MANAGEMENT SYSTEM CERTIFICATE

Certificate no.	Final assessment report no.	Effective date	Expiry date
6067GB452250411	6067AU20F	2025-04-11	2027-05-14

This is to certify that

Microtek Medical B.V.

Hekkehorst 24, 7207 BN Zutphen, The Netherlands

Has introduced, applies, and maintains a management system at the sites listed on the following pages.

This management system has been audited and found to conform to the quality management systems standard

EN ISO 13485:2016 + AC:2018 + A11:2021

This certificate is valid for the scope of activities and products/services indicated on the following pages.

Place and date
Hamburg, 2025-04-11

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-19630-04-00

For the issuing office
DNV MEDCERT GmbH
Pilatuspool 2, 20355 Hamburg, Germany

Markus Bianchi
Certification Body

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

Certificate no.: 6067GB452250411
Place and date: Hamburg, 2025-04-11

Activities and products/services covered by this certificate

Manufacturing and distribution of
- Ballon Compliance Catheters
- Finger Cots
- Probe Covers
- Equipment Drapes
- Disposable Linens

Sites covered by this certificate and associated (partial) scopes

Microtek Medical B.V., Hekkehorst 24, 7207 BN Zutphen, The Netherlands
Distribution of
- Ballon Compliance Catheters
- Finger Cots
- Probe Covers
- Equipment Drapes
- Disposable Linens

Microtek Medical B.V., Gesinkkamstraat 19, 7051 HR Varsseveld, The Netherlands
Manufacturing of
- Ballon Compliance Catheters
- Finger Cots
- Probe Covers

SAFEGUARDING LIFE, PROPERTY AND THE ENVIRONMENT
DNV
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