MED-EL

Declaration of Conformity

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

as manufacturer, declares under its sole responsibility that the

Mi1260 SONATA 2 COCHLEAR IMPLANT AND ITS ACCESSORIES

consisting of the following Active Implantable Medical Devices (AIMD)

Mi1260 SONATA 2 Cochlear Implant with the following variants:		
• Mi1260 SONATA 2	STANDARD	38538
• Mi1260 SONATA 2	MEDIUM	38539
• Mi1260 SONATA 2	COMPRESSED	38540
• Mi1260 SONATA 2	FLEX^{20}	38542
• Mi1260 SONATA 2	FLEX^{24}	38543
• Mi1260 SONATA 2	FLEX^{26}	38544
• Mi1260 SONATA 2	FLEX^{28}	38545
• Mi1260 SONATA 2	FLEX^{SOFT}	38541
• Mi1260 SONATA 2	FORM^{19}	38546
• Mi1260 SONATA 2	FORM^{24}	38547
EC Design-Examination Certificate: No. I7 017853 0141 Rev. 02 (Valid until: 2024-04-25)		
Mi1250 Implant Template		
• Mi1250 Implant Template	36894	
EC Design-Examination Certificate: No. I7 017853 0141 Rev. 02 (Valid until: 2024-04-25)		

fulfill 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 (ISO13485:2016) DIN EN ISO 13485:2016.

MED EL

Innsbruck, August 10, 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: I7 017853 0141 Rev. 02 (Valid until: 2024-04-25)
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