

Certificate US11/82084

The management system of

## Utah Medical Products, Inc.

SGS

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

has been assessed and certified as meeting the requirements of

**ISO 13485:2016**

**EN ISO 13485:2016**

For the following activities

**The Scope of Registration appears on page 2 of this certificate**

This certificate is valid from 19 April 2024 until 12 August 2025 and remains valid subject to satisfactory surveillance audits.

Issue 16. Certified since 01 August 2011

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

*Jonathan M. Hall*

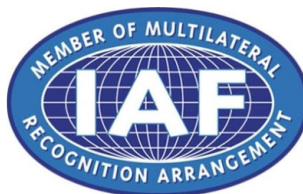
Authorised by

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## ISO 13485:2016 EN ISO 13485:2016

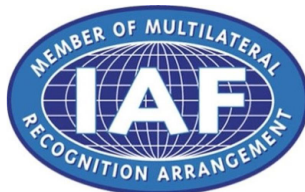
Issue 16

Design, development, manufacture, warehouse, contract 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, nonsterile Neonatal Respiratoral Hoods, sterile Blood Filtration Systems, sterile and nonsterile 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, 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.

Contract manufacture of sterile and nonsterile pressure and flow sensor systems, sterile Femoral Canal Sponges, sterile Suprapubic Catheter Introducers, sterile Female Surgical Contraception Systems, sterile Hormone Replacement Therapy Systems.

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.

Business management in support of the Contract manufacture of sterile Femoral canal sponges, sterile Female surgical contraception systems and sterile Hormone replacement therapy systems.



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## ISO 13485:2016

## EN ISO 13485:2016

Issue 16

### Sites

Utah Medical Products, Inc.

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

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, nonsterile Neonatal respirator hoods, sterile Blood filtration systems, sterile and nonsterile 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, 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.

Contract manufacture of sterile and nonsterile Pressure and flow sensor systems and sterile Suprapubic catheter introducers.

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

Utah Medical Products, Inc.

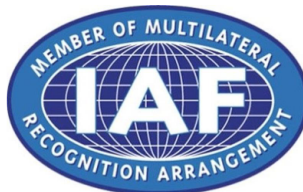
Athlone Business and Technology Park, Dublin Road, Westmeath County, Athlone, N37 XK74, Ireland

Warehouse, 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.

Contract manufacture of sterile and non-sterile Pressure and flow sensor systems, sterile Femoral canal sponges, sterile Suprapubic catheter introducers, sterile Female surgical contraception systems, sterile Hormone replacement therapy systems.

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

Business management in support of the Contract manufacture of sterile Femoral canal sponges, sterile Female surgical contraception systems and sterile Hormone replacement therapy systems.



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