

EC Declaration of Conformity

according to Annex II of Directive 93/42/EEC concerning medical devices, as amended by Directive 2007/47/EC

Classification according to Directive 2005/50/EC: Class III

We

Waldemar Link GmbH & Co. KG
Barkhausenweg 10
D-22339 Hamburg

declare under our own responsibility that

NON ACTIVE IMPLANTS FOR JOINT REPLACEMENT:

MP® RECONSTRUCTION PROSTHESIS

meet the respective provisions of the Directive 93/42/EEC concerning medical devices, as amended by Directive 2007/47/EC and we are solely responsible for the preparation of this declaration. The relevant technical documentation is archived by the QM department.

The product is marked (CE0482) by MEDCERT Zertifizierungs- und Prüfgesellschaft für die Medizin GmbH Pilatuspool 2, D-20355 Hamburg.

Hamburg, 04.03.20 i.A. T. L.
Place, date signature Quality Management

Hamburg, 04.03.2020 i.A. [Signature]
Place, date signature Management Representative

Valid from: 04.03.2020
Valid to: 27.05.2024

Annex 1

Item number and description

MP® RECONSTRUCTION PROSTHESIS

Prosthesis stem, microporous, cementless

Item number	Description
172-916/12	X S-0, 160 mm
172-916/14	X S-1, 160 mm
172-916/16	X S-2, 160 mm
172-916/18	X S-3, 160 mm
172-916/20	X S-4, 160 mm
172-916/22	X S-5, 160 mm
172-916/25	X S-6, 160 mm
172-918/12	S-0, 180 mm
172-918/14	S-1, 180 mm
172-918/16	S-2, 180 mm
172-918/18	S-3, 180 mm
172-918/20	S-4, 180 mm
172-918/22	S-5, 180 mm
172-918/25	S-6, 180 mm
172-921/12	00, 210 mm
172-921/14	001, 210 mm
172-921/16	002, 210 mm
172-921/18	003, 210 mm
172-921/20	004, 210 mm
172-921/22	005, 210 mm
172-921/25	006, 210 mm
172-925/14	01, 250 mm
172-925/16	02, 250 mm
172-925/18	03, 250 mm

172-925/20	04, 250 mm
172-925/22	05, 250 mm
172-925/25	06, 250 mm
172-929/14	1, 290 mm
172-929/16	2, 290 mm
172-929/18	3, 290 mm
172-929/20	4, 290 mm
172-929/22	5, 290 mm
172-929/25	6, 290 mm
172-930/14	7, 330 mm
172-930/16	8, 330 mm
172-930/18	9, 330 mm
172-930/20	10, 330 mm
172-930/22	11, 330 mm
172-930/25	12, 330 mm
173-916/12	X S-0, 160 mm
173-916/14	X S-1, 160 mm
173-916/16	X S-2, 160 mm
173-916/18	X S-3, 160 mm
173-916/20	X S-4, 160 mm
173-916/22	X S-5, 160 mm
173-916/25	X S-6, 160 mm
173-918/12	S-0, 180 mm
173-918/14	S-1, 180 mm
173-918/16	S-2, 180 mm
173-918/18	S-3, 180 mm
173-918/20	S-4, 180 mm
173-918/22	S-5, 180 mm
173-918/25	S-6, 180 mm
173-921/12	00, 210 mm

173-921/14	001, 210 mm
173-921/16	002, 210 mm
173-921/18	003, 210 mm
173-921/20	004, 210 mm
173-921/22	005, 210 mm
173-921/25	006, 210 mm
173-925/14	01, 250 mm
173-925/16	02, 250 mm
173-925/18	03, 250 mm
173-925/20	04, 250 mm
173-925/22	05, 250 mm
173-925/25	06, 250 mm
173-929/14	1, 290 mm
173-929/16	2, 290 mm
173-929/18	3, 290 mm
173-929/20	4, 290 mm
173-929/22	5, 290 mm
173-929/25	6, 290 mm
173-930/14	7, 330 mm
173-930/16	8, 330 mm
173-930/18	9, 330 mm
173-930/20	10, 330 mm
173-930/22	11, 330 mm
173-930/25	12, 330 mm

Prosthesis stem, 2 distal bores, cementless

Item number	Description
99-0925/20	04, 250 mm
99-0925/22	05, 250 mm
99-0925/27	06, 250 mm

99-0929/22	05, 290 mm
99-0930/22	11, 330 mm
99-0930/27	12, 330 mm
173-926/20	04, 250 mm
173-926/22	05, 250 mm
173-926/27	06, 250 mm
173-928/22	05, 290 mm
173-931/22	11, 330 mm
173-931/27	12, 330 mm

Modular revision stem, anatomically curved, cementable

Item number	Description
172-900/12	Ø 12 mm, 200 mm
172-900/14	Ø 14 mm, 200 mm
172-900/16	Ø 16 mm, 200 mm
172-901/12	Ø 12 mm, 240 mm
172-901/14	Ø 14 mm, 240 mm
172-901/16	Ø 16 mm, 240 mm
172-902/12	Ø 12 mm, 280 mm
172-902/14	Ø 14 mm, 280 mm
172-902/16	Ø 16 mm, 280 mm
172-903/12	Ø 12 mm, 320 mm
172-903/14	Ø 14 mm, 320 mm
172-903/16	Ø 16 mm, 320 mm
173-900/12	Ø 12 mm, 200 mm
173-900/14	Ø 14 mm, 200 mm
173-900/16	Ø 16 mm, 200 mm
173-901/12	Ø 12 mm, 240 mm
173-901/14	Ø 14 mm, 240 mm

