



Certificate GB97/9963

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 13485:2016 EN ISO 13485:2016



For the following activities

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

This certificate is valid from 09 February 2018 until 06 February 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 06 February 2021
Issue 25. Certified since 21 May 1997

*Expiry date of last certificate: 06 February 2018
End date of last recertification audit: 25 January 2018*

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

Authorised by

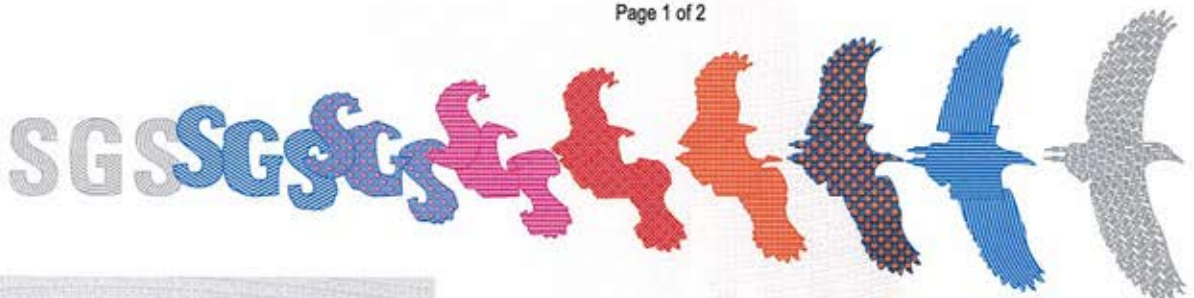


0005

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118 M2

Page 1 of 2



This document is issued by the Company subject to its General Conditions of Certification Services accessible at www.sgs.com/terms_and_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at <http://www.sgs.com/en/certified-clients-and-products/certified-client-directory>. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

Sterimedix Ltd

ISO 13485:2016
EN ISO 13485:2016



Issue 25

Detailed scope

Design, manufacture and contract manufacture of sterile and non-sterile cannulae, needles, cystotomes, tubing sets, handpieces, reservoirs, handles and scleral markers/fixation plates for use in ophthalmic procedures

Design, manufacture and contract manufacture of sterile and non-sterile intradermal cannulae and needles for use in reconstructive surgery

Design and manufacture of sterile vitreoretinal trocar sets

Additional facilities

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



0005