

CERTIFICATE

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

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

Dinamica Generale S.p.A.

Via Mondadori, 15

IT – 46025 Poggio Rusco (MN)

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

Design and contract manufacturing of components with measurement function intended for blood processing equipment and devices with blood parameter acquisition, processing and display function, devices for ex vivo organ preservation, transport and perfusion, flow generation devices for CPAP therapies.
Contract manufacturing of extracorporeal circulation equipment.

Through an Audit, Report No. 7988787040LM27, 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 0132401**

This Certificate is valid from 2024/03/15 to 2027/03/19

The reference date for all the next audits is (day-month): 05/03

Milan, 2024/03/15. First Certification: 2009/03/20

Firmato
Elena Re digitalmente
da Elena Re

The certification responsible: Elena Re
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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