

EU Quality Management System 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: not available

with locations listed in the appendix

has introduced, applies and maintains a quality management system for the medical devices/groups of medical devices listed in the appendix.

The compliance of this quality management system to the requirements of the
Regulation (EU) 2017/745 on medical devices was verified by assessment according to:

Annex IX Chapter I

Any applicable limitations of this certification for certain medical devices are included in the appendix. This certification is subject to surveillance by MEDCERT.

Effective date: 2021-02-26

Expiry date: 2025-09-30

Final assessment report No.: 7402IA06F

Procedure No.: QS – 7402

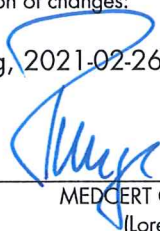
Certificate No.: 7402GB448210226A

Preceding certificate No.: —

Preceding certificate date: —

Identification of changes: —

Hamburg, 2021-02-26



MEDCERT Certification Body
(Lorenz Runge)

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Appendix of EU Quality Management System Certificate

Procedure No.: QS – 7402

Certificate No.: 7402GB448210226A

Locations included in the scope of certificate

Waldemar Link GmbH & Co. KG – Production (Plant 1)
Oststraße 4 - 10
22844 Norderstedt
Germany

Waldemar Link GmbH & Co. KG – Production (Plant 2)
Harckesheyde 95
22844 Norderstedt
Germany

Waldemar Link GmbH & Co. KG – Production (Plant 3)
Werkstraße 7
22844 Norderstedt
Germany

Waldemar Link GmbH & Co. KG – Warehouse
Oststraße 1
22844 Norderstedt
Germany

DERU GmbH
Oststraße 4 - 10
22844 Norderstedt
Germany

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Procedure No.: QS – 7402

Certificate No.: 7402GB448210226A

Class I reusable medical devices

For class I reusable medical devices, the certification only covers the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing, and the related instructions.

Category of devices	Medical devices/groups of medical devices
MDN 1208	Non-active non-implantable instruments

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Appendix of EU Quality Management System Certificate

Procedure No.: QS – 7402

Certificate No.: 7402GB448210226A

Class IIa medical devices

Category of devices	Medical devices/groups of medical devices
MDN 1208	L0911 Orthopaedic prostheses instruments, reusable

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Procedure No.: QS – 7402

Certificate No.: 7402GB448210226A

Class III custom-made implantable devices

Category of devices	Medical devices/groups of medical devices
MDN 1102	Non-active osteo- and orthopaedic implants

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Class III medical devices

For placing on the market of the following class III medical devices covered by this certificate, an additional **EU Technical Documentation Assessment Certificate according to Annex IX Chapter II** of Regulation (EU) 2017/745 is required, which also contains the exact determination of medical devices covered by certification.

Category of devices	Medical devices/groups of medical devices
MDN 1102	Non-active osteo- and orthopaedic implants

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