



DNV

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.
6092GB451250217

Final assessment report no.
6092AU20F

Effective date
2025-02-17

Expiry date
2027-09-29

This is to certify that the management system of

MeVis Medical Solutions AG

Caroline-Herschel-Straße 1, 28359 Bremen, Germany

Facility ID: F005748

With the sites as mentioned on the following pages

Has been found to conform to the quality management system standard

ISO 13485:2016 and the following country-specific requirements

Australia:	Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1
Canada:	Medical Devices Regulations (SOR/98-282) – Part 1 (applicable requirements)
United States:	21 CFR 803; 21 CFR 806; 21 CFR 807; 21 CFR 820

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

Place and date
Hamburg, 2025-02-17

DNV MEDCERT is an MDSAP
authorised auditing organisation

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

Markus Bianchi
Director 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

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

AUTHORISED UNIT: DNV MEDCERT GmbH (previously: MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH)
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Certificate no.: 6092GB451250217
Place and date: Hamburg, 2025-02-17

Activities and products/services covered by this certificate

Design and development, manufacture, distribution, and installation of

- Software for evaluation of medical image data
- Software for interventional guidance

Sites covered by this certificate

MeVis Medical Solutions AG, Caroline-Herschel-Straße 1, 28359 Bremen, Germany
Facility ID: F005748

Site-specific scope

Design and development, manufacture, distribution, and installation of

- Software for evaluation of medical image data
- Software for interventional guidance