173-901/16	Ø 16 mm, 240 mm
173-902/12	Ø 12 mm, 280 mm
173-902/14	Ø 14 mm, 280 mm
173-902/16	Ø 16 mm, 280 mm
173-903/12	Ø 12 mm, 320 mm
173-903/14	Ø 14 mm, 320 mm
173-903/16	Ø 16 mm, 320 mm

Neck segment with collar, taper 12/14 mm, microporous

Item number	Description
172-960/26	126° CCD, 65 mm
172-960/35	135° CCD, 65 mm
172-961/26	126° CCD, 35 mm
172-961/35	135° CCD, 35 mm
173-960/26	126° CCD, 65 mm
173-960/35	135° CCD, 65 mm
173-961/26	126° CCD, 35 mm
173-961/35	135° CCD, 35 mm

Neck segment without collar, taper 12/14 mm, microporous

Item number	Description
172-964/26	126° CCD, 65 mm
172-964/35	135° CCD, 65 mm
172-965/26	126° CCD, 35 mm
172-965/35	135° CCD, 35 mm
173-964/26	126° CCD, 65 mm
173-964/35	135° CCD, 65 mm
173-965/26	126° CCD, 35 mm
173-965/35	135° CCD, 35 mm

Neck segment XXL with collar, taper 12/14 mm, microporous

Item number	Description
172-980/26	126° CCD, 65 mm
172-980/35	135° CCD, 65 mm
172-981/26	126° CCD, 35 mm
172-981/35	135° CCD, 35 mm
173-980/26	126° CCD, 65 mm
173-980/35	135° CCD, 65 mm
173-981/26	126° CCD, 35 mm
173-981/35	135° CCD, 35 mm

Neck segment XXL without collar, taper 12/14 mm, microporous

Item number	Description
172-984/26	126° CCD, 65 mm
172-984/35	135° CCD, 65 mm
172-985/26	126° CCD, 35 mm
172-985/35	135° CCD, 35 mm
173-984/26	126° CCD, 65 mm
173-984/35	135° CCD, 65 mm
173-985/26	126° CCD, 35 mm
173-985/35	135° CCD, 35 mm

Neck segment XXL without collar, taper 12/14 mm, microporous, additional bore

Item number	Description
99-0984/26	126° CCD, 65 mm
99-0984/28	126° CCD, 35 mm
173-984/26	126° CCD, 65 mm
173-984/28	126° CCD, 35 mm

Neck segment without collar, taper 12/14 mm, microporous, additional bore

Item number	Description
99-0984/30	126° CCD, 65 mm
99-0984/32	126° CCD, 35 mm
173-984/30	126° CCD, 65 mm
173-984/32	126° CCD, 35 mm

Proximal spacers

Item number	Description
172-950/05	5 mm
172-950/10	10 mm
172-950/20	20 mm
173-950/05	5 mm
173-950/10	10 mm
173-950/20	20 mm

Expansion bolts

Item number	Description
172-947/38	41 mm
172-947/58	61 mm
173-947/38	41 mm
173-947/58	61 mm

Base component

Item number	Description
172-970	UHMWPE
173-970	UHMWPE

Extension

Item number	Description
172-971/10	Ø 16,5 mm, H = 10 mm

172-971/20	Ø 16,5 mm, H = 20 mm
172-972/10	Ø 20,5 mm, H = 10 mm
172-972/20	Ø 20,5 mm, H = 20 mm
173-971/10	Ø 16,5 mm, H = 10 mm
173-971/20	Ø 16,5 mm, H = 20 mm
173-972/10	Ø 20,5 mm, H = 10 mm
173-972/20	Ø 20,5 mm, H = 20 mm

Terminal

Item number	Description
172-974/01	Ø 16,5 mm, H = 10 mm
172-974/02	Ø 20,5 mm, H = 10 mm
173-974/01	Ø 16,5 mm, H = 10 mm
173-974/02	Ø 20,5 mm, H = 10 mm

Neck segment, low offset, slim

Item number	Description
137-045/32	136° CCD, 45 mm
173-045/32	136° CCD, 45 mm

Neck segment, standard, slim

Item number	Description
137-045/38	131° CCD, 45 mm
137-065/38	131° CCD, 65 mm
173-045/38	131° CCD, 45 mm
173-065/38	131° CCD, 65 mm

Neck segment, lateralized, slim

Item number	Description
137-065/46	126° CCD, 65 mm
173-065/46	126° CCD, 65 mm

Neck segment, standard, defect reconstruction

Item number	Description
137-145/38	131° CCD, 45 mm
173-145/38	131° CCD, 45 mm
137-165/38	131° CCD, 65 mm
173-165/38	131° CCD, 65 mm

Neck segment, lateralized, defect reconstruction

Item number	Description
137-165/46	126° CCD, 65 mm
173-165/46	126° CCD, 65 mm