

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

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), 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:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2018-12-13

Effective Date: 2024-12-07

Expiry Date: 2027-12-06



BSI Group America Inc. is an MDSAP recognised auditing organization

Page: 1 of 3

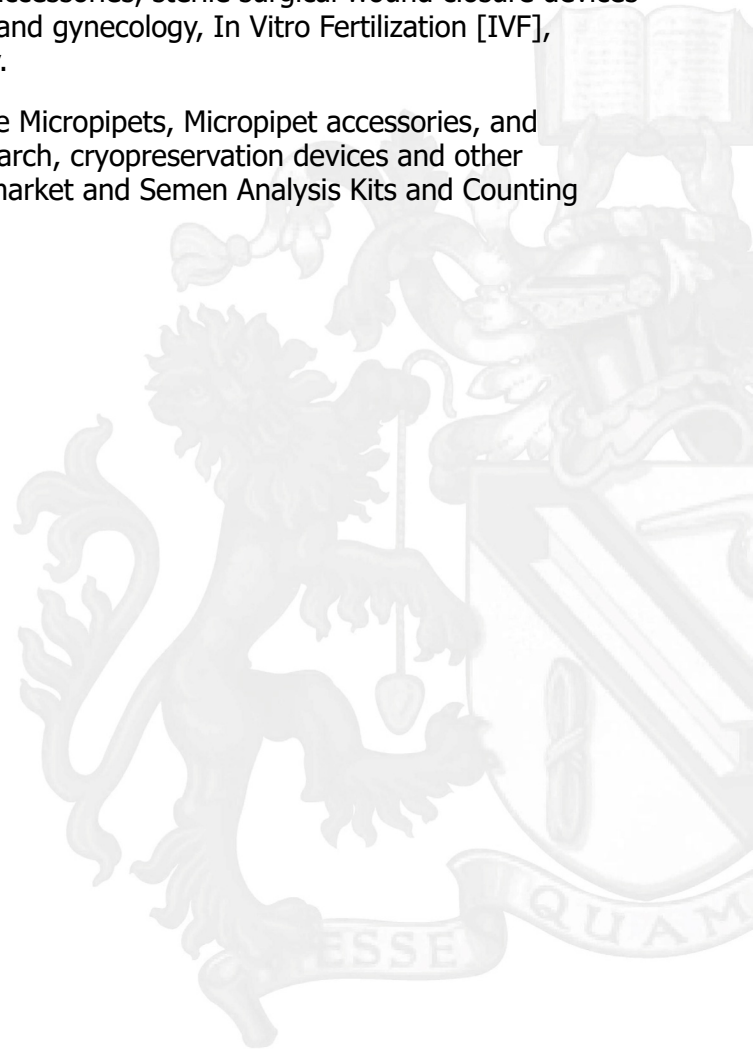
...making excellence a habit.™

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: 2024-12-07

Expiry Date: 2027-12-06

Page: 2 of 3

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](#). Printed copies can be validated at 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
CooperSurgical, Inc. also trading as Ackrad, Prism, Milex, Medscand, Wallach Surgical Devices, 95 Corporate Drive Trumbull Connecticut 06611 USA Facility ID Number: F000142	Receiving, Component/material Stock, inspection, manufacturing, testing, labeling, storage, and service & repair.
Cooper Medical, SRL Edificio N° B49, 51 Ave 0 Parque Industrial Zona Franca Coyol La Garita, Alajuela 20113 Costa Rica Facility ID Number: F007482	Manufacture of catheters, needles, micro pipettes, assisted reproductive media formulations, sterile sperm selection medical device, IVD device for sperm analysis, Vaginal Pessaries & Fitting Set, Contraceptive Diaphragms & Fitting Sets, and Sterile Surgical Wound Closure Devices.
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.
CooperSurgical, Inc. 75 Corporate Drive Trumbull Connecticut 06611 USA Facility ID Number: F000142	Top management, boardroom, finance, HR, IT, Sales & Marketing.

Original Registration Date: 2018-12-13

Effective Date: 2024-12-07

Expiry Date: 2027-12-06

Page: 3 of 3

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at 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.