MED-EL

Declaration of Conformity

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

as manufacturer, declares under its sole responsibility that the

Mi1250 SYNCHRONY 2 (PIN) COCHLEAR IMPLANT AND ITS ACCESSORIES

consisting of the following Active Implantable Medical Devices (AIMD)

Mi1250 SYNCHRONY 2 (PIN) Cochlear Implant with the following variants:		
• Mi1250 SYNCHRONY 2 PIN	STANDARD	36671
• Mi1250 SYNCHRONY 2	STANDARD	36672
• Mi1250 SYNCHRONY 2 PIN	MEDIUM	36673
• Mi1250 SYNCHRONY 2	MEDIUM	36674
• Mi1250 SYNCHRONY 2 PIN	COMPRESSED	36675
• Mi1250 SYNCHRONY 2	COMPRESSED	36676
• Mi1250 SYNCHRONY 2 PIN	FLEX^{20}	37174
• Mi1250 SYNCHRONY 2	FLEX^{20}	37175
• Mi1250 SYNCHRONY 2 PIN	FLEX^{24}	36679
• Mi1250 SYNCHRONY 2	FLEX^{24}	36680
• Mi1250 SYNCHRONY 2 PIN	FLEX^{26}	36901
• Mi1250 SYNCHRONY 2	FLEX^{26}	36902
• Mi1250 SYNCHRONY 2 PIN	FLEX^{28}	36681
• Mi1250 SYNCHRONY 2	FLEX^{28}	36682
• Mi1250 SYNCHRONY 2 PIN	FLEX^{SOFT}	36677
• Mi1250 SYNCHRONY 2	FLEX^{SOFT}	36678
• Mi1250 SYNCHRONY 2 PIN	FORM^{19}	37176
• Mi1250 SYNCHRONY 2	FORM^{19}	37177
• Mi1250 SYNCHRONY 2 PIN	FORM^{24}	37178
• Mi1250 SYNCHRONY 2	FORM^{24}	37179
EC Design-Examination Certificate: No. I7 017853 0141 Rev. 02 (Valid until: 2024-04-25)		

Digitally signed by Timuş Andrei
Date: 2026.02.27 11:35:28 EET
Reason: MoldSign Signature
Location: Moldova

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Mi1250 SYNCHRONY 2 (PIN) Cochlear Implant with S-Vector Magnet with the following electrode variants:			
• Mi1250 SYNCHRONY 2 PIN	STANDARD	S-Vector Magnet	39534
• Mi1250 SYNCHRONY 2	STANDARD	S-Vector Magnet	39535
• Mi1250 SYNCHRONY 2 PIN	MEDIUM	S-Vector Magnet	39536
• Mi1250 SYNCHRONY 2	MEDIUM	S-Vector Magnet	39537
• Mi1250 SYNCHRONY 2 PIN	COMPRESSED	S-Vector Magnet	39538
• Mi1250 SYNCHRONY 2	COMPRESSED	S-Vector Magnet	39539
• Mi1250 SYNCHRONY 2 PIN	FLEX^{20}	S-Vector Magnet	39548
• Mi1250 SYNCHRONY 2	FLEX^{20}	S-Vector Magnet	39549
• Mi1250 SYNCHRONY 2 PIN	FLEX^{24}	S-Vector Magnet	39542
• Mi1250 SYNCHRONY 2	FLEX^{24}	S-Vector Magnet	39543
• Mi1250 SYNCHRONY 2 PIN	FLEX^{26}	S-Vector Magnet	39546
• Mi1250 SYNCHRONY 2	FLEX^{26}	S-Vector Magnet	39547
• Mi1250 SYNCHRONY 2 PIN	FLEX^{28}	S-Vector Magnet	39544
• Mi1250 SYNCHRONY 2	FLEX^{28}	S-Vector Magnet	39545
• Mi1250 SYNCHRONY 2 PIN	FLEX^{SOFT}	S-Vector Magnet	39540
• Mi1250 SYNCHRONY 2	FLEX^{SOFT}	S-Vector Magnet	39541
• Mi1250 SYNCHRONY 2 PIN	FORM^{19}	S-Vector Magnet	39550
• Mi1250 SYNCHRONY 2	FORM^{19}	S-Vector Magnet	39551
• Mi1250 SYNCHRONY 2 PIN	FORM^{24}	S-Vector Magnet	39552
• Mi1250 SYNCHRONY 2	FORM^{24}	S-Vector Magnet	39553
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)

(Dr. 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