

## EU Quality Management System Certificate

### 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**

**SRN: DE-MF- 000005418**

with locations listed in the appendix

has introduced, applies and maintains a quality management system for the medical devices/groups of medical devices listed in the appendix.

The compliance of this quality management system to the requirements of the **Regulation (EU) 2017/745 on medical devices** was verified by assessment according to:

### Annex IX Chapter I

Any applicable limitations of this certification for certain medical devices are included in the appendix. This certification is subject to surveillance by MEDCERT.

**Effective date:** 2022-02-07  
**Expiry date:** 2027-01-27

Final assessment report No.: 6092IA16F  
Procedure No.: QS – 6092  
Certificate No.: 6092GB448220207

Preceding certificate No.: —  
Preceding certificate date: —  
Identification of changes: —

Hamburg, 2022-02-07

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MEDCERT Certification Body  
(Markus Bianchi)

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To verify the validity of this certificate, contact [info@medcert.de](mailto:info@medcert.de).

MEDCERT Notified Body Identification Number: 0482

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Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)

BS-MDR-096

## Appendix of EU Quality Management System Certificate

Procedure No.: QS – 6092  
Certificate No.: 6092GB448220207

### Locations included in the scope of certificate

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

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

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## Appendix of EU Quality Management System Certificate

Procedure No.: QS – 6092  
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### Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
<b>MDA 0315</b>	<b>Z11030682</b>	COMPUTED TOMOGRAPHY SCANNING SYSTEMS (CT) - SOFTWARE

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