



Certificate Number US21/819944363

The management system of

LSL Healthcare, Inc

6200 W. Howard St., Niles, 60714, United States

Facility identification number : F004892

has been audited against the criteria stated below and found to conform to those criteria for the scope contained in this certificate



MDSAP (ISO 13485:2016)

Canada:

Medical Devices Regulations – Part 1 SOR 98/282

United States:

21 CFR 820 / 21 CFR 803 / 21 CFR 806 / 21 CFR 807 – Subparts A to D

For the following activities and devices

See second page for the scope

The certificate is valid from

Effective Date: 2021-05-14 until Expiry Date: 2024-05-13

And remains valid subject to satisfactory surveillance audits.

Re certification audit due before 2024-03-25

Issue 1. Certified since 2021-05-14

Authorised by L Henderson
Business Manager



L Henderson

SGS United Kingdom Ltd

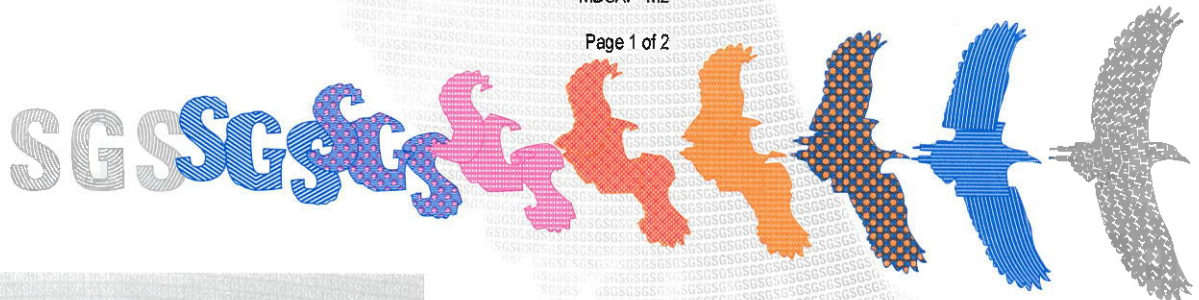
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MDSAP M2

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LSL Healthcare, Inc

MDSAP (ISO 13485:2016)

Issue 1



Detailed scope

**The Manufacturer of Sterile and Non-Sterile procedure packs of
 ADAPTOR, URETERAL CATHETER, Arthrogram tray, BAG,
 URINE COLLECTION, LEG, FOR EXTERNAL USE,
 STERILE Bandage, liquid, skin protectant, BASIN, EMESIS,
 Bath (sitz, non-powered), BEDPAN, SCALPEL,
 Blood and urine collection kit (excludes HIV testing),
 Body fluid clean up kit, Body fluids barrier kit,
 BRUSH (CLEANING, TRACHEAL TUBE),
 BRUSH (SCRUB, OPERATING-ROOM), Catheter care tray,
 IRRIGATION CATHETER, PERITONEAL CATHETER,
 CONTAINER LIQUID MEDICATION, GRADUATED,
 CONTAINER SPECIMEN STERILE,
 INTRAVASCULAR CATHETER SECUREMENT DEVICE,
 for the areas of surgical Drape, Dressing change tray, Enema kit,
 MEDICAL, ABSORBENT FIBER, FORCEPS, GENERAL & PLASTIC
 SURGERY FORCEPS, General surgery tray, I.V. start kit,
 IODINE (TINCTURE), surgical instrument Kit disposable,
 SKIN MARKER, surgical Mask, CATHETER NEEDLE, CONDUCTION,
 ANESTHETIC NEEDLE (W/WO INTRODUCER), hypodermic,
 single lumen Needle, Nerve block tray, Orotracheal intubati
 on guide kit, Patient personal hygiene kit,
 Peripheral catheter insertion kit, Polymer patient examination glove,
 SURGICAL RAZOR, amniotic fluid Sampler (amniocentesis tray),
 SCISSORS MEDICAL DISPOSABLE, eye ophthalmic Shield
 (including sunlamp protective eyewear and post-mydriatic eyewear),
 Skin prep tray, REMOVABLE (SKIN) STAPLE,
 medical support Stocking (to prevent pooling of blood in legs),
 Suture kit, Suture removal kit, ENT SYRINGE,
 IRRIGATING SYRINGE (NON DENTAL), piston Syringe,
 Tape and bandage, adhesive, electronic clinical Thermometer,
 NONPNEUMATIC TOURNIQUET, Tracheostomy kit, BIOPSY TRAY,
 BIOPSY WITHOUT INSTRUMENTS, SURGICAL TRAY, SURGICAL,
 INSTRUMENT TRAY, tracheal Tube (w/wo connector), URINAL,
 Urinary drainage collection kit for indwelling catheter,
 EATING UTENSIL, Wound dressing kit.**

