



EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 017853 0172 Rev. 01

Manufacturer:

MED-EL

Elektromedizinische Geräte GmbH

Fürstenweg 77A
6020 Innsbruck
AUSTRIA

SRN Manufacturer - AT-MF-000020243

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation are described on the following page(s).

The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The technical documentation assessment included an assessment of the clinical evaluation assessment.

The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result.

Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH.

In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.

For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G70 017853 0172 Rev. 01

Report No.: 713353844

Preceding Certificate No.: G70 017853 0172 Rev. 00

Valid from: 2025-06-10

Valid until: 2030-04-28

Date of Initial Issuance: 2025-04-29

Christoph Dicks

Head of Certification/Notified Body

Issue date: 2025-06-10



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Classification:	Class IIb
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.
Device(s):	Passive Middle Ear Implant For device variants/models and parameters please see List 1 at the end of this certificate
Classification:	Class IIb
Basic UDI-DI:	9008737PMEIST48
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.
Device(s):	Passive Middle Ear Implant For device variants/models and parameters please see List 2 at the end of this certificate

List 1 - 9008737PMEITY4M

mXACT Partial Prosthesis (0.75 mm) (art. 58033)
 mXACT Partial Prosthesis (1.00 mm) (art. 58035)
 mXACT Partial Prosthesis (1.25 mm) (art. 58037)
 mXACT Partial Prosthesis (1.50 mm) (art. 58039)
 mXACT Partial Prosthesis (1.75 mm) (art. 58041)
 mXACT Partial Prosthesis (2.00 mm) (art. 58043)
 mXACT Partial Prosthesis (2.25 mm) (art. 58045)
 mXACT Partial Prosthesis (2.50 mm) (art. 58047)
 mXACT Partial Prosthesis (3.00 mm) (art. 58051)
 mXACT Partial Prosthesis (3.50 mm) (art. 58053)
 mXACT Total Prosthesis Offcenter (3.00 mm) (art. 58055)
 mXACT Total Prosthesis Offcenter (3.25 mm) (art. 58057)
 mXACT Total Prosthesis Offcenter (3.50 mm) (art. 58059)
 mXACT Total Prosthesis Offcenter (3.75 mm) (art. 58061)
 mXACT Total Prosthesis Offcenter (4.00 mm) (art. 58063)
 mXACT Total Prosthesis Offcenter (4.25 mm) (art. 58065)
 mXACT Total Prosthesis Offcenter (4.50 mm) (art. 58067)
 mXACT Total Prosthesis Offcenter (4.75 mm) (art. 58069)
 mXACT Total Prosthesis Offcenter (5.00 mm) (art. 58071)
 mXACT Total Prosthesis Offcenter (5.50 mm) (art. 58075)
 mXACT Total Prosthesis Offcenter (6.00 mm) (art. 58077)
 mXACT Total Prosthesis Offcenter (6.50 mm) (art. 58079)
 mXACT Total Prosthesis Offcenter (7.00 mm) (art. 58081)
 mXACT Total Prosthesis Center (3.00 mm) (art. 58083)
 mXACT Total Prosthesis Center (3.25 mm) (art. 58085)
 mXACT Total Prosthesis Center (3.50 mm) (art. 58087)
 mXACT Total Prosthesis Center (3.75 mm) (art. 58089)
 mXACT Total Prosthesis Center (4.00 mm) (art. 58091)

