

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

CooperSurgical, Inc. also trading as  
Ackrad, Prism, Milex, Medscand, Wallach  
Surgical Devices,  
SAGE and Lone Star Medical Products  
95 Corporate Drive  
Trumbull  
Connecticut  
06611  
USA

Holds Certificate No:

**FM 72267**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Please see scope page.

For and on behalf of BSI:



Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2002-12-13

Latest Revision Date: 2018-12-13

Effective Date: 2018-12-13

Expiry Date: 2021-12-06



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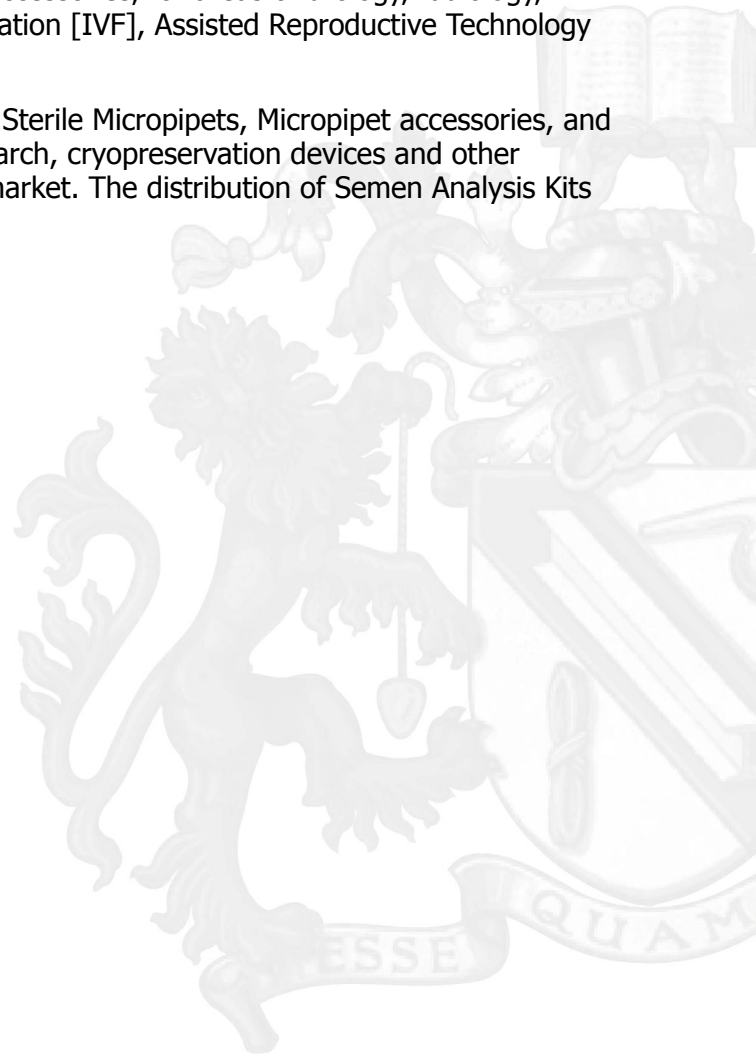
...making excellence a habit.™

Certificate No: **FM 72267**

## Registered Scope:

The design, development, manufacture and distribution of sterile and non-sterile devices including obstetric and gynecology products, colposcopes, cytology sampling devices, vacuum assist delivery devices, gel packs, cystometry systems, speculums, amniotomes, cryosurgical equipment and probes, electrosurgical generators and electrodes, dopplers, catheters, needles, anoscopes, connectors, operating room instrumentation, assisted reproductive media formulations, fertility devices, IVF and ART products and laboratory instruments, critical care respiratory products, irrigation/drainage devices, bone sonometers, general surgery kits, urological devices and accessories, for areas of urology, radiology, ophthalmology, obstetrics and gynecology, In Vitro Fertilization [IVF], Assisted Reproductive Technology [ART] and dermatology.

The manufacture of Pasteur Pipets and the distribution of Sterile Micropipets, Micropipet accessories, and Pasteur Pipets for In Vitro Fertilization, and stem cell research, cryopreservation devices and other products for the artificial reproductive technology [ART] market. The distribution of Semen Analysis Kits and Counting Chambers.



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To be read in conjunction with the scope above or the attached appendix.

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Location	Registered Activities
CooperSurgical, Inc. also trading as Ackrad, Prism, Milex, Medscand, Wallach Surgical Devices, SAGE and Lone Star Medical Products 95 Corporate Drive Trumbull Connecticut 06611 USA	Receiving, Component/material Stock, Inspection, Assembly, testing, labeling, storage, and service & repair. This address is used as legal manufacture address and used on all our labels.
CooperSurgical, Inc. 50 Corporate Drive Trumbull Connecticut 06611 USA	Distribution Center, overflow/excess storage of materials to be used at 95 Corporate Drive, storage of unused equipment. Regulatory, Labeling and R & D Engineering offices.
CooperSurgical, Inc. 75 Corporate Drive Trumbull Connecticut 06611 USA	Top management, boardroom, finance, HR, IT, Sales & Marketing.
Lone Star Medical Products 11211 Cash Road Stafford Texas 77477 USA	Design and manufacture of sterile and non-sterile general surgery kits, devices and accessories, urological devices, Trocars, Cannulas and Trocar / Cannula kits.
Cooper Medical, SRL Edificio N° B49, 51 Ave 0 Parque Industrial Zona Franca Coyol La Garita, Alajuela Costa Rica	Manufacture of catheters, needles and micro pipettes.

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