

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:

BIMOBILE CUP SYSTEM

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, 17.03.2019 
Place, date signature Quality Management

Hamburg, 12.03.2018 
Place, date signature Management Representative

Valid from: 08.03.2019
Valid to: 02.07.2022

Annex 1

Item number and description

BIMOBILE CUP SYSTEM

BiMobile™ Dual Mobility System – Shell

Item number	Description
184-001/42	Size 42; CoCrMo acc. ISO 5832-12
184-001/44	Size 44; CoCrMo acc. ISO 5832-12
184-001/46	Size 46; CoCrMo acc. ISO 5832-12
184-001/48	Size 48; CoCrMo acc. ISO 5832-12
184-001/50	Size 50; CoCrMo acc. ISO 5832-12
184-001/52	Size 52; CoCrMo acc. ISO 5832-12
184-001/54	Size 54; CoCrMo acc. ISO 5832-12
184-001/56	Size 56; CoCrMo acc. ISO 5832-12
184-001/58	Size 58; CoCrMo acc. ISO 5832-12
184-001/60	Size 60; CoCrMo acc. ISO 5832-12
184-001/62	Size 62; CoCrMo acc. ISO 5832-12
184-001/64	Size 64; CoCrMo acc. ISO 5832-12
184-001/66	Size 66; CoCrMo acc. ISO 5832-12
184-001/68	Size 68; CoCrMo acc. ISO 5832-12
184-001/70	Size 70; CoCrMo acc. ISO 5832-12

BiMobile™ Dual Mobility System TiCaP® Shell

Item number	Description
184-101/42	Size 42; CoCrMo acc. ISO 5832-12; TiCaP acc. ASTM F1580, ASTM F1609
184-101/44	Size 44; CoCrMo acc. ISO 5832-12; TiCaP acc. ASTM F1580, ASTM F1609
184-101/46	Size 46; CoCrMo acc. ISO 5832-12; TiCaP acc. ASTM F1580, ASTM F1609
184-101/48	Size 48; CoCrMo acc. ISO 5832-12; TiCaP acc. ASTM F1580, ASTM F1609
184-101/50	Size 50; CoCrMo acc. ISO 5832-12; TiCaP acc. ASTM F1580, ASTM F1609
184-101/52	Size 52; CoCrMo acc. ISO 5832-12; TiCaP acc. ASTM F1580, ASTM F1609
184-101/54	Size 54; CoCrMo acc. ISO 5832-12; TiCaP acc. ASTM F1580, ASTM F1609
184-101/56	Size 56; CoCrMo acc. ISO 5832-12; TiCaP acc. ASTM F1580, ASTM F1609
184-101/58	Size 58; CoCrMo acc. ISO 5832-12; TiCaP acc. ASTM F1580, ASTM F1609
184-101/60	Size 60; CoCrMo acc. ISO 5832-12; TiCaP acc. ASTM F1580, ASTM F1609
184-101/62	Size 62; CoCrMo acc. ISO 5832-12; TiCaP acc. ASTM F1580, ASTM F1609
184-101/64	Size 64; CoCrMo acc. ISO 5832-12; TiCaP acc. ASTM F1580, ASTM F1609
184-101/66	Size 66; CoCrMo acc. ISO 5832-12; TiCaP acc. ASTM F1580, ASTM F1609
184-101/68	Size 68; CoCrMo acc. ISO 5832-12; TiCaP acc. ASTM F1580, ASTM F1609
184-101/70	Size 70; CoCrMo acc. ISO 5832-12; TiCaP acc. ASTM F1580, ASTM F1609

