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, placing on the market of active medical devices for the transport of organs intended for transplantation, for conservation and ex situ perfusion of organs intended for transplantation. Design, management of the manufacture and placing on the market of non-active medical devices for the transport of organs intended for transplantation, for conservation and ex situ perfusion of organs intended for transplantation. Trading of medical devices and therapeutic systems for nephrology and dialysis, critical care, haematology, cardiac surgery and transplantation.

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 1411706**.

This Certificate is valid from 2025/12/04 to 2028/12/03.

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

Milan, 2025/12/01. First Certification: 2020/04/24

Elena Re Firmato 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

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Management System
EN ISO 13485:2016
+AC:2018+A11:2021

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ID 9000005702

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