

bsi.

Certificate

Production Quality Assurance

No. CE 69386



Issued to:

**CooperSurgical Inc.,
also trading as Ackrad Laboratories
Prism Healthcare, Milex, Medscand,
Wallach Surgical Devices,
SAGE In-Vitro Fertilization and
Lone Star Medical Products
95 Corporate Drive, Trumbull, Connecticut
06611
USA**

In respect of:

The manufacture of devices as detailed in the Supplementary Information

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex V, 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: **30 Aug 2002**

Date: **29 Nov 2013**

Expiration Date: **28 Aug 2017**

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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.

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Supplementary Information to CE 69386

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Trumbull, Connecticut
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The manufacture of
CT CloseSure Systems and CT CloseSure XL
Fetal and Vascular Dopplers
Gelpacks for heat therapy
Ophthalmic, Gynaecology and Dermatology Cryosurgery Systems
Sterile Colpotomizer Systems
Sterile Disposable Uterine Manipulator-Injectors
Sterile Esophageal Balloon Catheters
Sterile Retractors
Sterile Surgery Kits, Retractor Kits, Stays and Dilamezinsert
Sterile Trocars, Cannulas and Trocar/Cannula Kits
Sterile Vacuum Assisted Delivery Extractor Cups, Delivery Pumps and Delivery Kits
Vaginal Pessaries

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Those aspects of Annex V relating to securing and maintaining sterility in the manufacture of
Curettes
Cytology Sampling Devices
Embryo Transfer Catheters
Endometrial suction curettes
Fiberoptic Catheters
INCA Nasal Cannulae Set with sterile nasal prongs
Intrauterine Insemination Catheters
Laparoscopic Smoke Evacuation Systems
Retractors
Sterile Elliptosphere Catheters
Sterile H/S Catheter sets with Kraylon Balloons
Sterile Tampa Catheters

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Those aspect of Annex V relating to metrology in the manufacture of
Contraceptive Diaphragm fitting sets
Fiberoptic Cystometry Systems
Vaginal Pessary Fitting Kit

First Issued: **30 Aug 2002**Date: **29 Nov 2013**Expiration Date: **28 Aug 2017**

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Certificate

List of Significant Subcontractors

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

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Subcontractor	Service(s) supplied
Emergo Europe Molenstraat 15 2513 BH The Hague Netherlands	EU Representative
Steris Isomedix Services 435 Whitney Street Northborough Massachusetts 01532 USA	Gamma Irradiation Sterilization
STERIS Isomedix Services Business Unit Headquarters 1880 Industrial Drive Illinois 60048 USA	Gamma Irradiation Sterilization
Sage In-Vitro Fertilization, Inc. a CooperSurgical Company 1979 East Locust Street Pasadena California 91107 USA	Manufacture
Pristech Products Inc. 6952 Fairgrounds Parkway San Antonio Texas 78238 USA	Manufacture



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Subcontractor	Service(s) supplied
Sterigenics US, LLC 84 Park Road Glens Falls New York 12804 USA	ETO Sterilization
Steris Isomedix 3459 S. Clinton Avenue South Plainfield New Jersey 07080 USA	ETO Sterilization
Leisegang Feinmechanik GmbH Leibnizstrasse 32 D-10625 Berlin Germany	EU Representative
Lone Star Medical Products 11211 Cash Road Stafford Texas 77477 USA	Manufacture

