



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

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex V
(Devices in class I with measuring function)

No. G2M 105847 0003 Rev. 01

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
Category(ies):**

**Non-sterile single use scleral markers and
fixation plates**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for the manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with the metrological requirements 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.:

713171899

Valid from:

2020-02-07

Valid until:

2024-05-26

Date,

2020-02-07

Christoph Dicks
Head of Certification/Notified Body