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MED-EL

EU declaration of conformity

As per Annex VI of Directive 2014/53/EU "Radio Equipment Directive" (RED)

Manufacturer: MED-EL Elektromedizinische Geräte GmbH
Address: Fürstenweg 77a, A-6020 Innsbruck, Austria

We declare on our sole responsibility, that the following products:

Product: **SONNET 2 (Me1510, Me1511, Me1512, Me1513), SONNET 2 EAS (Me1520, Me1521, Me1522, Me1523) (audio processors) and FineTuner (remote control)**
Description: Audio processor for cochlear implant including an inductive remote control receiver and a 2.4GHz transceiver with integral antenna

are in compliance with the essential requirements of directive 2014/53/EU (RED) as follows:

- Essential requirement Article 3.1 (a) - health and safety:
  Applied Standard(s) or other means of providing conformity:
  - EN 60601-1:2006 + A1:2013
  - EN 45502-1:2015, EN 45502-2-3:2010
- Essential requirement Article 3.1 (b) - electromagnetic compatibility (EMC):
  Applied Standard(s) or other means of providing conformity:
  - EN 60601-1-2:2015
- Essential requirement Article 3.2 - efficient use of radio frequency spectrum:
  Applied Standard(s) or other means of providing conformity:
  - ETSI EN 300 330:2017 (V2.1.1)
  - ETSI EN 302 195:2016 (V2.1.1)
  - ETSI EN 300 440:2017 (V2.1.1)
  - ETSI EN 300 328:2019 (V2.2.2)

Other Union harmonization legislation (where applicable):
In addition, these devices fall into the Directive (90/385/EEC) on Active Implantable Medical Devices (AIMDD), Annex 2 (4) and the conformity assessment of the essential requirements was carried out by TÜV SÜD Product Service GmbH Notified Body (0123) who issued the EC Design-Examination Certificate. MED-EL has implemented a Full Quality Assurance System for design, manufacture and final inspection of the devices and has been certified according to the standard EN ISO 13485:2016: Medical devices – Quality Management Systems – Requirements for Regulatory purposes (ISO 13485:2016) DIN EN ISO 13485:2016.

Accessories and components:
The FineTuner allows the user to modify various parameters as e.g. volume or microphone sensitivity of the SONNET 2 & SONNET 2 EAS. The FineTuner is certified as an accessory to an AIMD according to the Directive (90/385/EEC) and is listed on an EC Design-Examination Certificate issued by TÜV SÜD Product Service GmbH Notified Body (0123).
The 2.4 GHz wireless network functionality incorporated into SONNET 2 and SONNET 2 EAS is used to communicate with various external devices, it allows digital streaming of external audio data and enables fitting sessions to be performed wirelessly. The SONNET 2 and SONNET 2 EAS with 2.4 GHz wireless network functionality is certified as an accessory to an AIMD according to the Directive (90/385/EEC) and is listed on the EC Design-Examination Certificate issued by TÜV SÜD Product Service GmbH Notified Body (0123).
The software which activates the SONNET 2 & SONNET 2 EAS and allows the audio processors to be adjusted to the user's needs is the MED-EL CI software and is certified as an AIMD according to the Directive (90/385/EEC) and listed on an EC Design-Examination Certificate issued by TÜV SÜD Product Service GmbH Notified Body (0123).

Innsbruck, 2021-05-19

Ingeborg Hochmair	Elizabeth Gfoeller	Martin Herzog
Chief Executive Officer	Corporate Director, Regulatory Affairs	Corporate Director, Quality Assurance

EC-Design-Examination Certificate (for SONNET 2, SONNET 2 EAS & FineTuner) No. 17 17 10 17853 125 (valid until 2022-10-18)
EC Certificate Full Quality Assurance No. 11 05 17853 127 Rev. 01 (valid until 2024-05-26)
EN ISO 13485:2016 Certificate No. Q5 017853 0129 Rev. 02 (valid until 2021-09-09)

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 Munich, Germany.
Notified Body Identification Number: 0123