



Certificate

acc. to ISO 13485:2016

Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

Certificate Registration No.: **18-1608**

TUV USA, Inc. hereby certifies that the quality management system of the company mentioned below is in conformance with ISO 13485:2016 under MDSAP for Medical Devices Requirements under the following jurisdictions: **Australia:** Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure; **Canada:** Medical Devices Regulations – Part 1- SOR 98/282; **Japan:** MHLW Ministerial Ordinance 169, Article 4 to Article 68; **USA:** United States: 21 CFR 820; 21 CFR 803; 21 CFR 806; 21 CFR 807 – Subparts A to D

Microtek Medical, Inc.
602 Lehmburg Road
Columbus, MS 39702, USA

DUNS number: **07-851-6490**

Additional sites covered by QM System: See Annex 1

List of Products: See Annex 2

Design, development, manufacturing and distribution of sterile and non-sterile equipment drapes, patient drapes, probe covers, fluid decanters, orthopaedic suction systems, surgical gowns, enema sets, vaginal irrigation sets, CPR assist/barrier devices, supralottic airway laryngopharyngeal tubes, disposable medical bedding, organ bags, radiation protection devices, smoke evacuators, EMS splints and mattresses, surgical slush consoles, solution warmer consoles, and fluid warming & slush drapes. Manufacturing and servicing of deep vein thrombosis systems.

The validity of this certification document can be obtained by contacting the TUV USA Office

TUV USA, Inc. (Member of the TÜV NORD Group)
215 Main Street, Suite 1, Salem, NH 03079, USA
Tel: 001-603-870-8023, Fax: 001-603-870-8026



Audit Report Reference No: **18-8036 RC-CA**

Initial Issue date: **07-SEP-2018**

Effective Date:
07-SEP-2018 / ed. 1

Expiry date
06-SEP-2021

Bradley Chen
Director, Medical Products Division
TUV USA, Inc.



Annex 1, page 1 of 1
(Annex 1 MUST be displayed with the main certificate)

Certificate Registration No. : 18-1608 / ed. 1
Company Name: **Microtek Medical, Inc.**
Central Office Address: **602 Lehmborg Road, Columbus, MS 39702, USA**

Locations

Microtek Medical, Inc., a subsidiary of Ecolab, Inc.
512 Lehmborg Road, Columbus, MS 39702, USA
DUNS number: 13-090-8986

Ecolab, Inc.
13500 Tradeport Circle East, Jacksonville, FL 32218, USA
DUNS number: 08-010-8308

Ecolab, Inc.
13000 Deerfield Parkway, Suite 300, Alpharetta, GA 30004, USA
DUNS number: 06-686-7820

Ecolab, Inc.
1 Ecolab Place, St. Paul, MN 55102, USA
DUNS number: 00-615-4611

Microtek Dominicana, S.A.
Zona Franca II, La Romana 22000, Dominican Republic
DUNS number: 87-148-3186

Microtek Dominicana, S.A.
Las Americas Free Zone Park
Km 22, Autopista Las Americas, Santo Domingo, Dominican Republic
DUNS number: 81-746-8339

---End of list---

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Certificate Registration No. : 18-1608 / ed. 1
Company Name: *Microtek Medical Inc.*
Central Office Address: *602 Lehmborg Road, Columbus, MS 39702, USA*

Products	UMDNS	GMDN
Fluid Decanters	---	43324
Orthopedic Suction Systems	---	35356
Surgical Gowns	---	35091
Disposable Medical Bedding	---	47456, 47454, 37165, 60823
Organ Bags	---	33522
Radiation Protection Devices	---	38369
Smoke Evacuators	---	48027
EMS Splints and Mattresses	---	35358
Surgical Slush Consoles	---	36756
Solution Warmer Consoles	---	33512

---Continued Annex 2, Page 2 of 2---

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Central Office Address: *602 Lehmburg Road, Columbus, MS 39702, USA*

Products	UMDNS	GMDN
Fluid Warming and Slush Drapes	---	42891, 45021
Equipment Drapes, various types	---	12535, 45021, 37450, 44977
Patient Drapes, Patient Drapes with Microban	---	16006, 47782, 47783
Probe Covers, various types	---	44713, 44714, 60608, 60609
Deep Vein Thrombosis Systems	---	10969, 44769
Vaginal Irrigation Set	---	34630
Enema Set	---	35050
CPR Assist/Barrier Devices	---	36066, 35693
Supraglottic Airway Laryngopharyngeal Tube	---	42424
Fluid Decanters	---	43324

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