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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 0155 Rev. 00

Manufacturer:

MED-EL
Elektromedizinische Geräte GmbH
Fürstenweg 77A
6020 Innsbruck
AUSTRIA

Product:

External components for Cochlear Implant Systems
and Auditory Brainstem Implant System

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.: 713175392

Valid from: 2020-05-07
Valid until: 2024-05-26

Date, 2020-05-07

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Timuş Andrei
Date: 2026.02.27 11:13:32 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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

A4 / 07.17

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

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

No. I7 017853 0155 Rev. 00

Model(s): **RONDO 3**

Product: **External Components for Cochlear Implant Systems and Auditory Brainstem Implant System**

Test Report No.: 713175392

Model:

RONDO 3 Audio Processor

Components:

Processor Unit
-RONDO 3 Processor Unit
(Me1550, Me1551, Me1552, Me1553)

External Power Supply Options
-Mini Battery Pack
-Mini Battery Pack Cable for RONDO 3
-Charging Cable

External Cables
-MAX Programming Cable for RONDO 2

Covers
-RONDO 3 Cover
-RONDO 3 Mini Cover

External Adapter
-Telecoil Adapter

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