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mXACT Total Prosthesis Center (4.25 mm) (art. 58093)
mXACT Total Prosthesis Center (4.50 mm) (art. 58095)
mXACT Total Prosthesis Center (4.75 mm) (art. 58097)
mXACT Total Prosthesis Center (5.00 mm) (art. 58099)
mXACT Total Prosthesis Center (5.50 mm) (art. 58103)
mXACT Total Prosthesis Center (6.00 mm) (art. 58105)
mXACT Total Prosthesis Center (6.50 mm) (art. 58107)
mXACT Total Prosthesis Center (7.00 mm) (art. 58109)
mCLIP Partial Prosthesis (0.75 mm) (art. 58111)
mCLIP Partial Prosthesis (1.00 mm) (art. 58113)
mCLIP Partial Prosthesis (1.25 mm) (art. 58115)
mCLIP Partial Prosthesis (1.50 mm) (art. 58117)
mCLIP Partial Prosthesis (1.75 mm) (art. 58119)
mCLIP Partial Prosthesis (2.00 mm) (art. 58121)
mCLIP Partial Prosthesis (2.25 mm) (art. 58123)
mCLIP Partial Prosthesis (2.50 mm) (art. 58125)
mCLIP Partial Prosthesis (3.00 mm) (art. 58127)
mCLIP Partial Prosthesis (3.50 mm) (art. 58129)
mCLIP ARC Partial Prosthesis (0.75 mm) (art. 58502)
mCLIP ARC Partial Prosthesis (1.00 mm) (art. 58504)
mCLIP ARC Partial Prosthesis (1.25 mm) (art. 58506)
mCLIP ARC Partial Prosthesis (1.50 mm) (art. 58508)
mCLIP ARC Partial Prosthesis (1.75 mm) (art. 58510)
mCLIP ARC Partial Prosthesis (2.00 mm) (art. 58512)
mCLIP ARC Partial Prosthesis (2.25 mm) (art. 58514)
mCLIP ARC Partial Prosthesis (2.50 mm) (art. 58516)
mCLIP ARC Partial Prosthesis (3.00 mm) (art. 58518)
mCLIP ARC Partial Prosthesis (3.50 mm) (art. 58520)
mXACT PRO Partial Prosthesis Kit (art. 58496)
mXACT PRO Total Prosthesis Kit (art. 58498)
mDISC Partial Prosthesis (art. 58850)
mGRIP Partial Prosthesis (0.75 mm) (art. 58669)
mGRIP Partial Prosthesis (1.00 mm) (art. 58671)
mGRIP Partial Prosthesis (1.25 mm) (art. 58673)
mGRIP Partial Prosthesis (1.50 mm) (art. 58675)
mGRIP Partial Prosthesis (1.75 mm) (art. 58677)
mGRIP Partial Prosthesis (2.00 mm) (art. 58679)
mGRIP Partial Prosthesis (2.25 mm) (art. 58681)
mGRIP Partial Prosthesis (2.50 mm) (art. 58683)
mGRIP Partial Prosthesis (3.00 mm) (art. 58685)
mGRIP Partial Prosthesis (3.50 mm) (art. 58687)
mGRIP Total Prosthesis (3.00 mm) (art. 58689)
mGRIP Total Prosthesis (3.25 mm) (art. 58691)
mGRIP Total Prosthesis (3.50 mm) (art. 58693)
mGRIP Total Prosthesis (3.75 mm) (art. 58695)
mGRIP Total Prosthesis (4.00 mm) (art. 58697)
mGRIP Total Prosthesis (4.25 mm) (art. 58699)
mGRIP Total Prosthesis (4.50 mm) (art. 58701)
mGRIP Total Prosthesis (4.75 mm) (art. 58703)
mGRIP Total Prosthesis (5.00 mm) (art. 58705)
mGRIP Total Prosthesis (5.50 mm) (art. 58707)
mGRIP Total Prosthesis (6.00 mm) (art. 58709)



