Declaration of Conformity

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

as manufacturer, declares under its sole responsibility that

the Implantable Hearing Prosthesis System

Bonebridge

consisting of the following products:

- Bone Conduction Implant (BCI 601) Kit consisting of
  - Bone Conduction Implant (BCI 601)
  - Coil-Sizer
  - Transducer-Sizer
  - Drill bit 1.5mm
  - Cortical Screw 6 mm
  - Emergency Screw 6 mm

- BCI 602 Kit consisting of
  - Bone Conduction Implant (BCI 602 Implant Kit) consisting of
    - Bone Conduction Implant (BCI 602)
    - Self-drilling cortical screws 5 mm
    - Emergency screw 5 mm
    - Surgical Screwdriver (SD 2)
  - BCI 602 Sizer Kit consisting of
    - Footprint-Sizer
    - Transducer-Sizer
    - Handle
- Audio Processor SAMBA BB
  - SAMBA BB (left side)
  - SAMBA BB (right side)
  - Remote Control (included within Kit)
  - Remote Control (sold separately with SAMBA)
  - Remote Control (sold separately with SAMBA 2)

- Audio Processor SAMBA 2 BB
  - SAMBA 2 BB (left side)
  - SAMBA 2 BB (right side)

- BCI Lifts 1 mm consisting of
  - BCI Lifts 1 mm
  - Cortical Screw 6 mm
  - Emergency Screw 6 mm

- BCI Lifts 2 mm & 3 mm consisting of
  - BCI Lifts 2 mm
  - BCI Lifts 3 mm
  - Cortical Screw 8 mm
  - Emergency Screw 8 mm

- BCI Lifts 4 mm consisting of
  - BCI Lifts 4 mm
  - Cortical Screw 10 mm
  - Emergency Screw 10 mm

- BCI 602 Lifts (1 mm) consisting of
  - BCI 602 Lifts 1 mm
  - Self-drilling cortical screws 5 mm
  - Emergency screw 5 mm

- BCI Sizer Kit consisting of
  - Coil-Sizer
  - Flat-Transducer-Sizer
  - Depth-Gauge
  - Depth-Gauge-Handle

- BCI 602 Sizer Kit consisting of
  - Footprint-Sizer
  - Transducer-Sizer
  - Handle

fulfils the essential requirements of the Directive 90/385/EEC on Active Implantable Medical Device (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 90/385/EEC on Active Implantable Medical Devices. This quality assurance system conforms to the provisions of this 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 (ISO13485:2016) DIN EN ISO13485:2016.

Innsbruck, September 23, 2020
(Place and date of issue)

Dr. Ingeborg Hochmair, CEO

Elizabeth Gfoeller
Corporate Director, Regulatory Affairs

Martin Herzog,
Corporate Director, Quality Assurance

EC Design-Examination Certificate No. I7 017853 0137 Rev. 02 (Valid until: 2024-05-26)
EC Full Quality Assurance Certificate No. I1 017853 0114 Rev. 01 (Valid until: 2024-05-26)

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