

Certificate US11/82084

The management system of

Utah Medical Products, Inc.

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

has been assessed and certified as meeting the requirements of

ISO 13485:2003 EN ISO 13485:2012



For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 06 June 2018 until 31 March 2019
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 31 March 2019
Issue 11. Certified since 01 August 2011

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by



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Utah Medical Products, Inc.

ISO 13485:2003 EN ISO 13485:2012



Issue 11

Detailed scope

Design, development, manufacture, 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, non-sterile Neonatal Respiratoral 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 Vacuum Erection Devices, non-sterile Securement Belts 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, Sterile Cervical Ripening Balloon Catheter. 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.



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Additional facilities

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

