

CERTIFICATE

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

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

Angiodroid S.p.A.

Via Speranza, 35

IT - 40068 San Lazzaro di Savena (BO)

Via Gramsci, 15

IT - 40062 Molinella (BO)

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

Design, manufacturing management and placing on the market of CO₂ injectors for angiography with related disposable sterile devices and of assisting intra-aortic counterpulsation consoles.

Through an Audit, Report No. 7989506010LM04, 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 1171410**.

This Certificate is valid from 2024/04/19 to 2027/04/26.

The reference date for all the next audits is (day-month): 27/02.

Milan, 2024/04/19. First Certification: 2015/04/27

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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