

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:

See certificate scope page.

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):



Gary E Slack, Senior Vice President Medical Devices

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

Date: **2020-03-13**

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

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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.

Certificate No: CE 69386

Certificate Scope:

The manufacture of Ophthalmic, Gynaecology and dermatology Cryosurgery Systems and accessories.

The manufacture of sterile and non-sterile obstetrics and gynaecology devices including;

- **Uterine Manipulators/Injectors and their accessories including colpotomizer cups**
- **Vaginal Pessaries**
- **Amniocentesis Needles**
- **Vacuum assisted Delivery systems and accessories**
- **Infant warmers**
- **Fetal and Vascular Ultrasound Dopplers**

The manufacture of sterile and non-sterile Artificial Reproductive Technology (ART) devices including;

- **Oocyte recovery needles**
- **Incubators**
- **Micropipettes**
- **Stripper Tips**

The manufacture of sterile general surgery devices including;

- **Esophageal balloon Catheters**
- **Laparoscopic cannulas/trocars**
- **Laparoscopic Port Closure Systems**
- **Stays, retractors and retractor kits**

Those aspects of Annex V relating to securing and maintaining sterility in the manufacture of;

Intrauterine Insemination Catheters, Embryo Replacement Catheters, Pasteur pipettes, Assisted Hatching pipettes, Laparoscopic Smoke Evacuation Systems, Hysteroscopy Saline/Air Contrast Injectors, Diagnostic Surveillance Cannulas, Adapter Drapes, Hysterosalpingography Catheters, Bi-nasal Oxygen Cannulas, Cervical Dilators, Gynaecological tissue sampling devices.

Those aspects of Annex V relating to metrology in the manufacture of;
Vaginal Pessary Fitting Kit and Contraceptive Diaphragm fitting sets

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Supplementary Information to CE 69386

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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 1103	Medical Heat Packs	---
MD 1302	Ultrasound dopplers	---
MD 1104	Cryosurgical systems	---
MD 1402	IVF Incubators G185 & G210	---
MD 0106	Adult Esophageal Balloon Catheter Set	---
MD 0106	Milex® Pessaries (Short term)	---
MD 0106	Uterine Manipulators/Injectors and Accessories	---
MD 0106	Fetal vacuum extraction system and Accessories	---
MD 0106	Carter-Thomason CloseSure System®	---
MD 0106	Stays and Retractors	---
MD 0106	Apple-Hunt Secondary Trocar Cannula	---
MD 0106	Carter-Thomason® II Port Closure System Suture Passer	---
MD 0102	Wallace® Amniocentesis Needle	---
MD 0109	Wallace® Oocyte Recovery Set	---
MD 0109	Micropipettes	---
MD 0109	Stripper Tips	---

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Number	Device Name	Intended purpose per IFU
Class Is		
MD 0106	Lone Star Retractor Rings	---
MD 0109	Pasteur Pipettes	---
MD 0109	Origio Assisted Hatching Pipettes	---
MD 0101	INCA® Nasal Cannula Set with sterile nasal prongs	---
MD 0109	Intrauterine Insemination Catheters	---
MD 0106	Cytology Sampling devices	---
MD 0106	Endometrial Suction Curette	---
MD 0106	Hysterosalpingography Catheter	---
MD 0106	Laparoscopic Smoke Evacuation Systems	---
MD 0106	Wallach Disposable OS Finders	---
MD 0106	CSI OS Finders	---
MD 0106	ABBI (Air Bubble Base Infuser)	---
MD 0106	EndoSee® Cannula	---
MD 0106	Sterile Adapter Drapes	---
MD 0109	Embryo Replacement Catheters	---
Class Im		
MD 0107	Vaginal Diaphragms Fitting Sets	---
MD 0106	Milex Pessaries Fitting Kit	---

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Certyfikat WE - Zapewnienie Jakości Produkcji

Dyrektywa 93/42/EWG dotycząca wyrobów medycznych, Annex V

Nr CE 69386

Wydany dla: **Coope Surgical Inc.**
również prowadząca działalność jako Ackrad Laboratories,
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W odniesieniu do:

na podstawie naszej kontroli systemu zapewnienia jakości zgodnie z wymaganiami Dyrektywy Rady 93/42 / EWG, Załącznik V. System zapewnienia jakości spełnia wymagania dyrektywy. Na wprowadzenie do obrotu wyrobów klasy IIb i klasy III wymagane jest zaświadczenie z Aneksu III.

Na rzecz i w imieniu BSI, jednostki notyfikowanej w zakresie powyższej Dyrektywy (Numer jednostki notyfikowanej 2797):

/podpis nieczytelny/

.....
Gary E Slack, Vice Prezes od Spraw Wyrobów Medycznych

Data pierwszego wydania: **2002-08-30**

Data: **2020-03-13**

Data wygaśnięcia: **2024-05-26**

Warunki aprobaty:

Certyfikat niniejszy zachowuje ważność pod warunkiem utrzymywania systemu jakości zgodnie z wymogami Dyrektywy: jak wykazano przez wymagane czynności nadzoru jednostki notyfikowanej.

Niniejsza aprobata nie obejmuje żadnych produktów zaprojektowanych i / lub wyprodukowanych przez stronę trzecią w imieniu firmy bez szczegółowych uzgodnień z BSI.

Niniejszy certyfikat wystawiony został elektronicznie i podlega warunkom kontraktu.

.....
/W stopce dane teleadresowe/

Zakres Certyfikatu

Producent systemów oraz akcesoriów do kriochirurgii okulistycznej, ginekologicznej i dermatologicznej

Produkcja sterylnych i niesterylnych położniczych i ginekologicznych wyrobów obejmuje:

- manipulatory maciczne/ wstrzykiwacze i akcesoria do nich, w tym kubki kolpotomizera
- pessary pochwowe
- igły do amniopunkcji
- próżniociągi do wspomagania porodu i akcesoria
- żelowe ogrzewacze dla noworodków
- Doppler USG płodu i naczyń

Produkcja sterylnych i niesterylnych wyrobów do technologii Wspomaganego Rozrodu (ART) obejmuje:

- igły do pobierania oocytów
- inkubatory
- mikropipety
- Stripper Tips

Produkcja sterylnych wyrobów do chirurgii ogólnej obejmuje:

- kateter balonowy do przetyku
- kaniule laparoskopowe/ trokary
- system do zamykania portów w laparoskopii
- odciąg (haki), retrakcyjne i zestawy retraktorów

Aspekty załącznika V odnoszące się do zabezpieczania i utrzymywania sterylności w procesie produkcji:

Cewniki do inseminacji wewnątrzmacicznej, Katetery do transferu embrionów, Pipety Pasteur, Pipety do wspomagania wylęgania zarodka (hatching), Laparoskopowe zestawy do odprowadzania dymu, Histeroskopy/ iniektor do wprowadzania kontrastu (sól/powietrze), kaniule diagnostyczne, osłony łączników, Katetery do histerosalpingografii, kaniule tlenowe donosowe, rozszerzacz szyjki macicy, przyrządy do pobierania próbek ginekologicznych,

Aspekty załącznika V odnoszące się do zabezpieczania i utrzymywania sterylności w procesie produkcji:

Pessary pochwowe/zestaw do dopasowania oraz zestawy do dopasowania błony antykoncepcyjnej Diaphragma

Certyfikat WE - Zapewnienie Jakości Produkcji**Informacje uzupełniające do CE 69386**

Wydany dla: **Coope Surgical Inc.**
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