



Certificate

No. Q5IT 093553 0001 Rev. 00

Registered Office:**Fondazione Democenter-Sipe**

Via Vivarelli, 2
41125 Modena
ITALY

Certification Mark:

The Certification Body of TÜV Italia S.r.l. certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s).

For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5IT_093553_0001_Rev_00

Scope of Certificate:

Provision of design services for raw material and components (biomaterial and sensor) for non active medical devices for dialysis, extracorporeal circulation and respiration. Provision of laboratory services for the biomedical sector; Chemical and physical analysis, biological analysis, development of microbiological analysis protocols, biocompatibility tests, toxicity test. Provision of consultancy services relating to the clinical validation of medical devices.

Applied Standard(s):

UNI CEI EN ISO 13485:2021

Operational Site(s):

**Fondazione Democenter-Sipe, divisione
Biomedicale Tecnopolo di Mirandola**
Via 29 Maggio, 6, 41037 Mirandola (MO), ITALY

See Scope of Certificate

Report No.:

ITA2002200007741

Valid from:

2026-06-11

Valid until:

2028-06-22

First Certification:

2019-06-20

The validity of this certificate is subject to periodic surveillance at 12-month intervals and a full review of the management system every three years.

Date,

2026-06-12

LORIS CHIUSOLI

Head of Certification Body