EU Quality Management System Certificate

We hereby certify the company

Dentaurum GmbH & Co. KG
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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	2025-12-23	Registration No.	D1002600049
Valid until	2028-02-02	Report No.	P24-00814-301950

Stuttgart, 2025-12-23

Notified Body

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

Devices:

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nickel-chromium dental alloys

Risk class: IIa

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cobalt-chromium dental alloys

Risk class: IIa

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titanium for prosthetics

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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titanium expansion screws, stainless steel expansion screws

Risk class: IIa

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accessories for brackets made of titanium and stainless steel

Risk class: IIa

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bands

Risk class: IIa

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class II appliances

Risk class: IIa

distalization appliances

Risk class: IIa

accessories for distalization appliances

Risk class: IIa

accessories for class II appliances

Risk class: IIa

pre-welded parts

Risk class: IIa

nickel-chromium joining materials

Risk class: IIa

cobalt-chromium joining materials

Risk class: IIa

osteotomes

Risk class: I (reusable)

components for impression-taking

Risk class: IIa

o-ring matrices

Risk class: IIa

components for planning and diagnosis

Risk class: IIa

screws

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

Risk class: IIb

components for instruments

Risk class: IIa

surgical instrument tray

Risk class: IIa

abutments

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

Risk class: IIb

dental instruments

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

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 ceramics

Risk class: IIa

arches

Risk class: IIa

wires

Risk class: IIa

wire elements

Risk class: IIa

orthodontic endosteal anchorage elements

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

Risk class: IIb

orthodontic instrument tray

Risk class: IIa

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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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set of orthodontic coupling elements

Risk class: IIa

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dental ceramic blanks

Risk class: IIa

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liquids for dental ceramics

Risk class: IIa

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screws

Risk class: IIa

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orthodontic coupling elements

Risk class: IIa

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abutments

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

Risk class: IIb

Notes:

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)

with the following changes to D1002600044:
Supplemented by the following products:
arches, wires, wire elements, dental ceramics, liquids for dental ceramics, orthodontic endosteal anchorage elements, abutments, orthodontic coupling elements, dental instruments, locking screws, orthodontic instrument tray, set of orthodontic coupling elements, osteotomes, components for impression-taking, o-ring matrices, components for planning and diagnosis, components for instruments, screws, surgical instrument tray, dental implants, abutments, closure screws, gingivaformer, dental ceramic blanks