

CERTIFICATE

The Certification Body TÜV Rheinland Italia S.r.l.

certifies, in accordance with the TÜV Rheinland Group procedures, that the Company

Cardioline S.p.a.

Via Linz, 151

IT - 38121 Trento (TN)

has established and applies a quality management system
for the following scope:

**Design, manufacturing, trading, installation and servicing of systems and electrical
medical devices and software for cardiology.**

Through an Audit, Report No. 7968894070LM18, proof has been furnished that the
quality management system fulfils the requirements of the standard

UNI CEI EN ISO 13485:2016

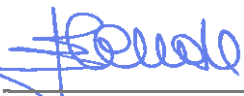
Please refer to the Quality Manual for the details about
the exclusions with respect to the requirements of the standard.

Certificate Registration No. **39 05 0631503**.

This Certificate is valid from 2021-04-25 to 2024-04-24.

The reference date for all the next audits is (day-month): 12-06.

Milan, 2021-04-25. First Certification: 2012-06-13



The certification responsible: Elena Re
TÜV Rheinland Italia S.r.l., Via E. Mattei, 3 - I - 20005 Pogliano Milanese (MI)

This certificate does not represent proof that the statutory requirements of
the Directives 93/42/EEC, 90/385/EEC or 98/79/EC have been fulfilled.



SGQ N° 083 A



Management
System
EN ISO
13485:2016

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