

EC Certificate Full Quality Assurance System: Certificate GB02/56790

The management system of

S.R.A. Developments Ltd

Bremridge House, Bremridge, Ashburton, Devon, TQ13 7JX, 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

**Lotus Ultrasonic Surgical Systems and Accessories
for laparoscopic and open surgery, consisting of:
Lotus Generators
Lotus Footswitches
Lotus Transducer Reusable Devices
Lotus Handpiece Sterile Single Use Devices
Lotus Double Blade Sleeve Sterile Single Use Devices
Lotus Thyroid Sleeve Sterile Single Use Device.**

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.

This certificate is valid from 30 January 2015 until 18 September 2019
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 18 September 2017
Issue 10. Certified since 18 September 2002

Certification is based on reports numbered GB/PC 208282

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

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