



# Certificate

No. Q5 090329 0004 Rev. 02

**Holder of Certificate:** **mbits imaging GmbH**  
Bergheimer Straße 147  
69115 Heidelberg  
GERMANY

**Facility(ies):** **mbits imaging GmbH**  
Bergheimer Straße 147, 69115 Heidelberg, GERMANY  
  
See Scope of Certificate

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production and Distribution of Medical Image Processing Software for Diagnosis, for Diagnostic and Therapy Support**

**Applied Standard(s):** ISO 13485:2016  
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)  
Medical devices - Quality management systems - Requirements for regulatory purposes

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 090329 0004 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_090329_0004_Rev._02)

**Report No.:** 713312027

**Valid from:** 2024-06-16  
**Valid until:** 2027-06-15

**Date,** 2024-03-05



Christoph Dicks  
Head of Certification/Notified Body