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Declaration of Conformity

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

as manufacturer, declares under its sole responsibility that the following accessories to Active Implantable Medical Devices (AIMD):

AudioKey
2.0.3

fulfills 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. 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 – Requirement for Regulatory purposes (ISO 13485:2016) DIN EN ISO13485:2016.

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

(Dr. Ingeborg Hochmair, CEO)

(Elizabeth Gfoeller, Corporate Director, Regulatory Affairs)

(Martin Herzog, Corporate Director, Quality Assurance)

EC Design Certificate Number: 17 017853 0132 Rev. 01 (Valid until: 2024-02-14)
EC Full Quality Assurance Certificate Number: 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