

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.

CE 82107

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 design and manufacture of high-frequency electrosurgical generators for laparoscopic, transvaginal and anogenital procedures, LEEP electrodes, sterile laparoscopic 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 of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

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



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **2004-11-08**

Date: **2017-08-07**

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.



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List of Significant Subcontractors

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

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95 Corporate Drive, Trumbull,
Connecticut
06611
USA**

Subcontractor:	Service(s) supplied
Emergo Europe B.V. Prinsessegracht 20 2514 AP The Hague The Netherlands	EU Representative
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 Sterilization

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Subcontractor:	Service(s) supplied
Leisegang Feinmechanik Optik GmbH Leitnizstrasse 32 D-10625 Berlin Germany	EU Representative
Origio a/s Knardrupvej 2 2760 Måløv Denmark	Aseptic Processing EU Representative Manufacture

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