EN

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 product:

Product: AudioStream (Ma070401)
Description: Bluetooth Low Energy (BLE) wireless device for MED-EL compatible audio processors

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

Digitally signed by Timuş Andrei
Date: 2021.12.23 16:20:04 EET
Reason: MoldSign Signature
Location: Moldova

- 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 300 328:2019 (V2.2.2)

Other Union harmonization legislation (where applicable):
In addition, the AudioStream falls 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 im-plemented a Full Quality Assurance System for design, manufacture and final inspection of the device and has been certified according to the standard EN ISO 13485:2016: Medical devices – Quality Management Systems – Requirements for Regulatory purposes (ISO 13485:2016).

Compatible devices:
The AudioStream is compatible with the existing SONNET/SONNET EAS and SONNET 2/SONNET 2 EAS audio processors. These audio processors are certified as an accessory to an AIMD according to the Directive (90/385/EEC) and are listed on an EC Design-Examination Certificate issued by TÜV SÜD Product Service GmbH Notified Body (0123).

Innsbruck, 2020-08-10

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

EC Design-Examination Certificates No. 17 017853 0133 Rev. 01 (valid until 2024-05-20) & No. 17 017853 0125 Rev. 01 (valid until 2022-10-18)
EC Certificate Full Quality Assurance No. 11 017853 0114 (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