



Certificate

No. Q5 002403 0004 Rev. 02

Holder of Certificate: **SIFI S.p.A.**
Via E. Patti 36
95025 Aci S. Antonio (CT)
ITALY

Certification Mark:



Scope of Certificate: Design and development, production and distribution of liquid and semisolid medical devices for ophthalmic use, intraocular lenses and viscoelastic solutions for ophthalmic applications, balanced saline solutions for ophthalmic use, phacoemulsifiers and related accessories.
Distribution of medical devices for ophthalmic use. Servicing for equipments for processing diagnostic data and images for ophthalmology.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 002403 0004 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_002403_0004_Rev_02)

Report No.: ITA1529194B

Valid from: 2021-01-12

Valid until: 2023-09-12

Date, 2021-01-12



Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 002403 0004 Rev. 02

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): SIFI S.p.A.
Via E. Patti 34/b, 95025 Aci S. Antonio (CT), ITALY

Design, development and production intraocular lenses.

SIFI S.p.A.
Via E. Patti 36, 95025 Aci S. Antonio (CT), ITALY

Design and development, production and distribution of liquid and semisolid medical devices for ophthalmic use, viscoelastic solutions for ophthalmic applications, balanced saline solutions for ophthalmic use, phacoemulsifiers and related accessories.

Distribution of intraocular lenses and medical devices for ophthalmic use.

Servicing for equipments for processing diagnostic data and images for ophthalmology

/