

EC Certificate of Conformity

The Notified Body

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

herewith certifies that the company:

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

with locations listed in the appendix

has introduced, applies and maintains a quality assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex II without section 4

This certification is subject to surveillance by MEDCERT.

Effective date: 2021-01-15

Expiry date: 2024-01-27

Report No.: 6092FS13F

Process No.: QS – 6092

Certificate No.: 6092GB410210115A

Hamburg, 2021-01-15



MEDCERT Certification Body
(Dr. Andreas Schich)

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 Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



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Appendix of EC Certificate of Conformity

Process No.: QS – 6092

Certificate No.: 6092GB410210115A

List of locations included in the scope of certificate

MeVis BreastCare GmbH & Co. KG
Caroline-Herschel-Straße 1
28359 Bremen
Germany

– End of list –

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Appendix of EC Certificate of Conformity

Process No.: QS – 6092

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List of products / product categories included in the scope of certificate

**Software for evaluation of medical image data and
interventional guidance**

– End of list –

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