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Zertifikat / *Certificate*

TÜVNORD
TÜV NORD CERT GmbH
EN ISO 13485
tuev-nord.de

Hiermit wird bescheinigt, dass die Firma / *This certifies, that the company*

Microtek Medical LLC
Three Lakes Drive
Northfield, IL 60093
USA

für weitere Fertigungsstätten, Niederlassungen: siehe Anlage
for additional sites: see annex

ein Qualitätsmanagementsystem nach der Norm DIN EN ISO 13485:2021 / EN ISO 13485:2016 + AC:2018 + A11:2021 - Medizinprodukte - Qualitätsmanagementsysteme - Anforderungen für regulatorische Zwecke (ISO 13485:2016) - eingeführt hat und aufrechterhält. Dieses Zertifikat stellt nicht den erforderlichen Nachweis zur Anbringung der CE-Kennzeichnung dar.

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.

Geltungsbereich / *Scope*

Design, development, manufacturing, sales and distribution of sterile and non-sterile equipment drapes, patient drapes, probe covers, fluid warming drapes and slush drapes, radiation protection devices.
Design, development, manufacturing, sales and distribution of surgical slush consoles and solution warmer consoles.
Contract design, development and manufacturing of drapes and disposable medical bedding.
Contract manufacturing of drapes, electrocautery hooks, electrocautery spatulas, tubing sets, patient positioning system, and surgical apparel.

Reg.-Nr. / *Reg.-No.* 44 221 117845
Bericht Nr. / *Report No.* 3538 5705

Gültigkeit / *Validity*
von / *from* 2025-06-24
bis / *until* 2027-08-14
Edition 13

Essen, 2025-06-24

Zertifizierungsstelle für Medizinprodukte / *Certification body for medical devices*

Visit our database to verify the validity of this certificate.

TÜV NORD CERT GmbH
Am TÜV 1, 45307 Essen
www.tuev-nord-cert.de
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D-ZM-12007-05-00

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Anlage / Annex

Reg.-Nr. / *Reg.-No.* 44 221 117845

Reg.-Nr. ***Reg.-No.***	**Weitere Fertigungsstätte/Niederlassungen** ***Additional sites***	**Geltungsbereich** ***Scope***
44 221 117845-001	Microtek Medical LLC 990 Lone Oak Rd, Ste 130 Eagan / MN 55121 USA	Design and development of sterile and non-sterile drapes. Production, packaging, contract manufacturing and distribution of drapes.
44 221 117845-002	Microtek Medical LLC 13500 Tradeport Circle East, Jacksonville / FL 32218 USA	Distribution of sterile and non-sterile equipment drapes, patient drapes, probe covers, fluid warming drapes and slush drapes, and radiation protective devices. Contract manufacturing and packaging of disposable medical bedding, electrocautery hooks, and electrocautery spatulas.
44 221 117845-003	Microtek Medical LLC 13000 Deerfield Parkway, Suite 300 Alpharetta / GA 30004 USA	Design and development of sterile and non-sterile equipment drapes, patient drapes, probe covers, fluid warming drapes and slush drapes, and radiation protection devices. Design and development of surgical slush consoles and solution warmer consoles. Contract design and development of drapes and disposable medical bedding.
44 221 117845-004	Microtek Dominicana, S.A.S Zona Franca II, La Romana 22000 Republica Dominicana	Production, packaging, contract manufacturing and distribution of equipment drapes, patient drapes, probe covers, fluid warming drapes and slush drapes, radiation protection devices, surgical apparel, tubing sets, and patient positioning system.

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44 221 117845-005	Microtek Dominicana, S.A.S Las Américas Industrial Free Zone Park, Km 22 Autopista Las Américas, Santo Domingo Republica Dominicana	Production, packaging, contract manufacturing and distribution of equipment drapes, probe covers, fluid warming drapes and slush drapes.
44 221 117845-006	Microtek Medical LLC Three Lakes Drive Northfield, IL 60093 USA	Corporate quality, administrative activities, regulatory affairs, supplier evaluation, and sterilization validation for: Design, development, manufacturing, sales and distribution of sterile and non-sterile equipment drapes, patient drapes, probe covers, fluid warming drapes and slush drapes, radiation protection devices. Design, development, manufacturing, sales and distribution of surgical slush consoles and solution warmer consoles. Contract design, development and manufacturing of drapes and disposable medical bedding. Contract manufacturing of drapes, electrocautery hooks, electrocautery spatulas, tubing sets, patient positioning system, and surgical apparel.

Bericht Nr. / *Report No.* 3538 5705

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Zertifizierungsstelle für Medizinprodukte / *Certification body for medical devices*

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