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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 0143 Rev. 00

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.:

713160561

Valid from:

2020-03-13

Valid until:

2024-05-26

Date,

2020-03-13

Christoph Dicks
Head of Certification/Notified Body

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ZERTIFIKAT ♦ CERTIFICATE ♦ 認證證書 ♦ CERTIFICADO ♦ CERTIFICAT



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No. I7 017853 0143 Rev. 00

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

Test Report No.: 713112125

Model: **Model No.:**

Audio processor: Me1150
RONDO 2

Components:

Processor Unit:
- RONDO 2 Processor Unit (Me 1150)

External Battery Pack:
- Mini Battery Pack
- Mini Battery Pack cable for RONDO 2

External Cables:
- MAX programming Cable for RONDO 2

Covers:
- RONDO 2 Design Cover

Remote Control:
- FineTuner

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