



D-Heart S.r.l.

Via Antonio Cantore, 8H/38 - 16149 GENOVA (GE) - ITALY

Certified site:

Via Antonio Cantore, 8H/38 - 16149 GENOVA (GE) - ITALY

Bureau Veritas Italia S.p.A. certifies that the Full Quality Assurance System of the above organization has been audited and found to be in accordance with the requirements of

DIRECTIVE 93/42/EEC as amended

(in accordance with Annex II - excluding paragraph 4)

In relation to the following products

Product subcategory :	Devices for monitoring of vital physiological parameters
Generic group:	Portable ECG device
Model:	D-Heart
Class:	Ila

Reference BV practice: ZIG. N. 9400215

Original cycle start date: **03/04/2018**

Expiry date of previous cycle: **NA**

Certification / Recertification Audit date: **15/02/2018**

Certification / Recertification cycle start date: **03/04/2018**

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: **02/04/2023**

Certificate No. - Version: IT280207 - 1

Revision date: **31/03/2021**

GIORGIO LANZAFAME - Local Technical Manager

This certificate is issued by Bureau Veritas Italia S.p.A. Viale Monza, 347-20126 Milan, as a notified body for the Directive 93/42/EEC, with identification number 1370

Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation. To check this certificate validity please refer to the website www.bureauveritas.it