MEDCERT®

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

GO German Orthopedic Implants GmbH
Barkhausenweg 10
22339 Hamburg
Germany

SRN: DE-MF-000006328

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:	**2021-06-11**
Expiry date:	**2025-11-09**
Final assessment report No.:	7353IA06F
Procedure No.:	QS – 7353
Certificate No.:	7353GB448210611
Preceding certificate No.:	–
Preceding certificate date:	–
Identification of changes:	–

Hamburg, 2021-06-11

MEDCERT Certification Body
(Lorenz Runge)

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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 Notified Body 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

Oststraße 1
22844 Norderstedt
Germany

Oststraße 4 - 10
22844 Norderstedt
Germany

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Class I medical devices

For class I medical devices that are reusable surgical instruments (class Ir), the audit of the quality management system was limited to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilisation, maintenance and functional testing, and the related instructions for use.

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

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Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN 1208	**L091199**	Orthopaedic prostheses instruments, reusable - others

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

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