

EC Declaration of Conformity

For the following equipment:

QardioBase

(Product Name)

B100 / QARDIO

(Model Designation / Brand Name)

Manufacturer: Ya Horng Electronic Co.,Ltd.

Factory: Atten Electronic(Dongguan) Co., Ltd.

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

(Manufacturer Name)

Manufacturer: No.35, Shalun, Anding Dist., Tainan City 745, Taiwan

**Facory: 188 Inidustrial Distrt, Ping Shan Administrative District, Tang Shia Town,
Dongguan, Guangdong, China**

**Factory:188 Inidustrial Distrt, Ping Shan Administrative District, Tang Shia Town,
Dongguan, Guangdong, China**

(Manufacturer Address)

Application of Council Directive(s):

Directive 2004/108/EC relating to electromagnetic compatibility(EMC Directive) AND Directive 2014/53/EU FOR COUNCIL DIRECTIVE (RTTE Directive) & WITH Directive 93/42/EEC (Medical devices (MDD)) AND 2011/65/EU FOR the 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)

Standard(s) to which Conformity is Declared:

- EN 60601-1:2006/A1:2013 : Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- ETSI 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 –3 v1.6.1: 2013 : Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 246 GHz
- 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
- 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

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

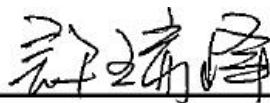
Kahl Handelsvertretung

(Company Name)

Isarstr. 33 40699 Erkrath Germany

(Company Address)

Person responsible for making this declaration:

Jerry Hsu		Director
(Name,Surname)		(Position/Title)
Ya Horng	<i>May 31 '17</i>	
(Place)	(Date)	(Legal Signature)