

Certificate

The Certification Body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Deutschland**

herewith certifies that the company

**MeVis Medical Solutions AG
Caroline-Herschel-Straße 1
28359 Bremen
Germany**

has introduced, applies and maintains a quality management system in the area of activities, products/services and locations listed in the appendix.

The conformity of this quality management system to the requirements of the following standard and country-specific requirements of the following jurisdictions¹ has been verified by an audit:

**ISO 13485:2016
Australia, Canada, United States of America**

This certification is subject to surveillance by MEDCERT.

**Effective date: 2022-02-07
Expiry date: 2025-01-27**

Report No.: 6092FS16F
Procedure No.: QS – 6092
Certificate No.: 6092GB451220207

Hamburg, 2022-02-07



MEDCERT Certification Body
Markus Bianchi

¹ Individual country-specific requirements are listed in the appendix.

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

MEDCERT is an MDSAP authorised auditing organisation.

Appendix of certificate

Procedure No.: QS – 6092
Certificate No.: 6092GB451220207

Activities and products/services in the scope of certification

Design and development, manufacture, distribution, and installation of

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

Country-specific requirements implemented in the quality management system

Australia – Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 (without 1.6)

Canada – Medical Devices Regulations SOR/98-282, Part 1 (applicable requirements)

United States of America – 21 CFR 803; 21 CFR 806; 21 CFR 807 (Subparts A to D); 21 CFR 820

This appendix is integral part of the above-referenced certificate.
The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT is an MDSAP authorised auditing organisation.

Appendix of certificate

Procedure No.: QS – 6092
Certificate No.: 6092GB451220207

Locations in the scope of certification

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

Design and development, manufacture, distribution, and installation of

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

MeVis BreastCare GmbH & Co. KG
Caroline-Herschel-Straße 1
28359 Bremen
Germany
Facility ID: F005748

(Contract) Design and development, manufacture, distribution, and installation of

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

This appendix is integral part of the above-referenced certificate.
The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT is an MDSAP authorised auditing organisation.