MED CERT®

Certification. Medical Only.

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

Digitally signed by Muntean Dorian
Date: 2022.01.10 10:02:21 EET
Reason: MoldSign Signature
Location: Moldova

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)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-096

MEDCERT Identification Number: 0482

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Appendix of EU Quality Management System Certificate

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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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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

This appendix is integral part of the above-referenced certificate.
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Class IIa medical devices

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

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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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