



Certificate Number US19/81841491

The management system of

# Utah Medical Products, Inc.

7043 South 300 West, Midvale, UT, 84047, United States

Facility identification number : F003171

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)

Australia:

Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure [including design]

Brazil:

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

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: 2022-03-25 until Expiry Date: 2025-03-24  
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 2025-03-24

Issue 3. Certified since 2019-04-02



Authorised by L Henderson  
Business Manager



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SGS United Kingdom Ltd is an MDSAP authorized auditing organization

MDSAP-M2

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The management system of

# Utah Medical Products, Inc. MDSAP (ISO 13485:2016)

Issue 3



Detailed scope

**Design, development, manufacture, and distribution of sterile and non-sterile Blood 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 Respirational 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, Balloon Tamponade Catheters, as well as OEM Components associated with the above devices for the areas of respiratory therapy, cardiovascular, gastroenterology, obstetrics & gynaecology, gastroenterology electrosurgical applications and urology.**

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

Additional facilities

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

**Production, packaging, storage, delivery, purchasing, monitoring and measuring, final product release**

