

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:

MEGASYSTEM-C®

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, 21.01.2020 i.A. [Signature]
Place, date signature Quality Management

Hamburg, 24.01.2020 i.A. [Signature]
Place, date signature Management Representative

Valid from: 21.01.2020
Valid to: 27.05.2024

Annex 1

Item number and description

MEGASYSTEM-C®

Neck segments, massive, Megasystem-C®

Item number	Description
15-8503/35	135° CCD, 65 mm
15-8503/26	126° CCD, 65 mm
15-8504/35	135° CCD, 35 mm
15-8504/26	126° CCD, 35 mm

Push-through stems for total femur replacement

Item number	Description
15-8523/70	Ø 14 mm, 120 mm
15-8523/71	Ø 14 mm, 160 mm
15-8523/72	Ø 14 mm, 200 mm
15-8523/73	Ø 14 mm, 240 mm
15-8523/74	Ø 14 mm, 280 mm
15-8523/75	Ø 14 mm, 320 mm
15-8523/76	Ø 14 mm, 360 mm
15-8522/70	Ø 16 mm, 120 mm
15-8522/71	Ø 16 mm, 160 mm
15-8522/72	Ø 16 mm, 200 mm
15-8522/73	Ø 16 mm, 240 mm
15-8522/74	Ø 16 mm, 280 mm
15-8522/75	Ø 16 mm, 320 mm
15-8522/76	Ø 16 mm, 360 mm

Coupling for diaphyseal spacer

Item number	Description
15-8522/65	Tilastan

Stem segments, Ø 28 mm

Item number	Description
15-8522/02	30 mm
15-8522/04	40 mm
15-8522/06	50 mm
15-8522/08	60 mm
15-8522/10	100 mm
15-8522/12	150 mm
15-8522/14	200 mm
15-8522/16	250 mm

Coupling components for femur replacement

Item number	Description
15-8522/24	Total femur replacement, short
15-8522/26	Total femur replacement, long
15-8522/28	Proximal femur replacement, short
15-8522/30	Proximal femur replacement, long

Support ring, height 10 mm

Item number	Description
15-8502/66	up to Ø 18 mm

Terminals, height 10 mm, oval

Item number	Description
15-8512/83	I-Ø 24,3 mm, 26x34 mm
15-8512/84	I-Ø 24,3 mm, 30x44 mm
15-8512/85	I-Ø 24,3 mm, 34x48 mm