



EC Certificate Full Quality Assurance System: GB96/7990

The management system of

Synergy Health (UK) Limited

1 Western Avenue, Matrix Park, Buckshaw Village,
Chorley, Lancashire, PR7 7NB, 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 22 August 2011 until 15 April 2016 and
remains valid subject to satisfactory surveillance audits.
Re certification audit due before 29 November 2013
Issue 22. Certified since 09 September 1996

Certification is based on reports numbered GB/PC 03782

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

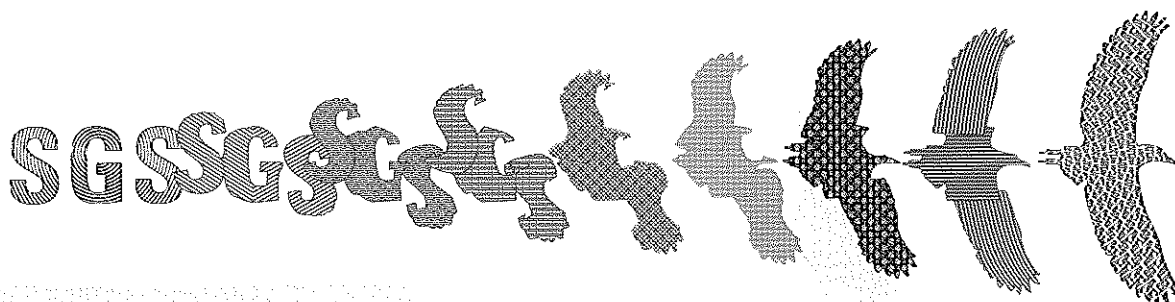
Authorised by

SGS United Kingdom Ltd, Notified Body 0120

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SGS CE 01 0311 M2

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Synergy Health (UK) Limited

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

Issue 22

Detailed scope

Sterile single-use surgical instruments, including staplers, staples and bipolar forceps.

**Sterile single-use laparoscopic surgical instruments and accessories.
Custom concept packs.**

Sterile and non-sterile x-ray detectable woven and non-woven swabs and rolls.

Sterile and non-sterile fast edge ribbon gauze.

Sterile paraffin gauze dressings.

Sterile bags for endoscopic retrieval of tissue.

Disinfecting wipes and sprays for use on medical equipment.

Sterile Asherman chest seals.

Sterile Carbopad VC activated charcoal dressings.

Sterile Hydrofera Blue polyvinyl alcohol foam dressings.

For placing on the market of Class III devices covered by this certificate, an EC Design Examination Certificate according to Annex II (Section 4) is required.

Additional facilities

**Unit 365 Walton Summit Industrial Estate, Four Oaks Road,
Bamber Bridge, Preston, PR5 8AS, UK**