

Certificate

acc. to **ISO 13485:2016**

Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

Certificate Registration No.: 18-1608-M

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 803; 21 CFR 806; 21 CFR 807 – Subparts A to D; 21 CFR 820.

Microtek Medical, Inc. (An Ecolab Company)
1 Ecolab Place
St. Paul, MN 55102, USA

Facility ID: **F002047**

Additional sites covered by QM System: **See Annex 1**

List of Products: **See Annex 2**

Scope:

Design, development, manufacturing and distribution of sterile and non-sterile equipment drapes, patient drapes, probe covers, fluid decanters, orthopaedic suction systems, surgical apparel, enema sets, vaginal irrigation sets, CPR assist/barrier devices, 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.

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

TUV USA, Inc. (a 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, Email: medical-usa@tuv-nord.com

TUV USA, Inc. is an MDSAP Recognised Auditing Organization



Audit Report Reference No.: 21-3932 RC-SA3

Certificate Initial Issue Date: 2018-09-07

Current Cycle Start Date: 2021-09-08

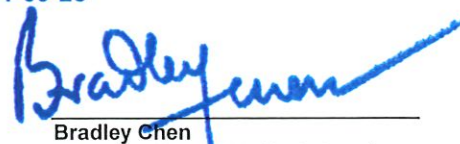
Certificate Revised Date: 2021-09-28

Effective Date:

2021-09-08 / ed. 2

Valid Until:

2024-09-06



Bradley Chen
Vice President – Medical, Americas
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-M / ed. 2
Company Name: Microtek Medical, Inc. (An Ecolab Company)
Central Office Address: 1 Ecolab Place, St. Paul, MN 55102, USA



Location

Headquarters [Facility ID: F002047]

Ecolab, Inc.
1 Ecolab Place
St. Paul, MN 55102, USA

Scope of Certification

Quality, regulatory and purchasing

Site 1 [Facility ID: F001154 (Campus)]

Microtek Medical, Inc. (An Ecolab Company)
512 & 602 Lehmborg Road
Columbus, MS 39702, USA

Manufacturing, packaging, sales and customer service

Site 2 [Facility ID: F002048]

Ecolab, Inc.
13500 Tradeport Circle East
Jacksonville, FL 32218, USA

Manufacturing and distribution

Site 3 [Facility ID: F002046]

Ecolab, Inc.
13000 Deerfield Parkway, Suite 300
Alpharetta, GA 30004, USA

Design and development

Site 4 [Facility ID: F002050]

Microtek Dominicana, S.A.
Zona Franca II
La Romana, Dominican Republic 22000

Manufacturing, packaging, contract manufacturing and distribution

Site 5 [Facility ID: F002049]

Microtek Dominicana, S.A.
Las Américas Industrial Free Zone Park
Km 22 Autopista Las Américas, Santo Domingo
Dominican Republic

Production, purchasing, warehousing, management, contract manufacturing and distribution

---End of list---

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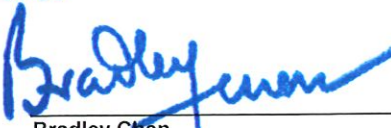
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Annex 2, page 1 of 1

(Annex 2 MUST be displayed with the main certificate)

Certificate Registration No. : 18-1608-M / ed. 2**Company Name:** Microtek Medical, Inc. (An Ecolab Company)**Central Office Address:** 1 Ecolab Place, St. Paul, MN 55102, USA

Products	UMDNS	GMDN
Personal Cleansing Sets	N/A	35050, 47605
CPR Assist Devices	N/A	36066
Splints and Mattresses	N/A	35358
Equipment Drapes	N/A	12535, 17977, 44977
Drainage Bags	N/A	58917, 58919, 56731, 14426, 58982
Probe Covers	N/A	60608, 60609, 44714, 44713
Disposable Medical Bedding	N/A	47456, 47454
Solution Warmer Consoles	N/A	33512
Fluid Warming and Slush Drapes	N/A	12535
Surgical Slush Consoles	N/A	36756, 33512
Organ Bags	N/A	33522, 58982
Decanters	N/A	43324
Patient Drapes	N/A	47783, 64134, 38375
Protective Restraints	N/A	44851
Radiation Protection	N/A	38375, 64134
Ring Cushion	N/A	34981
Smoke Evacuator	N/A	48027
Surgical Apparel	N/A	32292, 35102, 35091
Dressing	N/A	10284
Irrigation Tubing	N/A	16779
Instrument Management Bags	N/A	58968

---End of list---

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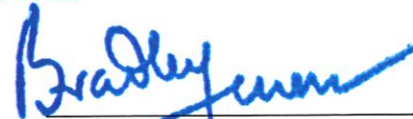
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