

CERTIFICATE

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

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

CARDIO CALM S.r.l.

**Corso Martiri della Libertà, 40
IT - 25018 Montichiari (BS)**

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

**Design, manufacture and place on the market of medical software for the analysis of
cardiovascular signals.**

Trade of medical devices for the analysis of cardiovascular signals.

Provision of telemedicine services.

Through an Audit, Report No. 7983849010AF02, proof has been furnished that the
quality management system fulfils the requirements of the standard

UNI CEI EN ISO 13485:2021


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 0731704**

This Certificate is valid from 2023/07/31 to 2026/07/30

The reference date for all the next audits is (day-month): 11/04

Milan, 2023/07/31. First Certification: 2017/07/31

 Firmato
digitalmente da
Lisa Menarini

The certification responsible: Lisa Menarini
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, 98/79/EC or
Regulations (UE) 2017/745, (UE) 2017/746 have been fulfilled



MS N° 0083

Membro degli Accordi di Mutuo
Riconoscimento EA, IAF e ILAC.
Signatory of EA, IAF and ILAC
Mutual Recognition Agreements.



Management
System
EN ISO
13485:2016

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