

CERTIFICATE

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

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

Comftech S.r.l.

Piazza Castello, 9 IT - 20900 Monza (MB)

Via Spalto Maddalena, 12 IT - 20900 Monza (MB)

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

**Design, production management and development of medical devices for hospital
and/or home care monitoring of physiological parameters.**

Through an Audit, Report No. 7974588010ER01, proof has been furnished that the
quality management system fulfils the requirements of the standard

UNI CEI EN ISO 13485:2016

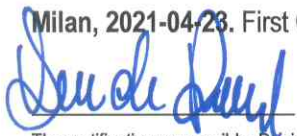
Please refer to the Quality Manual for the details about
the exclusions with respect to the requirements of the standard.

Certificate Registration No. **39 05 1251411**.

This Certificate is valid from 2021-04-23 to 2024-04-22.

The reference date for all the next audits is (day-month): 20-11.

Milan, 2021-04-23. First Certification: 2015-04-23



The certification responsible: Daniele Ricchi
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.



SGO N° 083 A

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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