

# Certificate

This certifies, that the company

**Utah Medical Products Inc**  
**7043 south 300 West, Midvale**  
**UT 84047**  
**United States of America**

**for additional sites: see annex**

has established and maintains a quality management system that meets the requirements of DIN EN ISO 13485: 2021 / EN ISO 13485:2016 + AC:2018 + A11:2021 - Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016). This certificate is not an authorisation to affix the CE mark.

Scope

**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 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 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 & gynaecology, gastroenterology electrosurgical applications and urology.**

**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**

**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.**

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

Reg.-No. 44 221 251005  
 Report No. 3540 0650

Validity  
 from 2025-08-13  
 until 2028-08-12  
 Edition 1

Essen, 2025-08-01

Certification body for medical devices




Visit our database  
 to verify the validity  
 of this certificate.

TÜV NORD CERT GmbH  
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 TÜV®



# Annex

Reg.-No. 44 221 251005

Reg.-No.	Additional sites	Scope
44 221 251005-001	Utah Medical Products, Inc Athlone Business and Technology Park Dublin Road, Westmeath County, Athlone N37 XK74 Ireland	<p>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.</p> <p>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.</p> <p>Manufacture, distribution and service of non-sterile Electrosurgical generators and non-sterile Smoke evacuation devices for the area of obstetrics &amp; gynecology and electrosurgical applications.</p> <p>Business management in support of the Contract manufacture of sterile Femoral canal sponges, sterile Female surgical contraception systems and sterile Hormone replacement therapy systems.</p> <p>Business management in support of the Contract manufacture of sterile Femoral canal sponges, sterile Female surgical contraception systems and sterile Hormone replacement therapy systems.</p>

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Certification body for medical devices

*B. Hoy*

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