



By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

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 of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Albert Roossien, Regulatory Lead

First Issued: **2002-08-30**

Date: **2019-02-19**

Expiry Date: **2022-08-08**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. 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.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Bay Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.



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Supplementary Information to CE 69386

Issued To:

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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
Limb Plethysmography Systems
IVF Incubators
Amniocentesis Needles
Oocyte Recovery Needles

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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
Sterile Air Bubble Based Infusers (ABBI)
Endosee Cannulas
Embryo Replacement Catheters

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Information and Contact: BSI, 389 Chiswick Park Avenue, Uxbridge, Middlesex, UK
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Those aspects of Annex V relating to securing and maintaining sterility in the manufacture of
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Sterile Os Finder Cervical Dilator

Sterile Adapter Drape

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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

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Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

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

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06611
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Subcontractor:	Service(s) supplied
Cooper Medical SRL Edificio N° B49, 51 Ave 0 Parque Industrial Zona Franca Coyol LaGuarita, Alajuela Costa Rica	Manufacture
Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	EU Representative
Isomedix Operation, Inc. North Facility 1880 Industrial Drive Illinois 60048 USA	Gamma Irradiation Gamma Sterilization

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95 Corporate Drive, Trumbull,
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USA**

Subcontractor:	Service(s) supplied
Isomedix Operations, Inc 3459 South Clinton Avenue South Plainfield New Jersey 07080 USA	ETO Sterilization
Isomedix Operations, Inc. 435 Whitney Street Northborough Massachusetts 01532 USA	Gamma Irradiation Gamma Sterilization
Leisegang Feinmechanik GmbH Leibnizstrasse 32 Berlin D-10625 Germany	EU Representative

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Subcontractor:	Service(s) supplied
Lone Star Medical Products 11211 Cash Road Stafford Texas 77477 USA	Manufacture
Pristech Products Inc. 6952 Fairgrounds Parkway San Antonio Texas 78238 USA	Manufacture
Research Instruments Ltd. Bickland Industrial Park Falmouth TR11 4TA United Kingdom	Manufacture

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Subcontractor:	Service(s) supplied
Sterigenics US,LLC 84 Park Road Queensbury NY 12804 USA	ETO Sterilization
Sterilization Services of Tennessee, Inc. 2396 Florida Street Memphis Tennessee 38109 USA	ETO Sterilization
UNISIS CORP. Saitama Plant 2675-1 Nishikata Koshigaya-shi Saitama 343-0822 Japan	Crucial Supplier

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