



Certificate

No. Q5 090409 0007 Rev. 00

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

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). See also notes overleaf.

Report No.:

JAQ235033263

Valid from:

2018-08-17

Valid until:

2021-08-16

Date,

2018-07-25

Stefan Preiß