



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



Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 105847 0002 Rev. 00

Manufacturer

Sterimedix Ltd

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

Facility(ies):

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

Product

Sterile ophthalmic handles

Category(ies):

Sterile vitreoretinal tubing sets

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: 713167357

Valid from: 2019-10-29

Valid until: 2020-02-06

Date, 2019-10-29

Christoph Dicks
Head of Certification/Notified Body

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