EU Quality Management System Certificate

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX, Chapters I and III

The Notified Body of TÜV NORD CERT GmbH certifies that the manufacturer

Microtek Medical LLC
Three Lakes Drive
Northfield, Illinois 60093
United States of America

has established, documented and implemented a quality management system in accordance with Article 10, paragraph 9 of Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The conformity assessment has been carried out and successfully completed in accordance with Annex IX, Chapters I and III. The result of the assessment, references to investigations carried out, relevant common specifications and test reports are summarised in the report mentioned below. The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The validity of this certificate is based on the maintenance of the quality management system in accordance with the requirements of the Regulation and its regular surveillance by the Notified Body in accordance with Annex IX, Chapter I, Section 3. For devices of class IIb and IIa the surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.

In addition to the CE marking, the identification number of the Notified Body must be affixed to the devices.

For the placing on the market of class III devices and class IIb implantable devices an additional EU technical documentation assessment certificate according to Annex IX, Chapter II is required.

Single Registration Number of the Manufacturer (SRN):	US-MF-000019222, US-PR-000022773
Authorised Representative:	see Section 1
Limitations and Conditions:	see Section 2
List of Products, Risk Classification and Details:	see Section 3
Certificate History:	see Section 4

Certificate number:	44 911 117845	Valid from:	2025-07-22
Certification decision report No.:	3536 5311	Valid until:	2030-07-21
		First issued:	2025-07-22
		Issue date:	2025-07-22
		Edition:	1

Essen, 2025-07-22

TÜV NORD CERT GmbH is a Notified Body with identification number 0044

TÜV NORD CERT GmbH
Am TÜV 1, 45307 Essen
tuev-nord-cert.de
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TÜV®

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-095

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Annex IX, Chapters I and III
Certificate number: 44 911 117845

Section 1, Authorised Representative

Company name:	Microtek Medical B.V.
Street, No.:	Hekkehorst 2
Postal Code, City:	Zutphen 7207
Country:	Netherlands

Section 2, Limitations and Conditions

The validity of this Certificate depends on:	N/A
and the following conditions:	None
and / or is limited to the following:	N/A

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Section 3, List of Products, Risk Classification and Details

CLASS IIA

Category of device (MDx Code):	MDN 1214
	General non-active non-implantable devices used in health care and other non-active non-implantable devices
TD assessment report no.:	3536 5421
Devices or groups of devices	Probe Covers

CLASS I, DEVICES IN STERILE CONDITION

Sterilisation method:	Ethylene oxide gas sterilisation (EOG)
Assessment report no.:	3536 5419, 3536 5420
Devices or groups of devices:	Fluid Warming Drapes Drape Armour FPS Equipment Drapes Patient Drapes Surgical Slush Drapes

For class Is devices placed on the market in a sterile condition, the involvement of the notified body in the conformity assessment procedure is limited to those aspects related to the manufacture, securing and maintenance of sterile conditions.

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Section 4, Certificate History

Edition	Date	Action leading to revision	Report reference
1	2025-07-22	Initial certification	3536 5311

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