



Certificate

No. Q5 091549 0067 Rev. 01

Holder of Certificate: **Sivantos GmbH**
Henri-Dunant-Strasse 100
91058 Erlangen
GERMANY

Certification Mark:



Scope of Certificate: **Design and development, production, sales, distribution and servicing of hearing aids with related software and components, hear- and speech-training instruments and audiological measurement equipment**

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.: 713165817

Valid from: 2019-12-05

Valid until: 2022-11-30

Date, 2019-12-05

Christoph Dicks
Head of Certification/Notified Body

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認 證 證 書 ◆ CERTIFICADO ◆ CERTIFIKAT ◆ CERTIFICATE ◆ ZERTIFIKAT ◆ CERTIFICATE

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| Applied Standard(s): | EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) DIN EN ISO 13485:2016 |
| Facility(ies): | Sivantos Pte. Ltd. 18 Tai Seng Street, #08-08, Singapore 539775, SINGAPORE Sivantos GmbH Henri-Dunant-Strasse 100, 91058 Erlangen, GERMANY Sivantos, Inc. 10 Constitution Avenue, Piscataway NJ 08854-1397, USA Sivantos (Suzhou) Co. Ltd. No. 120 Su Tong Road, China-Singapore Suzhou Industrial Park, 215021 Suzhou, PEOPLE'S REPUBLIC OF CHINA Sivantos Sp. z o.o. Bałtycka 6, 61-013 Poznan, POLAND Widex A/S Nymoellevvej 6, 3540 Lyngø, DENMARK Widex EESTI OÜ Saeveski 10a, 11214 Tallin, ESTONIA Widex Regional Operation Center EMEA Sp. z o.o. ul. Graniczna 8a, 54-610 Wrocław, POLAND |

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