MED-EL

Declaration of Conformity

MED-EL Elektromedizinische Geräte GmbH
Fürstenweg 77a
6020 Innsbruck, Austria

as manufacturer, declares under its sole responsibility that the

RONDO 2 Audio Processor

Consisting of the following components:

- RONDO 2 Processor Unit (Me1150)
- External Battery Packs:
  - 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
  - Fine Tuner

fulfills the essential requirements of the Directive 90/385/EEC on Active Implantable Medical Devices (AIMD).
MED-EL has implemented a quality assurance system for design, manufacture and final inspection of the above products according to Annex 2, section 3 of the Directive. This quality assurance system conforms to the provisions of the Directive.
A Design Examination on the above products has been carried out by the Notified Body according to Annex 2, section 4 of the Directive 90/385/EEC on Active Implantable Medical Devices. The design of the above devices conforms to the provisions of this Directive. The devices are designed and manufactured in compliance with the following standards: EN ISO 13485:2016: Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016) DIN EN ISO 13485:2016.

Digitally signed by Timuş Andrei
Date: 2021.06.08 16:35:47 EEST
Reason: MoldSign Signature
Location: Moldova

Innsbruck, May 06, 2020
(Place and date of issue)

Dr. Ingeborg Hochmair, Chief Executive Officer

Elizabeth Gfoeller, Crporate Director, Regulatory Affairs

Martin Herzog, Corporate Director, QA

EC-Design-Examination Certificate NO. I7 017853 0143 Rev.00 (Valid until 2024-05-26)
EC-Full Quality Assurance Certificate NO. I1 017853 0127 Rev. 01 (Valid until: 2024-05-26)
Notified Body: TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 Munich, Germany.
Notified Body Identification Number: 0123