For electronic distribution only
Nur zur elektronischen Verbreitung

EU Quality Management System Certificate

We hereby certify the company

Dentaurum GmbH & Co. KG
Turnstraße 31
75228 Ispringen
Germany

the introduction and application of a quality management system in accordance with Annex IX, Chapter I and III of Regulation (EU) 2017/745 for conformity assessment.

An audit by mdc has proven that this quality management system meets the following requirements:

Annex IX – Chapter I (Quality Management System)

of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Surveillance is carried out in accordance with Annex IX, Section 3 of Regulation (EU) 2017/745.

This certificate from mdc medical device certification GmbH (Notified Body 0483) consists of 7 pages. Details about the devices covered as well as further information and conditions are contained on the following pages.

Valid from	2026-06-10	Registration No.	D1002600051
Valid until	2028-02-02	Report No.	P24-00814-361609

Stuttgart, 2026-06-10

Notified Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-098

Devices:

nickel-chromium dental alloys

Risk class: IIa

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nickel-chromium joining materials

Risk class: IIa

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cobalt-chromium dental alloys

Risk class: IIa

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cobalt-chromium joining materials

Risk class: IIa

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titanium for prosthetics

Risk class: IIa

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titanium expansion screws, stainless steel expansion screws

Risk class: IIa

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titanium brackets, ceramic brackets, stainless steel brackets

Risk class: IIa

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titanium buccal tubes, stainless steel buccal tubes

Risk class: IIa

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accessories for brackets made of titanium and stainless steel

Risk class: IIa

pre-welded parts

Risk class: IIa

bands

Risk class: IIa

class II appliances

Risk class: IIa

accessories for class II appliances

Risk class: IIa

distalization appliances

Risk class: IIa

accessories for distalization appliances

Risk class: IIa

arches

Risk class: IIa

wires

Risk class: IIa

wire elements

Risk class: IIa

dental ceramics

Risk class: IIa

liquids for dental ceramics

Risk class: IIa

orthodontic endosseous anchoring elements

Intended purpose: Orthodontic endosteal anchorage elements are inserted into the jawbone to serve as a temporary anchor.

Risk class: IIb

abutments

Intended purpose: Abutments serve as a connection piece between an orthodontic endosteal anchorage element and orthodontic coupling elements

Risk class: IIb

orthodontic coupling elements

Risk class: IIa

dental instruments

Risk class: IIa

locking screws

Intended purpose: The connection screws serve as a connection piece between the orthodontic endosteal anchorage element and the abutment

Risk class: IIb

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orthodontic instrument tray

Risk class: IIa

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set of orthodontic coupling elements

Risk class: IIa

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osteotomes

Risk class: I (reusable)

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components for impression-taking

Risk class: IIa

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o-ring matrices

Risk class: IIa

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components for planning and diagnosis

Risk class: IIa

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components for instruments

Risk class: IIa

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screws

Intended purpose: Screws are used to fix abutments on the implants

Risk class: IIb

screws

Risk class: IIa

surgical instrument tray

Risk class: IIa

dental implants

Intended purpose: Implants are designed for insertion in the endosteal region of the maxilla or mandible. They are used for anchoring functional and aesthetic oral rehabilitations

Risk class: IIb

abutments

Intended purpose: Abutments are intended to connect the implants with the prosthetic restoration.

Risk class: IIb

closure screws

Intended purpose: Closure screws are intended to close the inserted implant or abutment during the healing period to prevent penetration of saliva.

Risk class: IIb

gingivaformer

Intended purpose: Gingiva formers are intended to close the inserted implant during the healing period to prevent penetration of saliva and to shape the surrounding soft tissue for the subsequent prosthetic restoration.

Risk class: IIb

dental ceramic blanks

Risk class: IIa

Orthodontic acrylics

Risk class: IIa

Otoplastic acrylics

Risk class: IIa

Notes:

In the case of class I devices that are reusable surgical instruments the involvement of mdc is limited to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing as well as the related instructions for use.

For the placing on the market of class III and IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors within the meaning of Regulation (EU) 2017/745, Art. 52 (4), 2nd paragraph and with the exception of custom-made devices of class III), an EU technical documentation assessment certificate is also required.

The certificate is based on the previous certificate

D1002600042 (2023-02-03)
D1002600044 (2023-03-20)
D1002600049 (2025-12-23)

with the following changes to D1002600049:
Supplemented by: Orthodontic acrylics and Otoplastic acrylics