



# Certificate

No. Q5 090409 0007 Rev. 01

**Holder of Certificate:** **SANTEC CORPORATION**



**5823 Ohkusa-Nenjozaka  
Komaki, Aichi  
485-0802 JAPAN**

**Facility(ies):** **SANTEC CORPORATION**  
**5823 Ohkusa-Nenjozaka, Komaki,  
Aichi, 485-0802 JAPAN**

See scope of certificate

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production and  
Distribution of Optical Coherence Tomography  
equipment**

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

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 090409 0007 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5 090409 0007 Rev. 01)

**Report No.:** **JA1612151**

**Valid from:** **2021-08-17**

**Valid until:** **2024-08-16**

**Date,** **2021-08-03**

Christoph Dicks  
Head of Certification/Notified Body