

# 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 Lehmberg 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, CPR assist/barrier devices and supraglottic airway laryngopharyngeal tubes. 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:  
2010-04-20 / ed. 2**

**Expiry date  
2012-08-13**

**Brent Anderson  
Regulatory Compliance Engineer**

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
SUPRAGLOTTIC AIRWAY LARYNGOPHARYNGEAL TUBE	



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Brent Anderson  
Regulatory Compliance Engineer

Registered No. 09-0021



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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Brent Anderson  
Regulatory Compliance Engineer