



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.

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For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2002-12-13 Latest Revision Date: 2021-12-06





Effective Date: 2021-12-07 Expiry Date: 2024-12-06

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...making excellence a habit.[™]

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.

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: 2002-12-13 Latest Revision Date: 2021-12-06 Effective Date: 2021-12-07 Expiry Date: 2024-12-06

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Certificate No: FM 72267

Location

USA

USA

USA

USA

CooperSurgical, Inc. also trading as Ackrad, Prism, Milex, Medscand, Wallach repair. Surgical Devices, SAGE and Lone Star Medical Products 95 Corporate Drive Trumbull Connecticut 06611 CooperSurgical, Inc. 50 Corporate Drive Trumbull Connecticut 06611 CooperSurgical, Inc. 75 Corporate Drive Marketing. Trumbull Connecticut 06611 Lone Star Medical Products 11211 Cash Road Stafford Texas 77477 Cooper Medical, SRL Edificio Nº B49, 51 Ave 0 Parque Industrial Zona Franca Coyol La Garita, Alajuela Fitting Sets. 20113 Costa Rica

Registered Activities

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

Distribution Center, overflow/excess storage of materials to be used at 95 Corporate Drive, storage of unused equipment. Regulatory, Lableing and R & D Engineering offices.

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

Manufacture of sterile and non-sterile general surgery kits, devices and accessories, urological devices, Trocars, Cannulas and Trocar / Cannula kits.

Manufacture of catheters, needles, micro pipettes, assisted reproductive media formulations, sterile sperm selection medical device, IVD device for sperm analysis, Vaginal Pessaries & Fitting Set and Contraceptive Diaphragms &

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