

EU Quality Management System Certificate

Certificate no.
4193GB448240604

Final Assessment Report no.
4193AU17F

Effective date
2024-06-04

Expiry date
2027-12-21

This is to certify that the quality system of

indigodental GmbH

Fahltskamp 5, 25421 Pinneberg, Germany

SRN: DE-MF-000005265

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

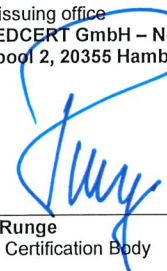
Any applicable limitations for certain medical devices are included in the following list or recorded in the final assessment report. This certification is subject to surveillance by DNV MEDCERT.

Place and date
Hamburg, 2024-06-04

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



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



DNV

Certificate no.: [4193GB448240604](#)
Place and date: [Hamburg, 2024-06-04](#)

Preceding certificate

Certificate no.	Issue date	Identification of changes
4193GB448240209	2024-02-09	Addition of MDN 1209

Sites covered by this certificate

indigodental GmbH, Fahltskamp 5, 25421 Pinneberg, Germany





Certificate no.: [4193GB448240604](#)
Place and date: [Hamburg, 2024-06-04](#)

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 1103	Q0190	Dental devices - various
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 1209	Q0106	Materials for the preparation of custom-made dental devices
MDN 1209	Q0199	Odontology devices - other

