



Product Service

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TÜV SÜD Product Service GmbH • Ridlerstraße 65 • 80339 Munich • Germany

To whom it may concern

Munich, 2024-07-17
Order No.: 713339860_1

Dedicated Confirmation Letter for MED-EL Elektromedizinische Geräte GmbH

Confirmation concerning certificates I7 017853 0100 Rev.01, I7 017853 0110 Rev. 01, I1 017853 0114 Rev. 01, I1 017853 0127 Rev.01, G1 017853 0131 Rev. 02, I7 017853 0132 Rev. 01, I7 017853 0133 Rev. 01, I7 017853 0134 Rev. 00, I7 017853 0137 Rev. 02, I7 017853 0140 Rev. 02, I7 017853 0141 Rev.02, I7 017853 0142 Rev. 00, I7 017853 0153 Rev. 00, I7 017853 0154 Rev. 00, I7 017853 0155 Rev. 00, I7 017853 0156 Rev. 00 and related medical devices

issued to the legal medical device manufacturer:

**MED-EL Elektromedizinische Geräte GmbH
Fürstenweg 77A
6020 Innsbruck
AUSTRIA**

and

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: AT-MF-000020243

The devices covered by the formal application and the written agreement mentioned above are identified in the Table below. In addition, this letter confirms that:

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry.

The transition timelines in accordance Article 120 (3a) of MDR that apply to the devices covered by this letter are subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR.

In case of inquiries please contact medical_devices@tuvsud.com.

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Devices in class III and IIb covered by formal application and written agreement:

Device name	MDR Device classification	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification	The transition time-line / Valid until
Mi1260 SONATA 2 [CI]	Class III	I7 017853 0141 Rev.02, NB0123 I1 017853 0127 Rev.01, NB0123	31 December 2027
Mi1250 SYNCHRONY 2 (PIN) [CI]	Class III	I7 017853 0141 Rev.02, NB0123 I1 017853 0127 Rev.01, NB0123	31 December 2027
Mi1210 SYNCHRONY ST [CI]	Class III	I7 017853 0141 Rev.02, NB0123 I1 017853 0127 Rev.01, NB0123	31 December 2027
Mi1200 SYNCHRONY (PIN) [CI]	Class III	I7 017853 0141 Rev.02, NB0123 I1 017853 0127 Rev.01, NB0123	31 December 2027
Mi1200 SYNCHRONY (PIN) [ABI]	Class III	I7 017853 0141 Rev.02, NB0123 I1 017853 0127 Rev.01, NB0123	31 December 2027
Mi1050 CONCERTO 2 [CI]	Class III	I7 017853 0153 Rev. 00, NB0123 I1 017853 0127 Rev.01, NB0123	31 December 2027
Mi1000 CONCERTO (PIN) [CI]	Class III	I7 017853 0153 Rev. 00, NB0123 I1 017853 0127 Rev.01, NB0123	31 December 2027
Mi1000 CONCERTO (PIN) [ABI]	Class III	I7 017853 0153 Rev. 00, NB0123 I1 017853 0127 Rev.01, NB0123	31 December 2027
SONATATI₁₀₀ implant [CI]	Class III	I7 017853 0100 Rev.01, NB0123 I1 017853 0127 Rev.01, NB0123	31 December 2027
ABI Placing Electrode	Class III	I7 017853 0110 Rev. 01, NB0123 I1 017853 0127 Rev.01, NB0123	31 December 2027
Fixation Clip	Class III	I7 017853 0134 Rev. 00, NB0123 I1 017853 0127 Rev.01, NB0123	31 December 2027
AUDIOKEY 2.0	Class III	I7 017853 0132 Rev. 01, NB0123 I1 017853 0127 Rev.01, NB0123	31 December 2027
SONNET / SONNET EAS Audio Processor	Class III	I7 017853 0133 Rev. 01, NB0123 I1 017853 0127 Rev.01, NB0123	31 December 2027
OPUS 2 Audio Processor	Class III	I7 017853 0142 Rev. 00, NB0123 I1 017853 0127 Rev.01, NB0123	31 December 2027
RONDO 3 Audio Processor	Class III	I7 017853 0155 Rev. 00, NB0123 I1 017853 0127 Rev.01, NB0123	31 December 2027
RONDO 2 Audio Processor	Class III	I7 017853 0143 Rev. 00, NB0123 I1 017853 0127 Rev.01, NB0123	31 December 2027
RONDO Audio Processor	Class III	I7 017853 0143 Rev. 00, NB0123 I1 017853 0127 Rev.01, NB0123	31 December 2027
MAESTRO 9.x	Class III	I7 017853 0154 Rev. 00, NB0123 I1 017853 0127 Rev.01, NB0123	31 December 2027
MAESTRO x.y	Class III	I7 017853 0156 Rev. 00, NB0123 I1 017853 0127 Rev.01, NB0123	31 December 2027
Bone Conduction Implant Kit, Model no.: BCI 602 Kit	Class III	I7 017853 0137 Rev. 02, NB0123 I1 017853 0114 Rev. 01, NB0123	31 December 2027
BCI 602 Lifts (1 mm)	Class III	I7 017853 0137 Rev. 02, NB0123 I1 017853 0114 Rev. 01, NB0123	31 December 2027
BCI 602 Sizer Kit	Class III	I7 017853 0137 Rev. 02, NB0123 I1 017853 0114 Rev. 01, NB0123	31 December 2027



