



# Certificate

acc. to CAN/CSA ISO 13485:2003

Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

Certificate Registration No.: 09-0021

TUV-USA, Inc. hereby certifies that the quality management system of the company mentioned below is in conformance with CAN/CSA ISO 13485:2003 for Medical Devices- Quality Management Systems-Requirements for Regulatory Purposes.

**Microtek Medical, Inc.  
512 Lehmburg Road  
Columbus, MS 39702  
USA**

List of Products: see Annex 1

Additional sites covered by QM System: see Annex 2

**Scope:**

**Design, manufacturing and distribution of sterile and non-sterile accessory film products, drapes, wound evacuation system, enema sets, vaginal irrigation sets and CPR assist/barrier devices. Manufacturing and servicing of deep vein thrombosis systems and electrical heating blankets.**

**TUV-USA, Inc., 215 Main Street, Suite 3, Salem, NH 03079**  
☎ 001-603-870-8023



CMDCAS  
Recognized  
Registrar

Effective date  
2009-08-14 / ed. 1

Expiry date  
2012-08-13

Jennifer Bromm  
Medical Products Manager



Registered No. 09-0021

Products	UMDNS-Code
INCISE DRAPE WITH MICROBAN	16-646
WOUND EVAC	16-521
VENODYNE PUMP AND SLEEVES	13-192
VAGINAL IRRIGATION SET	11-297
ENEMA SET	11-582
CPR MICROMASK	18-798
CPR MICROSHIELD-PLUS	18-799
CPR FILTERSHIELD-PLUS	18-799
CPR MICROMASK O <sub>2</sub>	18-798
CPR MICROSHIELD	18-799
HEATING PADS, ELECTRIC	11-989



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Medical Products Manager

Annex 2, page 1 of 1

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Additional sites covered by the QA-System:

Microtek Medical, Inc.  
7022 AC Skinner Parkway #290, Jacksonville, FL, USA  
*Sterilization and distribution activities*

Microtek Dominicana, S.A.  
Zona Franca #2, La Romana, Dominican Republic  
*Manufacturing activities*

Microtek Medical, Inc.  
602 Lehmborg Road, Columbus, MS 39702, USA  
*Design and Manufacturing activities*



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Jennifer Bromm  
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