



Certificate GB06/3777

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

ISO 13485:2003

For the following activities

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

Effective Date 13 September 2017 Expiry Date 06 February 2018
Re certification audit due before 06 February 2018
Valid subject to satisfactory surveillance audits.
Issue 19. Certified since 16 February 2006

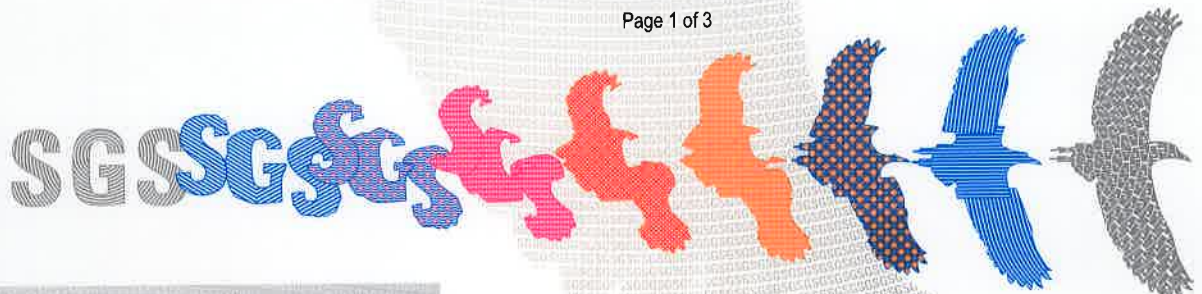
This is a multi-site certification.
Additional site details are listed on subsequent pages.

Authorised by
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CMDCAS recognised registrar

SGS 13485 CMDCAS 0911 MS M3

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Sterimedix Ltd
ISO 13485:2003



Issue 19

Detailed scope

**Design and manufacture of 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

**Design and manufacture of sterile and non-sterile Intradermal
Cannulae and Needles for use in reconstructive surgery**

Design and manufacture of sterile Trocar Sets for Vitreoretinal Surgery

**Design and manufacture of sterile dacryocystorhinostomy (DCR) sets
to establish patency between the lachrymal sac and nasal mucosa**



Sterimedix Ltd

ISO 13485:2003

Issue 19



Additional facilities

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

**Scope: Manufacture of 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
Surgical Corneal Cannulae
Viscocanalostomy Cannulae**

**Manufacture of sterile and non-sterile Intradermal Cannulae
and Needles for use in reconstructive surgery**

Manufacture of sterile Trocar Sets for Vitreoretinal Surgery

**Manufacture of sterile dacryocystorhinostomy (DCR) sets to establish patency
between the lachrymal sac and nasal mucosa**