BiMobile™ Dual Mobility System - PlasmaLink® Shell

Item number	Description
184-201/42	Size 42; CoCrMo acc. ISO 5832-12; TPS acc. ASTM F1580
184-201/44	Size 44; CoCrMo acc. ISO 5832-12; TPS acc. ASTM F1580
184-201/46	Size 46; CoCrMo acc. ISO 5832-12; TPS acc. ASTM F1580
184-201/48	Size 48; CoCrMo acc. ISO 5832-12; TPS acc. ASTM F1580
184-201/50	Size 50; CoCrMo acc. ISO 5832-12; TPS acc. ASTM F1580
184-201/52	Size 52; CoCrMo acc. ISO 5832-12; TPS acc. ASTM F1580
184-201/54	Size 54; CoCrMo acc. ISO 5832-12; TPS acc. ASTM F1580
184-201/56	Size 56; CoCrMo acc. ISO 5832-12; TPS acc. ASTM F1580
184-201/58	Size 58; CoCrMo acc. ISO 5832-12; TPS acc. ASTM F1580
184-201/60	Size 60; CoCrMo acc. ISO 5832-12; TPS acc. ASTM F1580
184-201/62	Size 62; CoCrMo acc. ISO 5832-12; TPS acc. ASTM F1580
184-201/64	Size 64; CoCrMo acc. ISO 5832-12; TPS acc. ASTM F1580
184-201/66	Size 66; CoCrMo acc. ISO 5832-12; TPS acc. ASTM F1580
184-201/68	Size 68; CoCrMo acc. ISO 5832-12; TPS acc. ASTM F1580
184-201/70	Size 70; CoCrMo acc. ISO 5832-12; TPS acc. ASTM F1580

BiMobile™ Dual Mobility System - UHMWPE Liner

Item number	Description
184-250/01	Size 42; UHMWPE acc. ISO 5834-1, ISO 5834-2
184-250/02	Size 44; UHMWPE acc. ISO 5834-1, ISO 5834-2
184-250/03	Size 46; UHMWPE acc. ISO 5834-1, ISO 5834-2
184-260/01	Size 48; UHMWPE acc. ISO 5834-1, ISO 5834-2
184-260/02	Size 50; UHMWPE acc. ISO 5834-1, ISO 5834-2
184-260/03	Size 52; UHMWPE acc. ISO 5834-1, ISO 5834-2
184-260/04	Size 54; UHMWPE acc. ISO 5834-1, ISO 5834-2
184-260/05	Size 56; UHMWPE acc. ISO 5834-1, ISO 5834-2
184-260/06	Size 58; UHMWPE acc. ISO 5834-1, ISO 5834-2
184-260/07	Size 60; UHMWPE acc. ISO 5834-1, ISO 5834-2
184-260/08	Size 62; UHMWPE acc. ISO 5834-1, ISO 5834-2
184-260/09	Size 64; UHMWPE acc. ISO 5834-1, ISO 5834-2
184-260/10	Size 66; UHMWPE acc. ISO 5834-1, ISO 5834-2
184-260/11	Size 68; UHMWPE acc. ISO 5834-1, ISO 5834-2
184-260/12	Size 70; UHMWPE acc. ISO 5834-1, ISO 5834-2

BiMobile™ Dual Mobility System – E-DUR® Liner

Item number	Description
184-270/01	Size 42; E-DUR® acc. ISO 5834-1, ISO 5834-2
184-270/02	Size 44; E-DUR® acc. ISO 5834-1, ISO 5834-2
184-270/03	Size 46; E-DUR® acc. ISO 5834-1, ISO 5834-2
184-280/01	Size 48; E-DUR® acc. ISO 5834-1, ISO 5834-2
184-280/02	Size 50; E-DUR® acc. ISO 5834-1, ISO 5834-2
184-280/03	Size 52; E-DUR® acc. ISO 5834-1, ISO 5834-2
184-280/04	Size 54; E-DUR® acc. ISO 5834-1, ISO 5834-2
184-280/05	Size 56; E-DUR® acc. ISO 5834-1, ISO 5834-2
184-280/06	Size 58; E-DUR® acc. ISO 5834-1, ISO 5834-2
184-280/07	Size 60; E-DUR® acc. ISO 5834-1, ISO 5834-2
184-280/08	Size 62; E-DUR® acc. ISO 5834-1, ISO 5834-2
184-280/09	Size 64; E-DUR® acc. ISO 5834-1, ISO 5834-2
184-280/10	Size 66; E-DUR® acc. ISO 5834-1, ISO 5834-2
184-280/11	Size 68; E-DUR® acc. ISO 5834-1, ISO 5834-2
184-280/12	Size 70; E-DUR® acc. ISO 5834-1, ISO 5834-2