

# 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:** FineTuner Echo (Ma010201)  
**Description:** Remote Control for a compatible MED-EL audio processor with 2.4 GHz transceiver

is 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 300 328 (V2.2.2)

#### Other Union harmonization legislation (where applicable):

In addition, this device falls in the scope of 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 device and has been certified according to the standard EN ISO 13485:2016: Medical devices – Quality Management Systems – Requirements for Regulatory purposes.

#### Accessories and components:

The FineTuner Echo is intended to be used as a remote control for patients with compatible MED-EL audio processors which support the 2.4 GHz radio frequency link. The 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, 2021-05-19



Ingeborg Hochmair  
Chief Executive Officer



Elizabeth Gfoeller  
Corporate Director, Regulatory Affairs



Martin Herzog  
Corporate Director, Quality Assurance

EC-Design-Examination Certificate No. 17 017853 0132 Rev. 01 (valid until: 2024-02-14)  
EC Certificate Full Quality Assurance No. II 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