

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.**

Through an Audit, Report No. 7982078010LM13, 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 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 '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.



SGQ N° 083 A

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

www.tuv.com
ID 9000065702



www.tuvitalia.com

The TÜVRheinland logo, featuring a blue triangle with a white 'A' inside, followed by the text 'TÜVRheinland' with a registered trademark symbol.