MED-EL

Declaration of Conformity

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

as manufacturer, declares under its sole responsibility that the product

mLOOP stapes prosthesis

Product name with dimensions	REF
mLOOP stapes prosthesis (0.4 x 3.50 mm)	58183
mLOOP stapes prosthesis (0.4 x 3.75 mm)	58185
mLOOP stapes prosthesis (0.4 x 4.00 mm)	58187
mLOOP stapes prosthesis (0.4 x 4.25 mm)	58189
mLOOP stapes prosthesis (0.4 x 4.50 mm)	58191
mLOOP stapes prosthesis (0.4 x 4.75 mm)	58193
mLOOP stapes prosthesis (0.4 x 5.00 mm)	58195
mLOOP stapes prosthesis (0.4 x 5.25 mm)	58197
mLOOP stapes prosthesis (0.4 x 5.50 mm)	58199
mLOOP stapes prosthesis (0.4 x 6.00 mm)	58433
mLOOP stapes prosthesis (0.4 x 7.00 mm)	58435
mLOOP stapes prosthesis (0.4 x 8.00 mm)	58437
mLOOP stapes prosthesis (0.4 x 9.00 mm)	58439
mLOOP stapes prosthesis (0.4 x 10.00 mm)	58441
mLOOP stapes prosthesis (0.6 x 3.50 mm)	58219
mLOOP stapes prosthesis (0.6 x 3.75 mm)	58221
mLOOP stapes prosthesis (0.6 x 4.00 mm)	58223
mLOOP stapes prosthesis (0.6 x 4.25 mm)	58225
mLOOP Stapes Prosthesis (0.6 x 4.50 mm)	58227
mLOOP Stapes Prosthesis (0.6 x 4.75 mm)	58229
mLOOP Stapes Prosthesis (0.6 x 5.00 mm)	58231
mLOOP Stapes Prosthesis (0.6 x 5.25 mm)	58233
mLOOP Stapes Prosthesis (0.6 x 5.50 mm)	58235
mLOOP Stapes Prosthesis (0.6 x 6.00 mm)	58443
mLOOP Stapes Prosthesis (0.6 x 7.00 mm)	58445
mLOOP Stapes Prosthesis (0.6 x 8.00 mm)	58447
mLOOP Stapes Prosthesis (0.6 x 9.00 mm)	58449
mLOOP Stapes Prosthesis (0.6 x 10.00 mm)	58451

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.

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

Fürstenweg 77a
6020 Innsbruck
Austria
Tel +43 512 28 88 89 0
Fax +43 512 29 33 81
office@medel.com

FN 48608h, DVR 1001795
Register Court:
Landesgericht Innsbruck
UID-No. ATU31722507

www.medel.com

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).

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

MED-EL Elektromedizinische Geräte Gesellschaft m.b.H.
Fürstenweg 77a
6020 Innsbruck
Austria
Tel +43 512 28 88 89 0
Fax +43 512 29 33 81
office@medel.com
FN 48608h, DVR 1001795
Register Court:
Landesgericht Innsbruck
UID-No. ATU31722507
www.medel.com