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EU Technical Documentation Assessment Certificate

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company

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

SRN: DE-MF-000005215

has established and maintains a technical documentation for the medical devices listed in the appendix.

The compliance of this technical documentation to the requirements of the **Regulation (EU) 2017/745 on medical devices** was verified by assessment according to:

Annex IX Chapter II

Any applicable limitations of this certification for certain medical devices are included in the appendix. This certificate assumes that MEDCERT has to be informed about any changes of the assessed device. Changes need further approval by MEDCERT.

Effective date:	**2021-06-11**
Expiry date:	**2026-06-06**
Final assessment report No.:	20213IA01F
Procedure No.:	PP – 20213
Certificate No.:	20213GB450210611

Preceding certificate No.:	–
Preceding certificate date:	–
Identification of changes:	–

For conditions or for limitations to the validity refer to the relevant final assessment report.

Hamburg, 2021-06-11

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(Lorenz Runge)

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Appendix of EU Technical Documentation Assessment Certificate

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Class III medical devices

For placing on the market of class III medical devices covered by this certificate, an additional **EU Quality Management System Certificate according to Annex IX Chapter I** of Regulation (EU) 2017/745 is required.

Examinations and tests performed, e. g. reference to relevant common specifications, harmonised standards, test reports and audit report(s) are recorded in the technical documentation assessment report **20213IA01B**.

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

Intended purpose: 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.

Model (Device REF#)	Device name
298-120/26	Prosthesis stem, CaP coated, 140°, Size 8
298-121/26	Prosthesis stem, CaP coated, 140°, Size 9
298-130/26	Prosthesis stem, CaP coated, 140°, Size 8
298-131/26	Prosthesis stem, CaP coated, 140°, Size 9

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Appendix of EU Technical Documentation Assessment Certificate

Procedure No.: PP – 20213
Certificate No.: 20213GB450210611

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

Intended purpose: 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.

Model (Device REF#)	Device name
165-012/26	Prosthesis stem, CaP coated, 130°, Size 8
165-013/26	Prosthesis stem, CaP coated, 130°, Size 9
165-014/26	Prosthesis stem, CaP coated, 130°, Size 10
165-015/26	Prosthesis stem, CaP coated, 130°, Size 11
165-016/26	Prosthesis stem, CaP coated, 130°, Size 12
165-017/26	Prosthesis stem, CaP coated, 130°, Size 13
165-018/26	Prosthesis stem, CaP coated, 130°, Size 14
165-019/26	Prosthesis stem, CaP coated, 130°, Size 15
165-020/26	Prosthesis stem, CaP coated, 130°, Size 16
292-126/26	Prosthesis stem, CaP coated, 130°, Size 18
292-127/26	Prosthesis stem, CaP coated, 130°, Size 20
215-001/30	Prosthesis stem, CaP coated, 130°, Size 8
215-004/30	Prosthesis stem, CaP coated, 130°, Size 9
215-007/30	Prosthesis stem, CaP coated, 130°, Size 10
215-008/30	Prosthesis stem, CaP coated, 130°, Size 11
215-010/30	Prosthesis stem, CaP coated, 130°, Size 12
265-123/30	Prosthesis stem, CaP coated, 130°, Size 13
265-124/30	Prosthesis stem, CaP coated, 130°, Size 14
265-125/30	Prosthesis stem, CaP coated, 130°, Size 15
265-126/30	Prosthesis stem, CaP coated, 130°, Size 16
265-127/30	Prosthesis stem, CaP coated, 130°, Size 18
265-128/30	Prosthesis stem, CaP coated, 130°, Size 20

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Procedure No.: PP – 20213
Certificate No.: 20213GB450210611

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

Intended purpose: 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.

