EU Quality Management System Certificate

Certificate no.	Final Assessment Report no.	Effective date	Expiry date
0529GB448240423	0529AU33F	2024-04-23	2025-12-03

This is to certify that the quality system of

OHST Medizintechnik AG

Grünauer Fenn 3, 14712 Rathenow, Germany

SRN: DE-MF-000008887

For design, production, and final product inspection/testing of

Medical devices/groups of medical devices listed on the following pages

Has been assessed and found to comply with respect to

The conformity assessment procedure described in Annex IX, Chapters I and III of Regulation (EU) 2017/745 on Medical Devices

Any applicable limitations for certain medical devices are included in the following list or recorded in the final assessment report. This certification is subject to surveillance by DNV MEDCERT.

Place and date
Hamburg, 2024-04-23

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

For the issuing office
DNV MEDCERT GmbH – Notified Body 0482
Pilatuspool 2, 20355 Hamburg, Germany

Lorenz Runge
Director Certification Body

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact Medcert-Info@dnv.com

Certificate no.: 0529GB448240423
Place and date: Hamburg, 2024-04-23

Preceding certificate

Certificate no.	Issue date	Identification of changes
0529GB448220825	2022-08-25	Extension by Class IIb implantable

Sites covered by this certificate

OHST Medizintechnik AG, Grünauer Fenn 3, 14712 Rathenow, Germany

NOTIFIED BODY 0482: DNV MEDCERT GmbH (previously: MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH)
Pilatuspool 2, 20355 Hamburg, Germany, Tel +49 40 2263325-0, www.med-cert.com, www.dnv.com

Certificate no.: 0529GB448240423
Place and date: Hamburg, 2024-04-23

Products covered by this certificate

Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN 1208	L091199	Orthopaedic prosthetics instruments, reusable - other

Class III custom-made implantable medical devices

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

Class IIb implantable non-WET* medical devices

For placing on the market of class IIb implantable 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

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

* Excluding WET (well-established technology) devices exempted according to Article 52 (4 and 5) from the requirement of assessment of technical documentation for every device.