



BUREAU
VERITAS

Bureau Veritas Certification

EU Quality Management System Certificate

Issued to

STRENA MEDICAL S.R.L. SOCIETA' BENEFIT

Via Antonio Cantore 8H/38 – 16149 Genova (GE) - Italia

Single Registration number: **IT-MF-000021080**

Certified site(s)

Via Antonio Cantore 8H/38 – 16149 Genova (GE) - Italia

Bureau Veritas Italia S.p.A. certifies that the Quality Management System of the above mentioned manufacturer has been audited and it complies with the requirements of

Regulation (EU) 2017/745

(in accordance with annex IX Chapter I)

In relation to the following Medical Device(s):

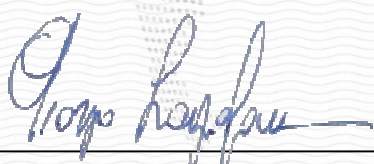
Model name (s):	D-Heart
Generic group	General purpose electrocardiographs
Category	MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters
Risk class	Ila
Basic UDI-DI	++G243DHEARTECG4L
Specific conditions or limitations of validity of the certificate	None

Certificate issue date: 26/07/2023

Subject to the continued satisfactory operation of the organization's management system, this certificate expires on: 25/07/2028

Certificate N°: IT324675 Version: 1 Issue date: 26/07/2023

Revision History	
Revision	Change description
Revision n. 01 Revision date : 26/07/2023	First issue


GIORGIO LANZAFAME - Local Technical Manager

This certificate is issued by Bureau Veritas Italia S.p.A. Viale Monza 375- 20126 Milano ITALY notified body according to the Regulation (EU) 2017/745 with identification number 1370.

Information on examinations and tests performed regarding relevant CS and harmonized standards, relevant test reports and audit report(s) are in the dossier (FLEX n. 15935589) available on request from medical.device@bureauveritas.com