D·Heart

CE 1370

DECLARATION OF CONFORMITY

Manufacturer: **D-Heart S.R.L.**, Via A. Cantore 8h/38-16149 Genova-Italy

Model: **D-Heart**

Description: Portable ECG Device

Code: **ECG000-DHR10**

Manufacturing site: SIAE MICROELETTRONICA S.p.A. Via M. Buonarroti 26 –Cologno Monzese 20093-Italy

progressive number attributed by System of registration of the database/repertoire of medical Devices: **1701246**

National Code of Medical Devices: **Z12059009**

We hereby declare that:

-The above device is manufactured in accordance with the requirements by Directive 93/42/EEC and S.M.I. (in accordance with Annex II-excluding paragraph 4).

-The above device shall be considered as belonging to **class IIa** in accordance with rule 10 of annex XII to the abovementioned directive.

-the EC certificate for the above device was issued by the notified Body N.: **1370** Bureau Veritas Italia S.p.A. (Viale Monza, 347-20126 Milan-Italy) certificate N. **IT280207**, start date of cycle: **03-Apr-2018**, Expiration Date: **02- Apr-2021**.

-All documentation concerning this device is stored in the technical file filed with the registered office of D-Heart S.R.L. and is kept for a period of at least 5 years from the date of last manufacture of the product;

-Company management system complies with the requirements specified in **ISO 9001:2015** and **ISO 13485:2012** (scope: Management of the design, manufacture and assistance of portable electrocardiographs), Certificates N. **IT280206** and N. **IT280205** issued by the notified Body N.: **1370** Bureau Veritas Italia S.p.A. (Viale Monza, 347-20126 Milan-Italy).

-The above device complies with the following standards:

- **ETSI EN 301 489-1 v 2.1.1** (2017-02)-Standard for radio equipment and services-part 17: Specific conditions for broadband data transmission systems;
- **ETSI EN 301 489-17 v 2.2.1** (2012-09)-Electromagnetic compatibility and radio spectrum issues (ERM) electro-magnetic compatibility (EMC) standard for radio equipment-part 17: Specific conditions for broadband data transmission systems;
- **CEI EN 60601-1-2:2016-04** -Electro-medical equipment-part 1-2: General requirements for basic safety and essential performance-collateral law: electromagnetic disturbances-requirements and tests;
- **ETSI EN 300 328: V 2.1.1** (2016-11)-data transmission equipment operating in the ISM band at 2.4 GHz and using broadband modulation techniques-harmonized standard meeting the essential requirements of Article 3.2 of Directive 2014/53/EU;
- **CEI EN 60601-1-11:2015** -Electro-medical equipment-part 1-11: General requirements for basic safety and essential performance-collateral: requirements for electromedical equipment and electromedical systems used in the domestic sanitary environment;
- **CEI EN 60601-1:2005** -Electromedical Equipment-Part 1: General requirements for basic safety and essential performance;
- **CEI EN 60601-2-25:2016-04** (*)-electro-medical equipment-part 2-25: Particular requirements for basic safety and essential performance of electrocardiographs;

(*) Compliance is limited to applicable tests (as reported in the CE technical file).

-The portable ECG device D-Heart has been qualified according to the qualification requirements SIG, declaration ID: **D038825**

This compliance is only valid for equipment identified when used in a manner consistent with the intent of the reference documents and according to the product usage manual.

Genova, 24/05/18

D-Heart S.R.L
Il legale Rappresentante
(Nicolò Briante)