



Product Service

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

Certificate

No. Q5 091549 0067 Rev. 01

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.
Baltycka 6, 61-013 Poznan, POLAND

Widex A/S
Nymoellevej 6, 3540 Lynge, DENMARK

Widex EESTI OÜ
Saeveski 10a, 11214 Tallin, ESTONIA

Widex Regional Operation Center EMEA Sp. z o.o.
ul. Graniczna 8a, 54-610 Wroclaw, POLAND

-/-