MED-EL

Declaration of Conformity

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

as manufacturer, declares under its sole responsibility that the Passive Middle Ear Implant

mXACT Total Prosthesis Offcenter

Product name with dimensions	REF Number
mXACT Total Prosthesis Offcenter (3.00 mm)	58055
mXACT Total Prosthesis Offcenter (3.25 mm)	58057
mXACT Total Prosthesis Offcenter (3.50 mm)	58059
mXACT Total Prosthesis Offcenter (3.75 mm)	58061
mXACT Total Prosthesis Offcenter (4.00 mm)	58063
mXACT Total Prosthesis Offcenter (4.25 mm)	58065
mXACT Total Prosthesis Offcenter (4.50 mm)	58067
mXACT Total Prosthesis Offcenter (4.75 mm)	58069
mXACT Total Prosthesis Offcenter (5.00 mm)	58071
mXACT Total Prosthesis Offcenter (5.50 mm)	58075
mXACT Total Prosthesis Offcenter (6.00 mm)	58077
mXACT Total Prosthesis Offcenter (6.50 mm)	58079
mXACT Total Prosthesis Offcenter (7.00 mm)	58081

is classified as a Class IIb medical device according to the Medical Device Directive (MDD) 93/42/EEC, Annex IX (Rule 8), to which this declaration relates is in conformity with the provisions of Medical Device Directive 93/42/EEC, Annex II (excluding section 4) and fulfilled the essential requirements of the Directive when it was produced.

The Notified Body declared that MED-EL has implemented a quality assurance system for design, manufacture and final inspection of the above products according to Annex II, section 3 of the Directive 93/42/EEC. This quality assurance system conforms to the provisions of this Directive. This quality Assurance System is subject to periodic surveillance by the Notified Body.

The device has been designed and manufactured in compliance with the following standard: EN ISO 13485: 2016 Medical devices – Quality Management systems – Requirements for regulatory purposes (ISO 13485: 2016).

Digitally signed by Timuș Andrei
Date: 2025.09.01 11:41:06 EEST
Reason: MoldSign Signature
Location: Moldova

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MED-EL Elektromedizinische Geräte Gesellschaft m.b.H.

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Register Court:
Landesgericht Innsbruck
UID-No. ATU31722507

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MED-EL

Innsbruck, 10th August 2020
(Place and date of issue)

Dr. Ingeborg Hochmair, CEO

Elizabeth Gfoeller
Corporate Director, Regulatory Affairs

Martin Herzog
Corporate Director, Quality Assurance

EN ISO 13485: 2016 Certificate no. Q5 017853 0129 Rev.02 (valid until 09.09.2021)
EC Certificate Full Quality Assurance no. G1 017853 0131 Rev.02 (valid until 26.05.2024)
Notified Body: TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 Munich, Germany.
Notified Body Identification Number: 0123

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