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mGRIP Total Prosthesis (6.50 mm) (art. 58711)
mGRIP Total Prosthesis (7.00 mm) (art. 58713)
mARC Total Prosthesis (3.00 mm) (art. 58852)
mARC Total Prosthesis (3.25 mm) (art. 58854)
mARC Total Prosthesis (3.50 mm) (art. 58856)
mARC Total Prosthesis (3.75 mm) (art. 58858)
mARC Total Prosthesis (4.00 mm) (art. 58860)
mARC Total Prosthesis (4.25 mm) (art. 58862)
mARC Total Prosthesis (4.50 mm) (art. 58864)
mARC Total Prosthesis (4.75 mm) (art. 58866)
mARC Total Prosthesis (5.00 mm) (art. 58868)
mARC Total Prosthesis (5.50 mm) (art. 58870)
mARC Total Prosthesis (6.00 mm) (art. 58872)
mARC Total Prosthesis (6.50 mm) (art. 58874)
mARC Total Prosthesis (7.00 mm) (art. 58876)

List 2 - 9008737PMEIST48

mAXIS Stapes Prosthesis (0.4 x 3.50 mm) (art. 58131)
mAXIS Stapes Prosthesis (0.4 x 3.75 mm) (art. 58133)
mAXIS Stapes Prosthesis (0.4 x 4.00 mm) (art. 58135)
mAXIS Stapes Prosthesis (0.4 x 4.25 mm) (art. 58137)
mAXIS Stapes Prosthesis (0.4 x 4.50 mm) (art. 58139)
mAXIS Stapes Prosthesis (0.4 x 4.75 mm) (art. 58141)
mAXIS Stapes Prosthesis (0.4 x 5.00 mm) (art. 58143)
mAXIS Stapes Prosthesis (0.4 x 5.25 mm) (art. 58145)
mAXIS Stapes Prosthesis (0.4 x 5.50 mm) (art. 58147)
mAXIS Stapes Prosthesis (0.5 x 3.50 mm) (art. 58149)
mAXIS Stapes Prosthesis (0.5 x 3.75 mm) (art. 58151)
mAXIS Stapes Prosthesis (0.5 x 4.00 mm) (art. 58153)
mAXIS Stapes Prosthesis (0.5 x 4.25 mm) (art. 58155)
mAXIS Stapes Prosthesis (0.5 x 4.50 mm) (art. 58157)
mAXIS Stapes Prosthesis (0.5 x 4.75 mm) (art. 58159)
mAXIS Stapes Prosthesis (0.5 x 5.00 mm) (art. 58161)
mAXIS Stapes Prosthesis (0.5 x 5.25 mm) (art. 58163)
mAXIS Stapes Prosthesis (0.5 x 5.50 mm) (art. 58165)
mAXIS Stapes Prosthesis (0.6 x 3.50 mm) (art. 58167)
mAXIS Stapes Prosthesis (0.6 x 3.75 mm) (art. 58169)
mAXIS Stapes Prosthesis (0.6 x 4.00 mm) (art. 58171)
mAXIS Stapes Prosthesis (0.6 x 4.25 mm) (art. 58173)
mAXIS Stapes Prosthesis (0.6 x 4.50 mm) (art. 58175)
mAXIS Stapes Prosthesis (0.6 x 4.75 mm) (art. 58177)
mAXIS Stapes Prosthesis (0.6 x 5.00 mm) (art. 58179)
mAXIS Stapes Prosthesis (0.6 x 5.25 mm) (art. 58181)
mLOOP Stapes Prosthesis (0.4 x 3.50 mm) (art. 58183)
mLOOP Stapes Prosthesis (0.4 x 3.75 mm) (art. 58185)
mLOOP Stapes Prosthesis (0.4 x 4.00 mm) (art. 58187)
mLOOP Stapes Prosthesis (0.4 x 4.25 mm) (art. 58189)
mLOOP Stapes Prosthesis (0.4 x 4.50 mm) (art. 58191)
mLOOP Stapes Prosthesis (0.4 x 4.75 mm) (art. 58193)

