D·Heart

CE 1370

EU DECLARATION OF CONFORMITY

Manufacturer: STRENA MEDICAL S.R.L. SOCIETA' BENEFIT
Address of registered place of business: Via A. Cantore 8h/38-16149 Genova-Italy

SRN: IT-MF-000021080

Model number (REF) - ECG000-DHR20 D-Heart Portable ECG Device
Basic UDI-DI: ++G243DHEARTECG4L
Intended purpose: The device is intended for supporting or providing useful information regarding the process of diagnosis or care of users at risk for or with heart diseases. The device is intended to be operated in hospital, general physician's office, pharmacies, out-of-hospital locations such as homecare environment.

We hereby declare under our **sole responsibility** that the above device is in conformity with Regulation (EU) 2017/745

Risk class of the device in accordance with the rules set out in Annex VIII: IIa, rule 10 and rule 11
References to any CS: None applicable

Conformity procedure: Annex IX, Chapter I - Conformity assessment based on a quality management system.
Name and identification number of the notified body: Bureau Veritas Italia Spa, NB: 1370

-All documentation concerning this device is stored in the technical file filed with the registered office of Strena Medical s.r.l. società benefit and is kept for a period of at least 10 years from the date of last manufacture of the product;

-The above device complies with the following standards:

- **IEC 62304 :2006+AMD1:2015** Medical device software - Software life cycle processes Equivalent to **EN 62304:2006/A1:2015**;
- **IEC 62366-1:2015+A1:2020** Medical Devices - Part 1: Application of Usability Engineering to Medical Devices Equivalent to **EN 62366-1:2015 + A1:2020**;
- **IEC 60601-1-6:2010+A1+A2:2021** Amendment 2 - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability Equivalent to **EN 60601-1-6:2010+A1+A2:2021**;
- **IEC 60601-1:2005+AMD2:2020** Medical electrical equipment - Part 1: General requirements for basic safety and essential performance;
- **IEC 60601-1-2:2014/AMD1:2020** Amendment 1 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances - Requirements and tests Equivalent to **EN 60601-1-2:2015&A1:2021**;
- **IEC 60601-1-11:2015+AMD1:2020** Equivalent to **EN 60601-1-11:2015;**
- **IEC 60601-2-25:2011** Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs Equivalent to **EN 60601-2-25:2015;**
- **Radio Tests (ETSI EN 300 328)** The objective of the tests is the evaluation the Radio performance for conformity of the EUT (Equipment Under Test) to the requirements of the standards and the test methods listed in the present Test Report;

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, 05/01/2024

Legal Representative:

Gian Marco Gerosa

strena medical

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