

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, 15
IT - 20900 Monza (MB)**

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

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

Through an Audit, Report No. 7985876010ER02, 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 1251411**.

This Certificate is valid from 2023/11/09 to 2024/04/22.

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

Milan, 2023/11/09. 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, 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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