

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
Stapesplasty Prosthesis

Variants:

mAXIS Stapes Prosthesis (0.4 x 3.50 mm)
mAXIS Stapes Prosthesis (0.4 x 3.75 mm)
mAXIS Stapes Prosthesis (0.4 x 4.00 mm)
mAXIS Stapes Prosthesis (0.4 x 4.25 mm)
mAXIS Stapes Prosthesis (0.4 x 4.50 mm)
mAXIS Stapes Prosthesis (0.4 x 4.75 mm)
mAXIS Stapes Prosthesis (0.4 x 5.00 mm)
mAXIS Stapes Prosthesis (0.4 x 5.25 mm)
mAXIS Stapes Prosthesis (0.4 x 5.50 mm)
mAXIS Stapes Prosthesis (0.5 x 3.50 mm)
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mAXIS Stapes Prosthesis (0.6 x 3.50 mm)
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mAXIS Stapes Prosthesis (0.6 x 5.00 mm)
mAXIS Stapes Prosthesis (0.6 x 5.25 mm)
mAXIS Stapes Prosthesis (0.6 x 5.50 mm)

mFIX Stapes Prosthesis (0.4 x 3.50 mm)
mFIX Stapes Prosthesis (0.4 x 3.75 mm)
mFIX Stapes Prosthesis (0.4 x 4.00 mm)
mFIX Stapes Prosthesis (0.4 x 4.25 mm)
mFIX Stapes Prosthesis (0.4 x 4.50 mm)
mFIX Stapes Prosthesis (0.4 x 4.75 mm)
mFIX Stapes Prosthesis (0.4 x 5.00 mm)
mFIX Stapes Prosthesis (0.4 x 5.25 mm)
mFIX Stapes Prosthesis (0.4 x 5.50 mm)
mFIX Stapes Prosthesis (0.6 x 3.50 mm)
mFIX Stapes Prosthesis (0.6 x 3.75 mm)
mFIX Stapes Prosthesis (0.6 x 4.00 mm)
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mFIX Stapes Prosthesis (0.6 x 4.75 mm)
mFIX Stapes Prosthesis (0.6 x 5.00 mm)
mFIX Stapes Prosthesis (0.6 x 5.25 mm)
mFIX Stapes Prosthesis (0.6 x 5.50 mm)

mLOOP Stapes Prosthesis (0.4 x 3.50 mm)
 mLOOP Stapes Prosthesis (0.4 x 3.75 mm)
 mLOOP Stapes Prosthesis (0.4 x 4.00 mm)
 mLOOP Stapes Prosthesis (0.4 x 4.25 mm)
 mLOOP Stapes Prosthesis (0.4 x 4.50 mm)
 mLOOP Stapes Prosthesis (0.4 x 4.75 mm)
 mLOOP Stapes Prosthesis (0.4 x 5.00 mm)
 mLOOP Stapes Prosthesis (0.4 x 5.25 mm)
 mLOOP Stapes Prosthesis (0.4 x 5.50 mm)
 mLOOP Stapes Prosthesis (0.4 x 6.00 mm)
 mLOOP Stapes Prosthesis (0.4 x 7.00 mm)
 mLOOP Stapes Prosthesis (0.4 x 8.00 mm)
 mLOOP Stapes Prosthesis (0.4 x 9.00 mm)
 mLOOP Stapes Prosthesis (0.4 x 10.00 mm)
 mLOOP Stapes Prosthesis (0.6 x 3.50 mm)
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mWING Stapes Prosthesis (0.4 x 3.50 mm)
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mZAM Stapes Prosthesis (0.4 x 3.50 mm)
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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.

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