

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 V
Restricted to the aspects of manufacture concerned with
securing and maintaining sterile conditions, and
the conformity of the devices with metrological requirements.

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 8. Certified since 14 May 2013

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

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

SGS CE 31 0613 M2

Page 1 of 2



Sterimedix Ltd

Directive 93/42/EEC

**on medical devices, Annex V
Restricted to the aspects of manufacture concerned with
securing and maintaining sterile conditions, and
the conformity of the devices with metrological requirements.**

Issue 8

Detailed scope

Sterile single use scleral markers and fixation plates

**Annex V (metrological aspects only) Restricted to the aspects
of manufacture concerned with the conformity of devices
with metrological requirements:**

Non-sterile single use scleral markers and fixation plates

**Annex V (sterility aspects only) Restricted to the aspects
of manufacture concerned with securing
and maintaining sterile conditions:**

**Sterile ophthalmic handles
Sterile vitreoretinal tubing sets**

Additional facilities

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