By Royal Charter

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:
Non-sterile pessaries and contraceptive vaginal diaphragms.
Sterile disposable electrodes for electrosurgery.
Sterile media with and without Human Serum Albumin and antibiotics for artificial reproduction technologies (ART) procedures.
Sterile oil for overlay of ART media during gamete and embryo culture and micromanipulation.

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):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2004-11-08** Date: **2020-03-19** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Supplementary Information to 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

Number	Device Name	Intended purpose per IFU
Class III		
---	SAGE™ Media	See CE 551319
---	SAGE™ Vitrification Kit SAGE™ Vitrification Warming Kit	See CE 653002
Class IIb		
58467	LEEP Electrodes	For electro-excisional procedures, loop and needle electrodes are used with BLEND-1 cut current whereas electrofulguration is performed with ball-shaped or needle-type electrodes using coagulation power outputs
58467	Wallach® LOOP Electrodes	Used to coagulate bleeding tissues, using Radio Frequency (RF) Energy from an electrosurgical generator. Used to excise target tissues, perform biopsies and control bleeding through a standard Monopolar Electrosurgical Generator.
58467	Fischer® Cone Biopsy Excisor	Indicated for Large Loop Excision of the Transformation Zone (LLETZ) in the diagnosis and treatment of some cervical intraepithelial neoplasias (CIN) and dysplasias and cervical conization procedures.
35237	Milex® Pessaries, Wallace® Pessaries (Long term)	For effective support of uterine prolapse or procidentia (or stress urinary incontinence).

First Issued: **2004-11-08** Date: **2020-03-19** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to 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

Number	Device Name	Intended purpose per IFU
42405	Vaginal Diaphragms	Intended for the prevention of pregnancy in women who elect to use diaphragms as a method of contraception
Class IIa		
MD 0109	Oil For Tissue Culture	---

First Issued: **2004-11-08** Date: **2020-03-19** Expiry Date: **2024-05-26**

...making excellence a habit.™

By Royal Charter

EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

Certificate No:	**CE 82107**
Date:	**2020-03-19**
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**

Subcontractor:	**Service(s) supplied**
CooperSurgical Distribution B.V Celsiusweg 35 5928 PR Venlo The Netherlands	**EU Representative**
Emergo 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**

...making excellence a habit.™

By Royal Charter

EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

Certificate No:	**CE 82107**
Date:	**2020-03-19**
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**

Subcontractor:	**Service(s) supplied**
Isomedix Operations, Inc. 435 Whitney Street Northborough Massachusetts 01532 USA	**Gamma Irradiation Gamma Sterilization**
Origio a/s Knardrupvej 2 2760 Måløv Denmark	**Aseptic Processing EU Representative Manufacture**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 82107**

Date: **2020-03-19**

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**

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.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 82107**

Date: **2020-03-19**

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**

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.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 82107**

Date: **2020-03-19**

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**

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 Apparecchi 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 Apparecchi Medicali as a subcontractor. Removal of sterile transvaginal applicators.
19 February 2019	8660161	Traceable to NB 0086. Administrative change to subcontractor Isomedix Operations, Inc. for 'Sterilization' to 'Gamma Sterilization.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 82107**

Date: **2020-03-19**

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**

Date	Reference Number	Action
Current	9770591	Early renewal. Leisegang Feinmechanik GmbH removed as EU Representative. CooperSurgical Distribution B.V. added as EU Representative. Removal of “high-frequency electrosurgical generators for laparoscopic, transvaginal and anogenital procedures” and “sterile laparoscopic applicators” from scope. Added “oil for overlay of ART media during gamete and embryo culture and micromanipulation” to scope for clarification. Previously covered by “In-Vitro Fertilization media”. Changed scope expression “LEEP electrodes” to “disposable electrodes for electrosurgery”.