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mLOOP Stapes Prosthesis (0.4 x 5.00 mm) (art. 58195)
mLOOP Stapes Prosthesis (0.4 x 5.25 mm) (art. 58197)
mLOOP Stapes Prosthesis (0.4 x 5.50 mm) (art. 58199)
mLOOP Stapes Prosthesis (0.4 x 6.00 mm) (art. 58433)
mLOOP Stapes Prosthesis (0.4 x 7.00 mm) (art. 58435)
mLOOP Stapes Prosthesis (0.4 x 8.00 mm) (art. 58437)
mLOOP Stapes Prosthesis (0.4 x 9.00 mm) (art. 58439)
mLOOP Stapes Prosthesis (0.4 x 10.00 mm) (art. 58441)
mLOOP Stapes Prosthesis (0.6 x 3.50 mm) (art. 58219)
mLOOP Stapes Prosthesis (0.6 x 3.75 mm) (art. 58221)
mLOOP Stapes Prosthesis (0.6 x 4.00 mm) (art. 58223)
mLOOP Stapes Prosthesis (0.6 x 4.25 mm) (art. 58225)
mLOOP Stapes Prosthesis (0.6 x 4.50 mm) (art. 58227)
mLOOP Stapes Prosthesis (0.6 x 4.75 mm) (art. 58229)
mLOOP Stapes Prosthesis (0.6 x 5.00 mm) (art. 58231)
mLOOP Stapes Prosthesis (0.6 x 5.25 mm) (art. 58233)
mLOOP Stapes Prosthesis (0.6 x 5.50 mm) (art. 58235)
mLOOP Stapes Prosthesis (0.6 x 6.00 mm) (art. 58443)
mLOOP Stapes Prosthesis (0.6 x 7.00 mm) (art. 58445)
mLOOP Stapes Prosthesis (0.6 x 8.00 mm) (art. 58447)
mLOOP Stapes Prosthesis (0.6 x 9.00 mm) (art. 58449)
mLOOP Stapes Prosthesis (0.6 x 10.00 mm) (art. 58451)
mZAM Stapes Prosthesis (0.4 x 3.50 mm) (art. 58237)
mZAM Stapes Prosthesis (0.4 x 3.75 mm) (art. 58239)
mZAM Stapes Prosthesis (0.4 x 4.00 mm) (art. 58241)
mZAM Stapes Prosthesis (0.4 x 4.25 mm) (art. 58243)
mZAM Stapes Prosthesis (0.4 x 4.50 mm) (art. 58245)
mZAM Stapes Prosthesis (0.4 x 4.75 mm) (art. 58247)
mZAM Stapes Prosthesis (0.4 x 5.00 mm) (art. 58249)
mZAM Stapes Prosthesis (0.4 x 5.25 mm) (art. 58251)
mZAM Stapes Prosthesis (0.4 x 5.50 mm) (art. 58253)
mZAM Stapes Prosthesis (0.5 x 3.50 mm) (art. 58453)
mZAM Stapes Prosthesis (0.5 x 3.75 mm) (art. 58455)
mZAM Stapes Prosthesis (0.5 x 4.00 mm) (art. 58457)
mZAM Stapes Prosthesis (0.5 x 4.25 mm) (art. 58459)
mZAM Stapes Prosthesis (0.5 x 4.50 mm) (art. 58461)
mZAM Stapes Prosthesis (0.5 x 4.75 mm) (art. 58463)
mZAM Stapes Prosthesis (0.5 x 5.00 mm) (art. 58465)
mZAM Stapes Prosthesis (0.5 x 5.25 mm) (art. 58467)
mZAM Stapes Prosthesis (0.5 x 5.50 mm) (art. 58469)
mZAM Stapes Prosthesis (0.6 x 3.50 mm) (art. 58255)
mZAM Stapes Prosthesis (0.6 x 3.75 mm) (art. 58257)
mZAM Stapes Prosthesis (0.6 x 4.00 mm) (art. 58259)
mZAM Stapes Prosthesis (0.6 x 4.25 mm) (art. 58261)
mZAM Stapes Prosthesis (0.6 x 4.50 mm) (art. 58263)
mZAM Stapes Prosthesis (0.6 x 4.75 mm) (art. 58265)
mZAM Stapes Prosthesis (0.6 x 5.00 mm) (art. 58267)
mZAM Stapes Prosthesis (0.6 x 5.25 mm) (art. 58269)
mZAM Stapes Prosthesis (0.6 x 5.50 mm) (art. 58271)
mFIX Stapes Prosthesis (0.4 x 3.50 mm) (art. 58273)
mFIX Stapes Prosthesis (0.4 x 3.75 mm) (art. 58275)
mFIX Stapes Prosthesis (0.4 x 4.00 mm) (art. 58277)



