

Certificate US19/81841491

The quality management system of

Utah Medical Products, Inc.

7043 South 300 West, Midvale, UT, 84047, United States Of America
Facility number: F003171

has been assessed and certified as meeting the requirements of

MDSAP (ISO 13485:2016)

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

Brazil: RDC ANVISA n. 665/2022 - Good Manufacturing Practices; RDC ANVISA n. 551/2021 - Field Actions; RDC ANVISA n. 67/2009 - Vigilance

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

Japan: Japan PMD Act (as applicable), MHLW Ministerial Ordinance No.169 (2004) as amended by MHLW Ordinance No. 60 (2021)

USA: 21 CFR Part 803 - Medical Device Reporting; 21 CFR Part 806 - Reports of Corrections and Removals; 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing, 21 CFR Part 820 - Quality System Regulation

For the following activities

The Scope of Registration appears on page 2 of this certificate

This certificate is valid from Effective date 2025-03-24 until Expiry date 2028-03-24 and remains valid subject to satisfactory surveillance audits.

Issue 4. Certified since 2019-04-02

Certified activities performed by additional sites are listed on subsequent pages.



Authorised by

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SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at www.SGS.com.



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MDSAP (ISO 13485:2016)

Issue 4

Design, development, manufacture, and distribution of sterile and non-sterile Blood Pressure Monitoring Systems, sterile and non-sterile Vacuum Assisted Delivery Systems, sterile Oropharyngeal Aspirators, sterile Intrauterine Pressure Monitoring Systems, sterile Umbilical Cord Management System, sterile Amniotomy Devices, sterile Labor and Delivery Management Catheters, sterile Vascular Access Catheter Systems, sterile Lumbar Puncture kits, sterile Forceps, non-sterile Neonatal Respiratory Hoods, sterile Blood Filtration Systems, sterile and non-sterile Enteral Feeding Systems, sterile Urinary Catheters and Kits, sterile Chest Drainage Catheters, sterile Peritoneal Dialysis Kits, sterile Orotracheal Protection Devices, sterile and non-sterile Electrosurgical Electrodes, sterile Electrosurgical pens, sterile Endometrial Tissue Samplers, sterile TVUS/HSG Catheters, sterile Uterine Manipulators, sterile Exam Speculum Lights, sterile Irrigators, non-sterile Incontinence Therapy Devices, non-sterile Securement Belts and Beanies, Sterile Cervical Ripening Balloon Catheter, Sterile Balloon Tamponade Catheters, sterile Suprapubic Catheter Introducers, spirometers, as well as OEM Components associated with the above devices for the areas of respiratory therapy, cardiovascular, gastroenterology, obstetrics & gynecology, gastroenterology electro-surgical applications and urology.
Design, development, manufacture, distribution, and service of non-sterile electro-surgical generators and non-sterile smoke evacuation devices for the area of obstetrics & gynecology and electro-surgical applications.



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MDSAP (ISO 13485:2016)

Issue 4

Sites

Utah Medical Products, Inc.
7043 South 300 West, Midvale, UT, 84047, United States Of America
Facility number: F003171

Design, development, manufacture, and distribution of sterile and non-sterile Blood Pressure Monitoring Systems, sterile and non-sterile Vacuum Assisted Delivery Systems, sterile Oropharyngeal Aspirators, sterile Intrauterine Pressure Monitoring Systems, sterile Umbilical Cord Management System, sterile Amniotomy Devices, sterile Labor and Delivery Management Catheters, sterile Vascular Access Catheter Systems, sterile Lumbar Puncture kits, sterile Forceps, non-sterile Neonatal Respiratory Hoods, sterile Blood Filtration Systems, sterile and non-sterile Enteral Feeding Systems, sterile Urinary Catheters and Kits, sterile Chest Drainage Catheters, sterile Peritoneal Dialysis Kits, sterile Orotracheal Protection Devices, sterile and non-sterile Electrosurgical Electrodes, sterile Electrosurgical pens, sterile Endometrial Tissue Samplers, sterile TVUS/HSG Catheters, sterile Uterine Manipulators, sterile Exam Speculum Lights, sterile Irrigators, non-sterile Incontinence Therapy Devices, non-sterile Securement Belts and Beanies, Sterile Cervical Ripening Balloon Catheter, Sterile Balloon Tamponade Catheters, sterile Suprapubic Catheter Introducers, spirometers, as well as OEM Components associated with the above devices for the areas of respiratory therapy, cardiovascular, gastroenterology, obstetrics & gynecology, gastroenterology electrosurgical applications and urology.

Design, development, manufacture, distribution, and service of non-sterile electrosurgical generators and non-sterile smoke evacuation devices for the area of obstetrics & gynecology and electrosurgical applications.



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Certificate US19/81841491, continued
Utah Medical Products, Inc.

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MDSAP (ISO 13485:2016)

Issue 4

Utah Medical Products, Inc.
Athlone Business and Technology Park, Dublin Road, Westmeath County, Athlone, N37 XK74, Ireland
Facility number: F003761

Manufacture, distribution, and purchasing of sterile and non-sterile Blood pressure monitoring systems, sterile Electrosurgical electrodes, sterile Electrosurgical pens, sterile Irrigators, sterile Peritoneal dialysis kits, as well as OEM components associated with the above devices.

Manufacture, distribution, and service of non-sterile Electrosurgical generators and non-sterile Smoke evacuation devices for the area of obstetrics & gynecology and electrosurgical applications.



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