

# 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

Facility ID Number: F000142

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; 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:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2018-12-13

Effective Date: 2021-12-07

Expiry Date: 2024-12-06



BSI Group America Inc. is an MDSAP authorized auditing organization

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...making excellence a habit.™

Certificate No: **MDSAP 681109**

## 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, sterile surgical wound closure devices for areas of urology, radiology, ophthalmology, obstetrics and gynecology, In Vitro Fertilization [IVF], Assisted Reproductive Technology [ART] and dermatology.

The manufacture and distribution of Pasteur Pipets, 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 and Semen Analysis Kits and Counting Chambers.



Original Registration Date: 2018-12-13

Effective Date: 2021-12-07

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This certificate remains the property of BSI and shall be returned immediately upon request.  
An electronic certificate can be authenticated [online](http://www.bsigroup.com/ClientDirectory). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: 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**

Location

Registered Activities

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95 Corporate Drive  
Trumbull  
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06611  
USA  
Facility ID Number: F000142

Receiving, Component/material Stock, inspection,  
manufacturing, testing, labeling, storage, and service &  
repair.

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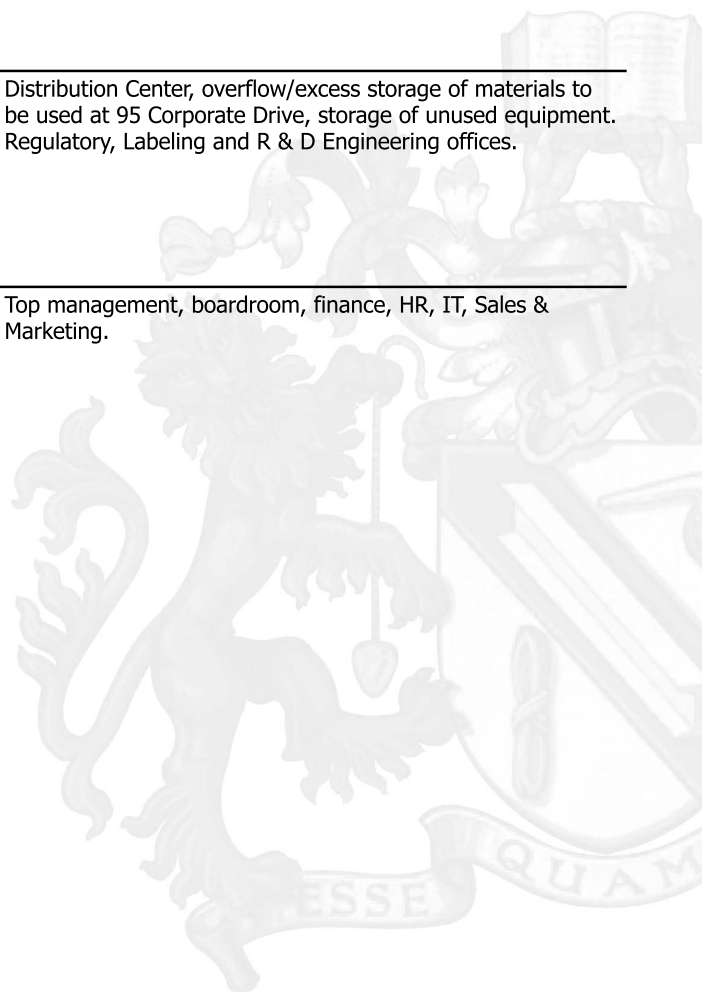
CooperSurgical, Inc.  
50 Corporate Drive  
Trumbull  
Connecticut  
06611  
USA  
Facility ID Number: F000142

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.

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CooperSurgical, Inc.  
75 Corporate Drive  
Trumbull  
Connecticut  
06611  
USA  
Facility ID Number: F000142

Top management, boardroom, finance, HR, IT, Sales &  
Marketing.



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