EC Declaration of Conformity

For the following equipment:

Product Name: **QardioBase2**

Model Designation / Brand Name: **B200 / QARDIO**

Manufacturer: Ya Horng Electronic Co.,Ltd.
Factory: Atten Electronic(Dongguan) Co., Ltd.
Factory: Ya Horng (Dongguan) Electronic Co., Ltd.

Manufacturer Address: No.35, Shalun, Anding Dist., Tainan City 745, Taiwan
Factory Address: 188 Industrial Dist., Ping Shan Administrative District, Tang Shia Town, Dongguan, Guangdong, China
Factory Address: 188 Industrial Dist., Ping Shan Administrative District, Tang Shia Town, Dongguan, Guangdong, China

Application of Council Directive(s):

Directive 2014/30/EU 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)

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 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 Radio Equipment 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 restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)

The following manufacturer / importer or authorized representative established within the electrocardiograph is responsible for this declaration:

Kahl Handelsvertretung

(Company Name)

Isarstr. 33 40699 Erkrath Germany

(Company Address)

Person responsible for making this declaration:

Jerry Hsu		**Director**
(Name,Surname)		(Position/Title)
Ya Horng	Oct 03 2017	
(Place)	(Date)	(Legal Signature)