ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 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

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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No. I7 017853 0143 Rev. 00

Model(s): **see below**

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

Test Report No.: 71393870

Model:	**Model No.:**
Audio processor: RONDO	Me1100

Components:

Control Unit:
- RONDO Control Unit

Battery Packs:
- RONDO Battery Pack
- Mini Battery Pack

External Battery Pack Cables:
- Mini Battery Pack cable RONDO with variant length

Remote Control:
- FineTuner

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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:
RONDO 2 Me1150

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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