

The management system of

Sterimedix Ltd

1 Madeley Road, North Moons Moat, Redditch,
Worcestershire, B98 9NB, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 12 August 2015 until 06 February 2020
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 06 February 2018
Issue 26. Certified since 21 May 1997

Certification is based on reports numbered GB/PC 07091

This is a multi-site certification.
Additional site details are listed on the subsequent page.

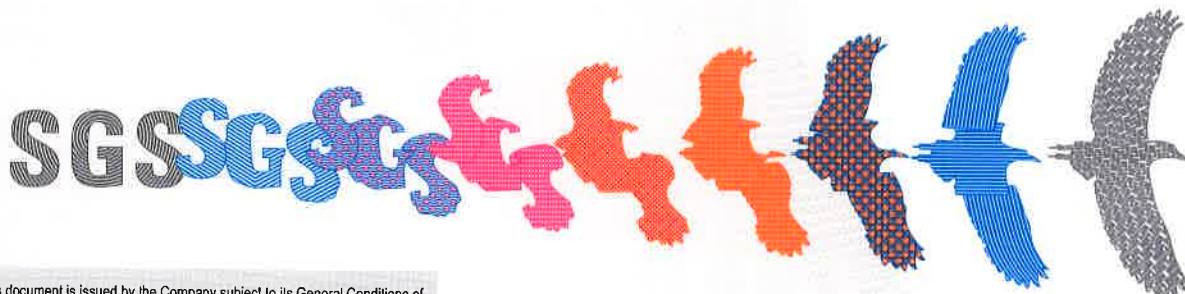
Authorised by

SGS United Kingdom Ltd, Notified Body 0120

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SGS CE 02 0315 M2

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Sterimedix Ltd

Directive 93/42/EEC on medical devices, Annex II (excluding section 4)

Issue 26

Detailed scope

- Sterile dacryocystorinostomy device.**
- Sterile and non sterile needles for subcutaneous injection of viscous materials.**
- Sterile and non-sterile ophthalmic cannulae.**
- Sterile and non-sterile ophthalmic handles.**
- Sterile extension tubing and sterile tubing sets.**
- Sterile intradermal cannulae.**
- Sterile and non-sterile Trocar Sets for Vitreoretinal Surgery.**

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market

Additional facilities

14 Madeley Road, North Moons Moat, Redditch, Worcestershire, B98 9NB, UK