

CERTIFICATE

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

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

Aferetica S.r.l.

Via Roma 19

IT - 40017 San Giovanni in Persiceto (BO)

Via 29 Maggio, 12

IT - 41037 Mirandola (MO)



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

Management of the design and manufacture of active medical devices for the preservation and ex vivo perfusion of liver and kidneys for transplantation.

Design and Management of the manufacture of non-active medical devices for organs preservation and ex vivo perfusion for transplantation. Trade of therapeutic medical devices and systems for nephrology and dialysis, critical care, hematology, cardiac surgery and transplants. EA 19, 14, 29A

Through an Audit, Report No. 7982078010LM13, proof has been furnished that the quality management system fulfils the requirements of the standard

UNI EN ISO 9001:2015

Please refer to the Quality Manual for the details about the exclusions with respect to the requirements of the standard.

Certificate Registration No. **39 00 1411706**.

This Certificate is valid from 2022-12-14 to 2025-12-03.

The reference date for all the next audits is (day-month): 04-09.

Milan, 2022-12-14. First Certification: 2020-04-24

A handwritten signature in blue ink, appearing to read "Heurke", is located below the certification details.

The certification responsible: Elena Re
TÜV Rheinland Italia S.r.l., Via E. Mattei, 3 - I - 20005 Pogliano Milanese (MI)



SGO N° 083 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements



Management System
ISO 9001:2015



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