Certificate

History of Quality Assurance Certificate

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Date	Reference Number	Action
30 August 2002	4316414	Original issue to CooperSurgical Inc for the manufacture of Fetal Dopplers and Sterile Disposable Uterine Manipulator-Injectors
04 October 2002	4386116	Amended certificate to add Sterile Colpotomizer Systems to scope
12 November 2002	4386116	Amended certificate to add the trading name of Ackrad Laboratories Inc. Also amended scope to include INCA Nasal Cannulae Set with sterile nasal prongs and Sterile Bronchitrac Suction Catheters, Esophageal Balloon Catheters, Elliptosphere Catheters, Tampa Catheters and H/S Catheter sets with Kraton Balloons
28 January 2004	4487082	Amended certificate to add the trading name of Prism Healthcare. Also amended scope to include Gelpacks for heat therapy, sterile and non-sterile Vacuum Assisted Delivery Pumps, sterile Vacuum Assisted Delivery Extractor Cups and Delivery Kits. Also added a new subcontractor Pristech Products Inc as manufacture of gelpacks for heat therapy
25 February 2004	n/a	Correction of typographical error to address
22 July 2004	4593904	Amended certificate to add the trading name of SAGE In-Vitro Fertilization Inc. Also, amended scope to include sterile oil and sterile water for Tissue Culture for use in in-vitro fertilization, and Sterile Phosphate Buffered Saline (PBS) for use in in-vitro fertilization Also, modified the Supplementary Information to highlight Class I Sterile devices



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Date	Reference Number	Action
27 September 2004	4634606	Amended certificate to include Vascular Dopplers within the scope
30 November 2004	4647383	Amended certificate to include Ophthalmic Cryosurgery Systems within the scope
27 April 2005	4657997	Amended certificate to include trading name of Milex and amended scope to include Sterile Curettes and Contraceptive Diaphragm fitting sets
19 September 2005	4739488	Extension of scope to include Fiberoptic Cystometry System, Sterile Fiberoptic Catheter and Cytology Sampling devices
16 July 2007	7073121	Certificate renewal Extension to scope to include Embryo Transfer Catheters
30 October 2007	7110759	Extension to scope to include Intrauterine Insemination Catheters
23 May 2008	7213846	Extension to scope to include Cryosurgery Systems for gynaecology and dermatology. Also addition of Wallach Surgical Devices as a trading name.
23 June 2008	7226858	Extension to scope to include CT CloseSure Systems and CT CloseSure Systems XL
22 October 2008	7284056	Extension to scope to include endometrial suction curettes



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Date	Reference Number	Action
31 March 2010	7507745	Addition of Lone Star Medical Products as a trading name and addition of Sterile Surgery Kits, Retractor Kits, Stays, Dilamezinsert and Sterile Retractors to scope. These were covered by Lone Star Medical Products BSI CE 553016 issued on 12 October 2009 which was originally transferred from SGS where Lone Star Medical Products, Inc. was certified since 4 February 1998. Steris Isomedix Services, Inc., Coventry, RI - Sterilization was removed and three new Subcontractors were added: Steris Isomedix, So. Plainfield, NJ - ETO Sterilization; Leisegang Feinmechanik GmbH, Berlin, Germany - EU Representative; and Lone Star Medical Products, Stafford, TX – Manufacture. With this revised certificate, CE 69386, the previous certificate CE 553016 is cancelled.
02 August 2010	7548521	Addition of Sterigenics US, LLC, 84 Park Road, Glen Falls, New York, 12804, to the list of significant subcontractors for ETO sterilization.
24 February 2011	7650994	Addition of Laparoscopic Smoke Evacuation Systems to scope. Addition of significant subcontractor Biotest Laboratories, Inc.

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Date	Reference Number	Action
13 February 2012	7752683	<ul style="list-style-type: none"> - Revised format of supplementary pages for clarity - Addition of vaginal pessaries to scope - Revision of the following devices to "Those aspects of Annex V relating to securing and maintaining sterility in the manufacture of" <ul style="list-style-type: none"> INCA Nasal Cannulae Set with sterile nasal prongs Intrauterine Insemination Catheters - Revision of the following devices to "Manufacture of" <ul style="list-style-type: none"> Vacuum Assisted Delivery Pumps Sterile Elliptosphere Catheters Sterile Tampa Catheters Sterile H/S Catheters sets with Kraton Balloons



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Date	Reference Number	Action
23 July 2013	8022947	Addition of Vaginal Pessary Fitting Kit
29 November 2013	8075064	Revision of the following devices to "Those aspects of Annex V relating to securing and maintaining sterility in the manufacture of" Elliptosphere catheters, H/S catheter sets with kraton balloons and tampa catheters Removal of Sterile Bronchitrac suction catheters from scope