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.
Sterile sperm selection devices.

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: **2021-05-11** Expiry Date: **2024-05-26**

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Supplementary Information to CE 82107

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Number	Device Name	Intended purpose per IFU
Class III		
---	SAGE™ Media SAGE™ Vitrification Kit SAGE™ Vitrification Warming Kit	See CE 551319
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).

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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
58052	Hyaluronan binding sperm selection device	Used in the treatment of infertile couples by Intracytoplasmic Sperm Injection (ICSI), the PICSI® Sperm Selection Device is indicated for the selection of mature sperm for injection.
Class IIa		
MD 0109	Oil For Tissue Culture	---

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