



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 091549 0084 Rev. 00

Manufacturer:

Sivantos GmbH
Henri-Dunant-Strasse 100
91058 Erlangen
GERMANY

Facility(ies):

Sivantos GmbH
Henri-Dunant-Strasse 100, 91058 Erlangen, GERMANY

Product Category(ies): Hearing-aids, Hearing aids-Software
and -Components,
Hear-Speech-Training Instruments and Systems,
Audiological Measurement Equipment

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

713155991

Valid from:

2019-06-19

Valid until:

2024-06-18

Date,

2019-05-24

Stefan Preiß
Head of Certification/Notified Body