-11: 2010: 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
- ETSI EN 300 328 V2.1.1:2016: Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU

- EN 301 489-1 v2.2.0:2017: ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU
- EN 301 489-17 V3.2.0:2016: ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
- EN 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 55011:2009/A1:2010: Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics Limits and methods of measurement
- 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
- 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
- BS EN 62479:2010: Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz).
- EN ISO 15223-1:2012: Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
- EN 62304:2006/AC:2008: Medical device software – Software life cycle processes
- Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment(RoHS)
- 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)

This declaration of conformity is valid from April 25, 2014.

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

Signature:

Marco Peluso, CEO