EU Quality Management System Certificate

Certificate no.	Final Assessment Report no.	Effective date	Expiry date
7092GB448221006A	7092AU14F	2022-12-05	2026-01-02

This is to certify that the quality system of

implantcast GmbH

Lüneburger Schanze 26, 21614 Buxtehude, Germany

SRN: DE-MF-000010002

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 Chapter I 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, 2022-12-05

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 info@medcert.de

Certificate no.: 7092GB448221006A
Place and date: Hamburg, 2022-12-05

Preceding certificate

Certificate no.	Issue date	Identification of changes
7092GB448221006	2022-10-06	Typo DNV MEDCERT intern

Sites covered by this certificate

implantcast GmbH, Lüneburger Schanze 26, 21614 Buxtehude, Germany

implantcast GmbH, Alter Postweg 10b, 21614 Buxtehude, Germany

Certificate no.: 7092GB448221006A
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Products covered by this certificate

Class I medical devices

For class I medical devices placed on the market in sterile condition (class Is), the audit of the quality management system was limited to the aspects relating to establishing, securing, and maintaining sterile conditions.

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	Class	Medical devices/groups of medical devices
————	Is	Sterile Systems and procedure packs
MDN 1208	Ir	Non-active non-implantable instruments

Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN 1208	L091199	Orthopaedic prosthetics instruments, reusable - other
MDN 1208	Z121305	Motorised orthopaedic surgery system instruments
MDN 1208	L091001	Instruments for insertion and extraction of materials for osteosynthesis, reusable
MDN 1208	L030199	General surgery surgical cannulas and handpieces, reusable - other
MDN 1208	L091201	Orthopaedic surgery rasps, reusable
MDN 1208	Z121390	Various orthopaedic and traumatology instruments
MDN 1208	L091102	Orthopaedic prostheses reamers and burs, reusable

Class III custom-made implantable medical devices

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