Certificate

Full Quality Assurance

No. CE 82107

Issued to:

CooperSurgical Inc.,
also trading as Milex and
Wallach Surgical Devices
and Sage In-Vitro Fertilization
95 Corporate Drive
Trumbull
Connecticut
06611
USA

In respect of:

The design and manufacture of, high-frequency electrosurgical generators for laparoscopic, transvaginal and anogenital procedures, LEEP electrodes, sterile laparoscopic and transvaginal applicators, vaginal pessaries, contraceptive diaphragms and In-Vitro Fertilization media with and without protein supplementation and antibiotic for use in assisted reproduction processes up to and including embryo/blastocyst implantation stage

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 3.2.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Gary Fenton, Global Assurance Director

First Issued: **8 Nov 2004**

Date: **9 Aug 2012**

Expiration Date: **28 Aug 2017**

Conditions of Approval
Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

raising standards worldwide™

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: +44 (0)845 080 9000

Certificate

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No.	**CE 82107**
Date:	**9 Aug 2012**
Issued to:	**CooperSurgical Inc.,** **also trading as Milex and Wallach Surgical Devices** **and Sage In-Vitro Fertilization** **Trumbull, Connecticut** **USA**

Subcontractor	Service(s) supplied
Steris Isomedix Services 435 Whitney Street Northborough Massachusetts 01532 USA	Sterilization
Sage In-Vitro Fertilization, Inc. a CooperSurgical Company 1979 East Locust Street Pasadena California 91107 USA	Aseptic Processing Manufacture
Emergo Europe Molenstraat 15 2513 BH The Hague Netherlands	EU Representative
Alsa Apparecchi Medicali s.r.l. Via C. Bonazzi, 16 Castel Maggiore Bologna Italy 40013	Manufacture

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Subcontractor	**Service(s) supplied**
Leisegang Feinmechanik Optik GmbH Leitnizstrasse 32 D-10625 Berlin Germany	EU Representative
STERIS Isomedix Services 3459 South Clinton Avenue South Plainfield New Jersey 07080 USA	Sterilization

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History of Quality Assurance Certificate

Certificate No: CE 82107
Issue Date: 9 Aug 2012
Issued to: CooperSurgical Inc.,
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Date	Reference Number	Action
08 November 2004		First issue
27 April 2005		Amended certificate to include trading name of Milex and amended scope to include vaginal pessaries and contraceptive diaphragms.
15 February 2007		Reissue due to extension to scope to include 'cardiac cryosurgical systems'.
30 August 2007		Re-issue due to extension to scope to include 'LEEP electrodes' and addition of Steris Isomedix Services as a significant subcontractor for sterilization.
25 March 2008	7181048	Re-issue to include additional trading name 'Wallach Surgical Devices' and removing cardiac cryosurgical systems.
23 March 2009	7254143	Re-issue to include additional trading name 'Sage In-Vitro Fertilization' and the scope extension to include In-Vitro Fertilization media without protein supplementation for use in assisted reproduction processes up to and including embryo/blastocyst implantation stage.
29 September 2009	7296871	Renewal of certificate. Addition of EU representative and STERIS Isomedix Services, 3459 South Clinton Avenue, South Plainfield, New Jersey, 07080, USA for the activity of sterilization to the list of significant sub-contractors and removal of Steris Isomedix Services, RI.

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Date	Reference Number	Action
6 November 2009	7454853	Certificate re-issue due to extension to scope to include 'anogenital' procedures for the electrosurgical generators. Addition of Alsa Apparecchi Medicali s.r.l. as significant sub-contract manufacturer for electrosurgical generators.
11 March 2011	7651165	Extension to scope to include IVF Media devices containing protein supplementation and antibiotic for use in assisted reproduction processes up to and including embryo/blastocyst implantation stage.
23 April 2012	7828288	Addition of Emergo Europe as EU representative
09 August 2012	7868381	Certificate Renewal. Correction of subcontractor name from 'Leisegang Feinmechanik GmbH' to 'Leisegang Feinmechanik Optik GmbH' and the correction of postcode for Apparecchi Medicali s.r.l. from '40012' to '40013'

BSI
Kitemark Court Davy Avenue Knowlhill
Milton Keynes MK5 8PP UK
Tel +44 (0)845 080 9000
www.bsigroup.co.uk

Our Ref – CS1322012b

February 13th 2012

Re: Confirmation of Certificate Validity

To Whom it May Concern,

BSI Confirms that

Coopersurgical Inc. (Also trading as Ackrad, Prism, Milex, Medscand, Wallach, SAGE and Lone Star Medical Products) with an office at

95 Corporate Drive
Trumbull
Connecticut
06611
USA

Hold the following certificates and that they continue to be valid

CE 82107, EC Annex II, 3
First Issued – 8th November 2004
Expires 7th November 2014

With scope

"The design and manufacture of, high-frequency electrosurgical generators for laparoscopic, transvaginal and anogenital procedures, LEEP electrodes, sterile laparoscopic and transvaginal applicators, vaginal pessaries, contraceptive diaphragms and In-Vitro Fertilization media with and without protein supplementation and antibiotic for use in assisted reproduction processes up to and including embryo/blastocyst implantation stage"

BSI

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CE 551319, EC Annex II, 4
First Issued – 11th March 2011
Expires – 10th March 2016

With scope

"In-Vitro Fertilization media incorporating Human Serum Albumin and /or gentamicin sulphate for use in assisted reproduction processes"

Under the EU Medical Device Directive 93/42/EEC the manufacturer may decide to complete a declaration of conformity and affix CE marking for the above devices providing they are within the scope of an appropriate conformity assessment procedure completed by a Notified Body. BSI confirms the above listed devices have gone through appropriate conformity assessment and are covered under the scope of CE69386.

Following the completion of the declaration of conformity, appropriately affixing the CE mark and taking account of local Member State requirements or restrictions the manufacturer can decide to freely place the relevant devices on the EU market

Yours sincerely

J. Newman

James Newman – Scheme Manager, BSI