



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-200.14.03



Product Service

EC Certificate

EC Design-Examination Certificate

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)

(Other devices than custom made or intended for clinical investigation)

No. I7 017853 0132 Rev. 01

Manufacturer:

MED-EL

Elektromedizinische Geräte GmbH

Fürstenweg 77A

6020 Innsbruck

AUSTRIA

Product:

**External components for Cochlear Implant
Systems**

and Auditory Brainstem Implant Systems

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with AIMDD Annex 2 (4). This design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex 2 certificate is mandatory. See also notes overleaf.

Report no.:

713140955

Valid from:

2019-03-11

Valid until:

2024-02-14

Date,

2019-03-11

Stefan Preiß



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Model(s): see below

Facility(ies): MED-EL Elektromedizinische Geräte GmbH
Fürstenweg 77A, 6020 Innsbruck, AUSTRIA

Design Facility(ies): MED-EL Elektromedizinische Geräte GmbH
Fürstenweg 77A, 6020 Innsbruck, AUSTRIA

Test Report : 713142248, 713147797

Model: **Model no.:**

AudioLink Ma070301

FineTuner Echo Ma010201

Test Report : 713140955

Model: **Model no.:**

Mobile Application Software (external) AudioKey x.y

(x.y= internal revision numbers)