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

mAXIS stapes prosthesis

Product name with dimensions	REF No.
mAXIS stapes prosthesis (0.4 x 3.50 mm)	58131
mAXIS stapes prosthesis (0.4 x 3.75 mm)	58133
mAXIS stapes prosthesis (0.4 x 4.00 mm)	58135
mAXIS stapes prosthesis (0.4 x 4.25 mm)	58137
mAXIS stapes prosthesis (0.4 x 4.50 mm)	58139
mAXIS stapes prosthesis (0.4 x 4.75 mm)	58141
mAXIS stapes prosthesis (0.4 x 5.00 mm)	58143
mAXIS stapes prosthesis (0.4 x 5.25 mm)	58145
mAXIS stapes prosthesis (0.4 x 5.50 mm)	58147
mAXIS stapes prosthesis (0.5 x 3.50 mm)	58149
mAXIS stapes prosthesis (0.5 x 3.75 mm)	58416
mAXIS stapes prosthesis (0.5 x 4.00 mm)	58151
mAXIS stapes prosthesis (0.5 x 4.25 mm)	58153
mAXIS stapes prosthesis (0.5 x 4.50 mm)	58155
mAXIS stapes prosthesis (0.5 x 4.75 mm)	58157
mAXIS stapes prosthesis (0.5 x 5.00 mm)	58159
mAXIS stapes prosthesis (0.5 x 5.25 mm)	58161
mAXIS stapes prosthesis (0.5 x 5.50 mm)	58163
mAXIS stapes prosthesis (0.6 x 3.50 mm)	58165
mAXIS stapes prosthesis (0.6 x 3.75 mm)	58167
mAXIS stapes prosthesis (0.6 x 4.00 mm)	58169
mAXIS stapes prosthesis (0.6 x 4.25 mm)	58171
mAXIS stapes prosthesis (0.6 x 4.50 mm)	58173
mAXIS stapes prosthesis (0.6 x 4.75 mm)	58175
mAXIS stapes prosthesis (0.6 x 5.00 mm)	58177
mAXIS stapes prosthesis (0.6 x 5.25 mm)	58179
mAXIS stapes prosthesis (0.6 x 5.50 mm)	58181

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

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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

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