



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 2797):

Albert Roossien, Regulatory Lead

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

Date: **2019-02-19**

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

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Page 1 of 1

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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| Subcontractor: | Service(s) supplied |
|---|--|
| Emergo Europe 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 Gamma Sterilization |

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

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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. |

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| Date | Reference Number | Action |
|-------------------|------------------|---|
| 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. |
| 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. |

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Page 2 of 4

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| Date | Reference Number | Action |
|------------------|------------------|--|
| 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 Aparecchi Medicali s.r.l. from '40012' to '40013'. |
| 11 November 2015 | 8427114 | Addition of Origio a/s as a significant subcontractor. |
| 11 March 2016 | 8485009 | Removal of SAGE In-Vitro Fertilization as significant subcontractor. |
| 21 June 2016 | 8548739 | Addition of ORIGIO a/s as EU Representative. |
| 07 August 2017 | 8695526 | Certificate renewal. Change of address for Emergo Europe; Change of name for Steris Isomedix to Isomedix Operations, Inc. Removal of ALSA Aparecchi Medicali as a subcontractor. Removal of sterile transvaginal applicators. |
| Current | 8660161 | Traceable to NB 0086. Administrative change to subcontractor Isomedix Operations, Inc. for 'Sterilization' to 'Gamma Sterilization.' |

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By Royal Charter

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Information and Contact: BSI, Bay Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
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