

EU Quality Management System Certificate

Certificate no.
7531GB448231219

Final Assessment Report no.
7531AU04F

Effective date
2023-12-19

Expiry date
2027-12-08

This is to certify that the quality system of

Bisico GmbH

Johanneswerkstraße 3, 33611 Bielefeld, Germany

SRN: DE-MF-000005871

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, 2023-12-19

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



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

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


Lorenz Runge
Director Certification Body



DNV

Certificate no.: 7531GB448231219
Place and date: Hamburg, 2023-12-19

Preceding certificate

Certificate no.	Issue date	Identification of changes
n/a	n/a	n/a

Sites covered by this certificate

Bisico GmbH, Johanneswerkstraße 3, 33611 Bielefeld, Germany





Certificate no.: [7531GB448231219](#)
Place and date: [Hamburg, 2023-12-19](#)

Products covered by this certificate

Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN 1103	Q0101	Devices for conservative dentistry and endodontics
MDN 1103	Q0102	Devices for prosthetic dentistry
MDN 1209	Q0101	Devices for conservative dentistry and endodontics
MDN 1209	Q0102	Devices for prosthetic dentistry
MDN 1209	Q0105	Instruments for dentistry, single-use
MDN 1214	Q0304	Otology devices
MDN 1214	Z121390	Various orthopaedic and traumatology instruments

