

CERTIFICATE

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

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

Intersurgical S.p.A.

Via Morandi 12, IT – 41037 Mirandola (MO)

Via Chiavica Mari 33, IT – 41039 San Possidonio (MO)

Via Roberto Longhi 1, IT – 41033 Concordia sulla Secchia (MO)

Via di Mezzo 45, IT – 41037 Mirandola (MO)

Via di Mezzo 59/A-B-C-D-E – IT 41037 Mirandola (MO)



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

Design, manufacture and marketing of medical devices and related accessories for non-invasive pulmonary mixing and/or ventilation, oral cavity care and infusion. Import and marketing of medical devices and related accessories for non-invasive pulmonary mixing and/or ventilation and oral care.

Through an Audit 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 1571910**

This Certificate is valid from 2026/05/24 to 2029/05/23

The reference date for all the next audits is (day-month): 16/01

Milan, 2026/05/21. First Certification: 2002/10/25

The certification responsible: Dario Scarabello
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



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