



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)

(Devices in Class IIa, IIb or III)

No. G1 002403 0003 Rev. 02

Manufacturer:

SIFI S.p.A.

Via E. Patti 36

95025 Aci S. Antonio (CT)

ITALY

Product Category(ies): **Intraocular lenses and viscoelastic solutions for ophthalmic applications. Phacoemulsifier and related accessories. Balanced saline solutions for ophthalmic use. Wetting and lubricating sterile ophthalmic solutions**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: ITA1406987

Valid from: 2020-04-21

Valid until: 2024-05-26

Date, 2020-04-21

Christoph Dicks

Head of Certification/Notified Body