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;

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, 27/07/2023

Gian Marco Gerosa

strena medical

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