



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 0125 Rev. 01

Manufacturer:

MED-EL

Elektromedizinische Geräte GmbH

Fürstenweg 77A
6020 Innsbruck
AUSTRIA

Product:

**External components for Cochlear Implant
Systems
and Auditory Brainstem Implants**

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.:

713174353

Valid from:

2020-04-21

Valid until:

2022-10-18

Date,

2020-04-21

Christoph Dicks
Head of Certification/Notified Body

ZERTIFIKAT • CERTIFICATE • CERTIFICADO • CERTIFICAT



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No. I7 017853 0125 Rev. 01

Model(s): SONNET 2

Product: External components for Cochlear Implant
Systems and Auditory Brainstem Implants

Test Report No.: 713111186, 713174353

Model:
SONNET 2 Audio Processor

Components:

Control Units:

- SONNET 2 (Me1510, Me1511, Me1512, Me1513)
- SONNET 2 EAS (Me1520, Me1521, Me1522, Me1523)

Coils:

- D Coil with cable
- DL-Coil with cable

Battery Packs:

- SONNET Battery Pack (incl. SONNET FM Battery Pack Cover, AudioStream Battery Pack Cover)
- SONNET Mini Battery Pack consisting of:
 - Mini Battery Pack
 - SONNET Mini Battery Pack Cable
 - SONNET Mini Battery Pack Adapter
- SONNET Rechargeable Battery Kit consisting of:
 - SONNET Rechargeable Battery
 - SONNET Rechargeable Battery micro
 - SONNET Rechargeable Battery Adapter
 - SONNET Battery Pack Cover micro
 - SONNET Charging System
- SONNET ActiveWear Cable (Length 27cm or 50cm)

Remote Control:

- FineTuner

Programming Cable:

- MAX Programming Cable SONNET

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TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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