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MED-EL

EU DECLARATION OF CONFORMITY

MED-EL Elektromedizinische Geräte GmbH
Fürstenweg 77a
6020 Innsbruck, Austria
SRN: AT-MF-000020243

as manufacturer, declares under its sole responsibility that the following product(s) is/are in conformity with the provisions of Regulation (EU) 2017/745 (MDR).

Product Name(s): Passive Middle Ear Implant
Tympanoplasty Prosthesis

Variants:

mARC Total Prosthesis (3.00 mm)
mARC Total Prosthesis (3.25 mm)
mARC Total Prosthesis (3.50 mm)
mARC Total Prosthesis (3.75 mm)
mARC Total Prosthesis (4.00 mm)
mARC Total Prosthesis (4.25 mm)
mARC Total Prosthesis (4.50 mm)
mARC Total Prosthesis (4.75 mm)
mARC Total Prosthesis (5.00 mm)
mARC Total Prosthesis (5.50 mm)
mARC Total Prosthesis (6.00 mm)
mARC Total Prosthesis (6.50 mm)
mARC Total Prosthesis (7.00 mm)

mCLIP Partial Prosthesis (0.75 mm)
mCLIP Partial Prosthesis (1.00 mm)
mCLIP Partial Prosthesis (1.25 mm)
mCLIP Partial Prosthesis (1.50 mm)
mCLIP Partial Prosthesis (1.75 mm)
mCLIP Partial Prosthesis (2.00 mm)
mCLIP Partial Prosthesis (2.25 mm)
mCLIP Partial Prosthesis (2.50 mm)
mCLIP Partial Prosthesis (3.00 mm)
mCLIP Partial Prosthesis (3.50 mm)

mCLIP ARC Partial Prosthesis (0.75 mm)
mCLIP ARC Partial Prosthesis (1.00 mm)
mCLIP ARC Partial Prosthesis (1.25 mm)
mCLIP ARC Partial Prosthesis (1.50 mm)
mCLIP ARC Partial Prosthesis (1.75 mm)
mCLIP ARC Partial Prosthesis (2.00 mm)
mCLIP ARC Partial Prosthesis (2.25 mm)
mCLIP ARC Partial Prosthesis (2.50 mm)
mCLIP ARC Partial Prosthesis (3.00 mm)
mCLIP ARC Partial Prosthesis (3.50 mm)

mDISC Partial Prosthesis

mGRIP Partial Prosthesis (0.75 mm)
mGRIP Partial Prosthesis (1.00 mm)
mGRIP Partial Prosthesis (1.25 mm)
mGRIP Partial Prosthesis (1.50 mm)
mGRIP Partial Prosthesis (1.75 mm)
mGRIP Partial Prosthesis (2.00 mm)
mGRIP Partial Prosthesis (2.25 mm)
mGRIP Partial Prosthesis (2.50 mm)
mGRIP Partial Prosthesis (3.00 mm)

mGRIP Partial Prosthesis (3.50 mm)
mGRIP Total Prosthesis (3.00 mm)
mGRIP Total Prosthesis (3.25 mm)
mGRIP Total Prosthesis (3.50 mm)
mGRIP Total Prosthesis (3.75 mm)
mGRIP Total Prosthesis (4.00 mm)
mGRIP Total Prosthesis (4.25 mm)
mGRIP Total Prosthesis (4.50 mm)
mGRIP Total Prosthesis (4.75 mm)
mGRIP Total Prosthesis (5.00 mm)
mGRIP Total Prosthesis (5.50 mm)
mGRIP Total Prosthesis (6.00 mm)
mGRIP Total Prosthesis (6.50 mm)
mGRIP Total Prosthesis (7.00 mm)

mXACT Partial Prosthesis (0.75 mm)
mXACT Partial Prosthesis (1.00 mm)
mXACT Partial Prosthesis (1.25 mm)
mXACT Partial Prosthesis (1.50 mm)
mXACT Partial Prosthesis (1.75 mm)
mXACT Partial Prosthesis (2.00 mm)
mXACT Partial Prosthesis (2.25 mm)
mXACT Partial Prosthesis (2.50 mm)
mXACT Partial Prosthesis (3.00 mm)
mXACT Partial Prosthesis (3.50 mm)

mXACT Total Prosthesis Center (3.00 mm)
mXACT Total Prosthesis Center (3.25 mm)
mXACT Total Prosthesis Center (3.50 mm)
mXACT Total Prosthesis Center (3.75 mm)
mXACT Total Prosthesis Center (4.00 mm)
mXACT Total Prosthesis Center (4.25 mm)
mXACT Total Prosthesis Center (4.50 mm)
mXACT Total Prosthesis Center (4.75 mm)
mXACT Total Prosthesis Center (5.00 mm)
mXACT Total Prosthesis Center (5.50 mm)
mXACT Total Prosthesis Center (6.00 mm)
mXACT Total Prosthesis Center (6.50 mm)
mXACT Total Prosthesis Center (7.00 mm)

mXACT Total Prosthesis Offcenter (3.00 mm)
mXACT Total Prosthesis Offcenter (3.25 mm)
mXACT Total Prosthesis Offcenter (3.50 mm)
mXACT Total Prosthesis Offcenter (3.75 mm)
mXACT Total Prosthesis Offcenter (4.00 mm)
mXACT Total Prosthesis Offcenter (4.25 mm)
mXACT Total Prosthesis Offcenter (4.50 mm)
mXACT Total Prosthesis Offcenter (4.75 mm)
mXACT Total Prosthesis Offcenter (5.00 mm)
mXACT Total Prosthesis Offcenter (5.50 mm)
mXACT Total Prosthesis Offcenter (6.00 mm)
mXACT Total Prosthesis Offcenter (6.50 mm)
mXACT Total Prosthesis Offcenter (7.00 mm)

mXACT PRO Partial Prosthesis Kit

mXACT PRO Total Prosthesis Kit

Basic UDI-DI:	9008737PMEITY4M
Intended Purpose:	The passive middle ear implant is an ossicular replacement prosthesis intended to restore sound transmission from the tympanic membrane to the oval window.
Risk Class in accordance with the rules set out in Annex VIII:	Class IIb

Common Specifications applied:	Not applicable
Other Union legislation (where applicable):	Not applicable
Notified Body Name:	TÜV SÜD Product Service GmbH
Notified Body Identification Number:	0123
Conformity Assessment Procedure applied:	☒ Annex IX chapters I – III ☐ Annex IX excluding chapter II ☐ Annex IX excluding chapter II (limited to aspects of sterility/measuring function/reuse of surgical instruments) ☐ Self-declaration
Certificate(s) issued:	G70 017853 0172 Rev. 01 G15 017853 0174 Rev. 01

Signed for and on behalf of MED-EL Elektromedizinische Geräte GmbH:

Innsbruck, 2025-10-13

Dr. Ingeborg Hochmair
Chief Executive Officer

Elizabeth Gfoeller
Corporate Director, Regulatory Affairs

Dr. Martin Herzog
Corporate Director, Quality Assurance