Device name	MDR Device classification	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification	The transition timeline / Valid until
Bone Conduction Implant Kit, Model no.: BCI 601 Kit	Class III	I7 017853 0137 Rev. 02, NB0123 I1 017853 0114 Rev. 01, NB0123	31 December 2027
BCI Lifts (1,2,3 and 4 mm)	Class III	I7 017853 0137 Rev. 02, NB0123 I1 017853 0114 Rev. 01, NB0123	31 December 2027
BCI Sizer Kit	Class III	I7 017853 0137 Rev. 02, NB0123 I1 017853 0114 Rev. 01, NB0123	31 December 2027
VORP 503 Implant Kit	Class III	I7 017853 0140 Rev. 02, NB0123 I1 017853 0114 Rev. 01, NB0123	31 December 2027
VORP 503 Sizer Kit	Class III	I7 017853 0140 Rev. 02, NB0123 I1 017853 0114 Rev. 01, NB0123	31 December 2027
Vibroplasty Couplers	Class III	I7 017853 0140 Rev. 02, NB0123 I1 017853 0114 Rev. 01, NB0123	31 December 2027
Vibrating Ossicular Prosthesis (right ear) Model No.: VORP 502A Vibrating Ossicular Prosthesis (left ear) Model No.: VORP 502B	Class III	I7 017853 0140 Rev. 02, NB0123 I1 017853 0114 Rev. 01, NB0123	31 December 2027
SAMBA 2 BB Audio Processor	Class III	I7 017853 0137 Rev. 02, NB0123 I1 017853 0114 Rev. 01, NB0123	31 December 2027
SAMBA 2 Audio Processor	Class III	I7 017853 0140 Rev. 02, NB0123 I1 017853 0114 Rev. 01, NB0123	31 December 2027
SAMBA BB Audio Processor	Class III	I7 017853 0137 Rev. 02, NB0123 I1 017853 0114 Rev. 01, NB0123	31 December 2027
SAMBA Audio Processor (incl. Remote Control)	Class III	I7 017853 0140 Rev. 02, NB0123 I1 017853 0114 Rev. 01, NB0123	31 December 2027
SYMFIT 8.0 [Application Software]	Class III	I7 017853 0140 Rev. 02, NB0123 I1 017853 0114 Rev. 01, NB0123	31 December 2027
SYMFIT 7.0 software	Class III	I7 017853 0140 Rev. 02, NB0123 I1 017853 0114 Rev. 01, NB0123	31 December 2027
SYMFIT BAO software	Class III	I7 017853 0140 Rev. 02, NB0123 I1 017853 0114 Rev. 01, NB0123	31 December 2027
PMEI Stapesplasty	Class IIb	G1 017853 0131 Rev. 02, NB0123	31 December 2027
PMEI Tympanoplasty	Class IIb	G1 017853 0131 Rev. 02, NB0123	31 December 2027
Mi1000 Implant Template	Class III*	I7 017853 0153 Rev. 00, NB0123 I1 017853 0127 Rev. 01, NB0123	31 December 2027
Mi1000 Implant Template PIN	Class III*	I7 017853 0153 Rev. 00, NB0123 I1 017853 0127 Rev. 01, NB0123	31 December 2027
Mi1200 Implant Template	Class III*	I7 017853 0141 Rev. 02, NB0123 I1 017853 0127 Rev. 01, NB0123	31 December 2027
Mi1200 Implant Template PIN	Class III*	I7 017853 0141 Rev. 02, NB0123 I1 017853 0127 Rev. 01, NB0123	31 December 2027
Implant Template, single-use, for the SO-NATA T1100	Class III*	I7 017853 0100 Rev. 01, NB0123 I1 017853 0127 Rev. 01, NB0123	31 December 2027
Mi1210 Implant Template	Class III*	I7 017853 0141 Rev. 02, NB0123 I1 017853 0127 Rev. 01, NB0123	31 December 2027



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Mi1250 Implant Template	Class III*	I7 017853 0141 Rev. 02, NB0123 I1 017853 0127 Rev. 01, NB0123	31 December 2027
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* Note: Currently under clarification with competent authority (Art. 51 MDR)

R. Köhler

Randolf Köhler
TÜV SÜD Product Service GmbH
PS-MHS-AU-9
Medical Health Services Foreign Affairs

