EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate no.	Final Assessment Report no.	Effective date	Expiry date
6067GB448250903	6067AU20F	2025-09-03	2028-05-14

This is to certify that the quality system of

Microtek Medical B.V.

Hekkehorst 24, 7207 BN Zutphen, The Netherlands

SRN: NL-MF-000006754

For design & development, manufacturing and final product inspection/testing of

Medical devices/groups of medical devices at locations as listed on the following pages

has been assessed and found to comply with respect to

The conformity assessment procedure described in Annex IX, Chapters I and III of Regulation (EU) 2017/745 on Medical Devices

Any applicable limitations for certain medical devices are included in the following list or recorded in the final assessment report. This certification is subject to surveillance by DNV MEDCERT.

Place and date
Hamburg, 2025-09-03

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-096

For the issuing office
DNV MEDCERT GmbH – Notified Body 0482
Pilatuspool 2, 20355 Hamburg, Germany

Marcus Harder
Certification Body Operations

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact medcert-info@dnv.com

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

820111 EN Rev. 6 2025.07.16

Certificate no.: 6067GB448250903
Place and date: Hamburg, 2025-09-03

Sites covered by this certificate

Microtek Medical B.V., Hekkehorst 24, 7207 BN Zutphen, The Netherlands

Microtek Medical B.V., Gesinkkamstraat 19, 7051 HR Varsseveld, The Netherlands

Preceding certificate

Certificate no.	Issue date	Identification of changes
6067GB448250411	2025-04-11	Extension of Class Is (WO-010657)

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Certificate no.: 6067GB448250903
Place and date: Hamburg, 2025-09-03

Products covered by this certificate

Class Is medical devices

For class I medical devices placed on the market in sterile condition (class Is), the audit of the quality management system was limited to the aspects relating to establishing, securing, and maintaining sterile conditions.

Category	Class	Medical devices/groups of medical devices
MDN 1201	Is	Non-active non-implantable devices for anaesthesia, emergency and intensive care

Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN 1201	T030199	COVERS, INSTRUMENTS AND EQUIPMENT - OTHER

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DNV
1864