

# 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

DUNS Number: 80-189-5244

Holds certificate No:

**MDSAP 681109**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure [if design controls are part of the certification]; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1-SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D

**Please see scope page.**

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk – Medical Devices

Original Registration Date: 2018-12-13

Effective Date: 2018-12-13

Expiry date: 2021-12-06

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...making excellence a habit.™



BSI Group America Inc. is an MDSAP authorized auditing organization

This certificate remains the property of BSI and shall be returned immediately upon request.  
To be read in conjunction with the scope above or the attached appendix.

Managed by: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA  
A Member of the BSI Group of Companies.

Certificate No:

**MDSAP 681109**

## Registered Scope:

The design, development, manufacture and distribution of sterile and non-sterile devices 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, anoscopes, connectors, operating room instrumentation, fertility devices, 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, and dermatology.

The manufacture of Pasteur Pipets, and 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.



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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 DUNS Number: 80-189-5244	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 DUNS Number: 80-189-5244	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 DUNS Number: 80-189-5244	Top management, boardroom, finance, HR, IT, Sales & Marketing.

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