





Certificate

No. Q5 005260 0001 Rev. 02

Holder of Certificate: Sentec AG

Ringstr. 39 4106 THERWIL SWITZERLAND

Facility(ies): Sentec AG

Ringstr. 39, 4106 THERWIL, SWITZERLAND

See Scope of Certificate

Certification Mark:



Scope of Certificate: Design and Development, Production and Sales

of Monitors and Sensors for Transcutaneous Blood Gas Monitoring and Pulse Oximetry

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:Q5-005260-0001-Rev.02

Report No.: 713334856

 Valid from:
 2024-11-15

 Valid until:
 2027-11-14

Date. 2024-08-20 Christoph Dicks

Head of Certification/Notified Body

