

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 13 September 2017 until 06 February 2020
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 06 February 2018
Issue 27. 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.

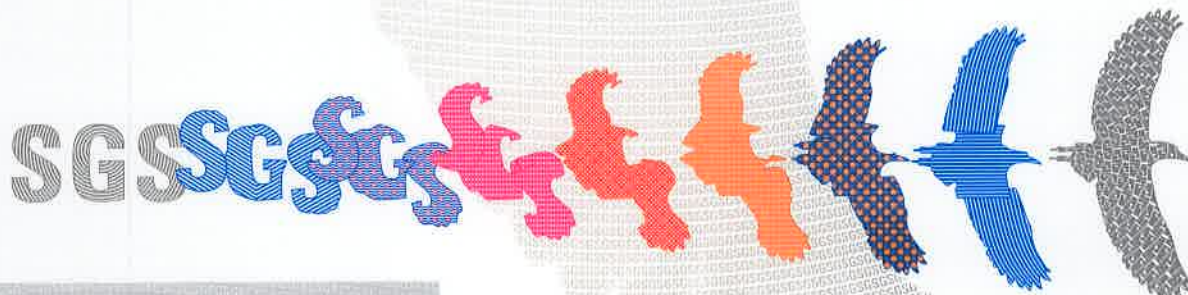
Authorised by

SGS United Kingdom Ltd, Notified Body 0120

SGS United Kingdom Ltd
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 02 0315 M2

Page 1 of 2



Sterimedix Ltd

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

Issue 27

Detailed scope

Sterile and non-sterile devices for use in ophthalmic procedures:

Anaesthetic Needles and Cannulae
Anterior Chamber Maintenance Cannulae
Capsule Polishing Cannulae
Cystotomes
Hydrodissection Cannula
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

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