

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 di Mezzo 59/A, B, C, D, E e 47, IT – 41037 Mirandola (MO)

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

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

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

Design and manufacture of medical devices and accessories for mixing and/or non-invasive pulmonary ventilation, oral care and infusion. Trade of medical devices for the respiratory system.

Through an Audit, Report No. 7979843020MT12, 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 2022-05-12 to 2023-05-23.

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

Milan, 2022-05-12. First Certification: 2002-10-25



The certification responsible: Cesare Gentile
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.



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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ID 9000005840



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