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mFIX Stapes Prosthesis (0.4 x 4.50 mm) (art. 58281)
mFIX Stapes Prosthesis (0.4 x 4.75 mm) (art. 58283)
mFIX Stapes Prosthesis (0.4 x 5.00 mm) (art. 58285)
mFIX Stapes Prosthesis (0.4 x 5.25 mm) (art. 58287)
mFIX Stapes Prosthesis (0.4 x 5.50 mm) (art. 58289)
mFIX Stapes Prosthesis (0.6 x 3.50 mm) (art. 58309)
mFIX Stapes Prosthesis (0.6 x 3.75 mm) (art. 58311)
mFIX Stapes Prosthesis (0.6 x 4.00 mm) (art. 58313)
mFIX Stapes Prosthesis (0.6 x 4.25 mm) (art. 58315)
mFIX Stapes Prosthesis (0.6 x 4.50 mm) (art. 58317)
mFIX Stapes Prosthesis (0.6 x 4.75 mm) (art. 58319)
mFIX Stapes Prosthesis (0.6 x 5.00 mm) (art. 58321)
mFIX Stapes Prosthesis (0.6 x 5.25 mm) (art. 58323)
mFIX Stapes Prosthesis (0.6 x 5.50 mm) (art. 58325)
mWING Stapes Prosthesis (0.4 x 3.50 mm) (art. 58717)
mWING Stapes Prosthesis (0.4 x 3.75 mm) (art. 58719)
mWING Stapes Prosthesis (0.4 x 4.00 mm) (art. 58721)
mWING Stapes Prosthesis (0.4 x 4.25 mm) (art. 58723)
mWING Stapes Prosthesis (0.4 x 4.50 mm) (art. 58725)
mWING Stapes Prosthesis (0.4 x 4.75 mm) (art. 58727)
mWING Stapes Prosthesis (0.4 x 5.00 mm) (art. 58729)
mWING Stapes Prosthesis (0.4 x 5.25 mm) (art. 58731)
mWING Stapes Prosthesis (0.4 x 5.50 mm) (art. 58733)
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mWING Stapes Prosthesis (0.5 x 3.75 mm) (art. 58737)
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mWING Stapes Prosthesis (0.5 x 5.25 mm) (art. 58749)
mWING Stapes Prosthesis (0.5 x 5.50 mm) (art. 58751)
mWING Stapes Prosthesis (0.6 x 3.50 mm) (art. 58753)
mWING Stapes Prosthesis (0.6 x 3.75 mm) (art. 58755)
mWING Stapes Prosthesis (0.6 x 4.00 mm) (art. 58757)
mWING Stapes Prosthesis (0.6 x 4.25 mm) (art. 58759)
mWING Stapes Prosthesis (0.6 x 4.50 mm) (art. 58761)
mWING Stapes Prosthesis (0.6 x 4.75 mm) (art. 58763)
mWING Stapes Prosthesis (0.6 x 5.00 mm) (art. 58765)
mWING Stapes Prosthesis (0.6 x 5.25 mm) (art. 58767)
mWING Stapes Prosthesis (0.6 x 5.50 mm) (art. 58769)



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The validity of this certificate -
depends on conditions and/or
is limited to the following:

Revision History:

Rev.	Dated	Report	Description
00	2025-04-29	713262885	Initial issuance
01	2025-06-10	713353844	Supplemented: Device(s)/group of device(s) added