Model (Device REF#)	Device name
165-112/26	Prosthesis stem, CaP coated, 125°, Size 8
165-113/26	Prosthesis stem, CaP coated, 125°, Size 9
165-114/26	Prosthesis stem, CaP coated, 125°, Size 10
165-115/26	Prosthesis stem, CaP coated, 125°, Size 11
165-116/26	Prosthesis stem, CaP coated, 125°, Size 12
165-117/26	Prosthesis stem, CaP coated, 125°, Size 13
165-118/26	Prosthesis stem, CaP coated, 125°, Size 14
165-119/26	Prosthesis stem, CaP coated, 125°, Size 15
165-120/26	Prosthesis stem, CaP coated, 125°, Size 16
292-186/26	Prosthesis stem, CaP coated, 125°, Size 18
292-187/26	Prosthesis stem, CaP coated, 125°, Size 20
265-018/26	Prosthesis stem, CaP coated, 125°, Size 8
265-019/26	Prosthesis stem, CaP coated, 125°, Size 9
265-020/26	Prosthesis stem, CaP coated, 125°, Size 10
265-021/26	Prosthesis stem, CaP coated, 125°, Size 11
265-022/26	Prosthesis stem, CaP coated, 125°, Size 12
265-023/26	Prosthesis stem, CaP coated, 125°, Size 13
265-024/26	Prosthesis stem, CaP coated, 125°, Size 14
265-025/26	Prosthesis stem, CaP coated, 125°, Size 15
265-026/26	Prosthesis stem, CaP coated, 125°, Size 16
265-027/26	Prosthesis stem, CaP coated, 125°, Size 18
265-028/26	Prosthesis stem, CaP coated, 125°, Size 20

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Procedure No.: PP – 20213
Certificate No.: 20213GB450210611

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

Intended purpose: 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.

Model (Device REF#)	Device name
165-312/26	Prosthesis stem, microporous, 130°, Size 8
165-313/26	Prosthesis stem, microporous, 130°, Size 9
165-314/26	Prosthesis stem, microporous, 130°, Size 10
165-315/26	Prosthesis stem, microporous, 130°, Size 11
165-316/26	Prosthesis stem, microporous, 130°, Size 12
165-317/26	Prosthesis stem, microporous, 130°, Size 13
165-318/26	Prosthesis stem, microporous, 130°, Size 14
165-319/26	Prosthesis stem, microporous, 130°, Size 15
165-320/26	Prosthesis stem, microporous, 130°, Size 16
165-321/26	Prosthesis stem, microporous, 130°, Size 18
165-322/26	Prosthesis stem, microporous, 130°, Size 20
210-001/30	Prosthesis stem, microporous, 130°, Size 8
210-004/30	Prosthesis stem, microporous, 130°, Size 9
210-007/30	Prosthesis stem, microporous, 130°, Size 10
210-008/30	Prosthesis stem, microporous, 130°, Size 11
210-010/30	Prosthesis stem, microporous, 130°, Size 12
265-109/30	Prosthesis stem, microporous, 130°, Size 13
265-110/30	Prosthesis stem, microporous, 130°, Size 14
265-111/30	Prosthesis stem, microporous, 130°, Size 15
265-112/30	Prosthesis stem, microporous, 130°, Size 16
265-113/30	Prosthesis stem, microporous, 130°, Size 18
265-114/30	Prosthesis stem, microporous, 130°, Size 20

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Procedure No.: PP – 20213
Certificate No.: 20213GB450210611

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

Intended purpose: 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.

Model (Device REF#)	Device name
165-412/26	Prosthesis stem, microporous, 125°, Size 8
165-413/26	Prosthesis stem, microporous, 125°, Size 9
165-414/26	Prosthesis stem, microporous, 125°, Size 10
165-415/26	Prosthesis stem, microporous, 125°, Size 11
165-416/26	Prosthesis stem, microporous, 125°, Size 12
165-417/26	Prosthesis stem, microporous, 125°, Size 13
165-418/26	Prosthesis stem, microporous, 125°, Size 14
165-419/26	Prosthesis stem, microporous, 125°, Size 15
165-420/26	Prosthesis stem, microporous, 125°, Size 16
165-421/26	Prosthesis stem, microporous, 125°, Size 18
165-422/26	Prosthesis stem, microporous, 125°, Size 20
265-004/26	Prosthesis stem, microporous, 125°, Size 8
265-005/26	Prosthesis stem, microporous, 125°, Size 9
265-006/26	Prosthesis stem, microporous, 125°, Size 10
265-007/26	Prosthesis stem, microporous, 125°, Size 11
265-008/26	Prosthesis stem, microporous, 125°, Size 12
265-009/26	Prosthesis stem, microporous, 125°, Size 13
265-010/26	Prosthesis stem, microporous, 125°, Size 14
265-011/26	Prosthesis stem, microporous, 125°, Size 15
265-012/26	Prosthesis stem, microporous, 125°, Size 16
265-013/26	Prosthesis stem, microporous, 125°, Size 18
265-014/26	Prosthesis stem, microporous, 125°, Size 20

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