EU Declaration of Conformity

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

as manufacturer, declares under its sole responsibility that the product

mXACT PRO Total Prosthesis shipped within the kit

Commercial name of the kit	REF number
mXACT PRO Total Prosthesis Kit	58498

is a passive middle ear implant 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 Timuş Andrei
Date: 2025.09.01 11:40:58 EEST
Reason: MoldSign Signature
Location: Moldova

MOLDOVA
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UID-No. ATU31722507
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MED EL

Innsbruck, 20th May 2021
(Place and date of issue)

Dr. Ingeborg Hochmair, CEO

Elizabeth Gfoeller
Corporate Director, Regulatory Affairs

Dr. Martin Herzog
Corporate Director, Quality Assurance

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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