

EC Declaration of Conformity

We

Waldemar Link GmbH & Co. KG
Barkhausenweg 10
22339 Hamburg, Germany

SRN: DE-MF-000005215

declare under our own responsibility that

NON ACTIVE IMPLANTS FOR JOINT REPLACEMENT

LCU HIP SYSTEM

meet the respective provisions of the Regulation (EU) 2017/745 including the General Safety and Performance Requirements on medical devices. We are solely responsible for the preparation of this declaration.

The product is certified based on the conformity assessment of the QM system and the technical documentation according to Annex IX of Regulation (EU) 2017/745 on medical devices by

MEDCERT Zertifizierungs- und Prüfgesellschaft für Medizin GmbH
Pilatuspool 2, 20355 Hamburg, Germany.

Certificate No.: 20213GB450210611

The product is marked (CE0482) by the above named Notified Body. The relevant technical documentation is archived by the quality management department.

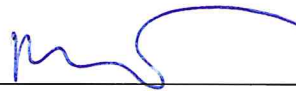
Classification: Class III

Rule: 8

Hamburg, Date 11.06.2021

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Regulatory Affairs

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Person Responsible for Regulatory Compliance

Valid from: 11.06.2021

Valid to: 06.06.2026

Intended use

The non-active, surgically-invasive implantable LCU Hip System manufactured by Waldemar Link GmbH & Co. KG is intended for long-term replacement of the femoral side of a diseased and / or defective hip joint in the human body. The LCU Hip System forms a total replacement of the hip joint when combined with the prosthesis head and if applicable the acetabular cup. The LCU Hip System can be used with full-grown, anesthetized patients of any ethnic origin and sex. The cementless LCU Hip System is implanted without cement.

The implants may only be used and operated in an aseptic medical environment by persons who have the required training, knowledge and experience in the orthopedic and surgical field. The implants are supplied in sterile condition individually packed as single-use products.

LCU Hip Stems, cementless, standard type, Ti6Al4V, HX Coating, taper 12/14, CCD angle 130°

Basic-UDI-DI: 4026575-1-HSP-001001-UX

#	Article number	UDI-DI	Description
1	165-012/26	04026575415281	Size 8, 115 mm Length, 38.0 mm Offset
2	165-013/26	04026575415298	Size 9, 130 mm Length, 38.5 mm Offset
3	165-014/26	04026575415304	Size 10, 140 mm Length, 39.2 mm Offset
4	165-015/26	04026575415311	Size 11, 145 mm Length, 40.0 mm Offset
5	165-016/26	04026575415328	Size 12, 150 mm Length, 40.7 mm Offset
6	165-017/26	04026575415335	Size 13, 155 mm Length, 41.5 mm Offset
7	165-018/26	04026575415342	Size 14, 160 mm Length, 42.0 mm Offset
8	165-019/26	04026575415359	Size 15, 165 mm Length, 43.0 mm Offset
9	165-020/26	04026575415366	Size 16, 170 mm Length, 43.5 mm Offset
10	292-126/26	04026575436422	Size 18, 180 mm Length, 44.5 mm Offset
11	292-127/26	04026575436415	Size 20, 190 mm Length, 45.0 mm Offset

LCU Hip Stems, cementless, medialized type, Ti6Al4V, HX Coating, taper 12/14, CCD angle 140°

Basic-UDI-DI: 4026575-1-HSP-001002-V2

#	Article number	UDI-DI	Description
12	298-120/26	04026575436392	Size 8, 115 mm Length
13	298-121/26	04026575436408	Size 9, 130 mm Length

LCU Hip Stems, cementless, lateralized type, + 7 mm offset, Ti6Al4V, HX Coating, taper 12/14, CCD angle 125°

Basic-UDI-DI: 4026575-1-HSP-001003-V5

#	Article number	UDI-DI	Description
14	165-112/26	04026575433629	Size 8, 115 mm Length, 45.0 mm Offset
15	165-113/26	04026575433636	Size 9, 130 mm Length, 45.5 mm Offset
16	165-114/26	04026575433643	Size 10, 140 mm Length, 46.2 mm Offset
17	165-115/26	04026575433650	Size 11, 145 mm Length, 47.0 mm Offset
18	165-116/26	04026575433667	Size 12, 150 mm Length, 47.7 mm Offset
19	165-117/26	04026575433674	Size 13, 155 mm Length, 48.5 mm Offset
20	165-118/26	04026575433681	Size 14, 160 mm Length, 49.0 mm Offset
21	165-119/26	04026575433698	Size 15, 165 mm Length, 50.0 mm Offset
22	165-120/26	04026575433735	Size 16, 170 mm Length, 50.5 mm Offset
23	292-186/26	04026575436361	Size 18, 180 mm Length, 51.5 mm Offset
24	292-187/26	04026575436378	Size 20, 190 mm Length, 52.0 mm Offset

LCU PoroLink Hip Stems, cementless, standard type, Ti6Al4V, taper 12/14, CCD angle 130°

Basic-UDI-DI: 4026575-1-HSP-001004-V8

#	Article number	UDI-DI	Description
25	165-312/26	04026575166824	Size 8, 115 mm Length, 38.0 mm Offset
26	165-313/26	04026575166831	Size 9, 130 mm Length, 38.5 mm Offset
27	165-314/26	04026575166848	Size 10, 140 mm Length, 39.2 mm Offset
28	165-315/26	04026575166855	Size 11, 145 mm Length, 40.0 mm Offset
29	165-316/26	04026575166862	Size 12, 150 mm Length, 40.7 mm Offset
30	165-317/26	04026575166879	Size 13, 155 mm Length, 41.5 mm Offset
31	165-318/26	04026575166886	Size 14, 160 mm Length, 42.0 mm Offset
32	165-319/26	04026575166893	Size 15, 165 mm Length, 43.0 mm Offset
33	165-320/26	04026575166909	Size 16, 170 mm Length, 43.5 mm Offset
34	165-321/26	04026575166916	Size 18, 180 mm Length, 44.5 mm Offset
35	165-322/26	04026575166923	Size 20, 190 mm Length, 45.0 mm Offset

LCU Porolink Hip Stems, cementless, lateralized type, + 7 mm offset, Ti6Al4V, taper 12/14, CCD angle 125°

Basic-UDI-DI: 4026575-1-HSP-001005-VB

#	Article number	UDI-DI	Description
36	165-412/26	04026575167340	Size 8, 115 mm Length, 45.0 mm Offset
37	165-413/26	04026575167357	Size 9, 130 mm Length, 45.5 mm Offset
38	165-414/26	04026575167364	Size 10, 140 mm Length, 46.2 mm Offset
39	165-415/26	04026575167371	Size 11, 145 mm Length, 47.0 mm Offset
40	165-416/26	04026575167388	Size 12, 150 mm Length, 47.7 mm Offset
41	165-417/26	04026575167395	Size 13, 155 mm Length, 48.5 mm Offset
42	165-418/26	04026575167401	Size 14, 160 mm Length, 49.0 mm Offset
43	165-419/26	04026575167418	Size 15, 165 mm Length, 50.0 mm Offset
44	165-420/26	04026575167425	Size 16, 170 mm Length, 50.5 mm Offset
45	165-421/26	04026575167432	Size 18, 180 mm Length, 51.5 mm Offset
46	165-422/26	04026575167449	Size 20, 190 mm Length, 52.0 mm Offset