

EU Declaration of Conformity

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

as manufacturer, declares under its sole responsibility that the product

mCLIP ARC Partial Prosthesis

Product name with dimensions	REF number
mCLIP ARC Partial Prosthesis (0.75 mm)	58502
mCLIP ARC Partial Prosthesis (1.00 mm)	58504
mCLIP ARC Partial Prosthesis (1.25 mm)	58506
mCLIP ARC Partial Prosthesis (1.50 mm)	58508
mCLIP ARC Partial Prosthesis (1.75 mm)	58510
mCLIP ARC Partial Prosthesis (2.00 mm)	58512
mCLIP ARC Partial Prosthesis (2.25 mm)	58514
mCLIP ARC Partial Prosthesis (2.50 mm)	58516
mCLIP ARC Partial Prosthesis (3.00 mm)	58518
mCLIP ARC Partial Prosthesis (3.50 mm)	58520

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).

mCLIP ARC Partial Prosthesis EU DoC Rev.1.0 (F-TYM142)

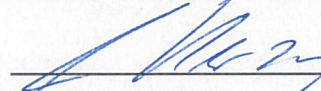
Innsbruck, 20th May 2021
(Place and date of issue)



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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