



Certificate

No. Q5 090409 0007 Rev. 03

Holder of Certificate:



santec OIS Corporation

5823 Ohkusa-Nenjozaka
Komaki, Aichi
485-0802 JAPAN

Facility(ies):

santec OIS 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):

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, Certification, Validation and Verification Regulations 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. 03

Report No.:

JA2142307

Valid from:

2024-08-17

Valid until:

2027-08-16

Date, 2024-06-11



Christoph Dicks

Head of Certification/Notified Body