

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)

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. 28111436 001, 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 2015-04-23 to 2018-04-22 and from 2018/06/11 to 22/04/2021.

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

Milan, 2018-06-11, First Certification: 2015-04-23

The certification responsible
TÜV Rheinland Italia S.r.l., Via E. Mattei, 3 - I - 20010 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° 083A SGA N° 052D

Membro degli Accordi di Mutuo
Riconoscimento EA, IAF e ILAC

Signatory of EA, IAF and ILAC
Mutual Recognition Agreement



Management
System
EN ISO
13485:2016

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