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

TÜV SÜD 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 105847 0001 Rev. 01

Manufacturer:

Sterimedix Ltd
Thornhill Road
North Moons Moat
Redditch, Worcestershire B98 9ND
UNITED KINGDOM

Product Category(ies):

Sterile and non-sterile devices for use in ophthalmic procedures:
Anaesthetic Needles and Cannulae, Anterior Chamber Maintenance Cannulae, Capsule Polishing Cannulae, Cystotomes, Hydrodissection Cannulae, Infusion Cannulae, Irrigation/Aspiration Cannulae and Hand Pieces, Lachrymal Cannulae, Lens Removal Cannulae, Refractive Cannulae, Vitreoretinal Cannulae, Vitreoretinal Handpieces, Surgical Corneal Cannulae, Viscocanalostomy Cannulae.
Sterile and non-sterile Intradermal Cannulae and Needles for use in reconstructive Surgery
Sterile Trocar Sets for Vitreoretinal Surgery
Sterile dacryocystorhinostomy (DCR) sets to establish patency between the lachrymal sac and nasal mucosa

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.: 713170902

Digitally signed by Pereteatco Alina
Date: 2021.10.07 23:54:42 EEST

Valid from: 2020-02-07
Valid until: 2024-05-26

Date, 2020-02-07

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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 105847 0001 Rev. 01

Facility(ies):

Sterimedix Ltd
Thornhill Road, North Moons Moat, Redditch,
Worcestershire B98 9ND, UNITED KINGDOM

./.

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany