

EU Quality Management System Certificate

mdc medical device certification GmbH

Kriegerstr. 6, 70191 Stuttgart, Germany
Notified body (identification number 0483)

hereby certifies that the company (SRN: DE-MF-000006299)

Dentaurum GmbH & Co. KG

Hörnstraße 31
71228 Ispringen
Germany

has implemented and applies a quality management system in accordance with Annex IX, Chapter I and III of Regulation (EU) 2017/745 for conformity assessment of the devices listed on the following pages.

An audit by mdc has proven that this quality management system fulfils 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 consists of 3 pages. Details of the devices affected by this certificate as well as further information and conditions are included on the following pages.

Valid from: 2023-03-20
Valid until: 2028-02-02

Registration No. D1002600044
Evaluation Report No. P22-01165-261976

Stuttgart, 2023-03-20

Head of Notified Body



Dieses Dokument wurde von
In Deutschland / In der EU
Stelle / Institution / Behörde



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

Industrie- und Handelskammer Nordschwarzwald
Pforzheim

Im Auftrag:

2023 Dez. 12.

(Behnisch)



APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Land: **Bundesrepublik Deutschland**
Country, Pays

Diese öffentliche Urkunde

This public document, Le présent acte public

2. ist unterschrieben von **Herrn T. Behnisch**
has been signed by, a été signé par

3. in seiner Eigenschaft als **Sachbearbeiter**
acting in the capacity of, agissant en qualité de

4. sie ist versehen mit dem Siegel/Stempel des (der)
bears the seal/stamp of, est revêtu du sceau/timbre de
Industrie- und Handelskammer Nordschwarzwald

Bestätigt

Certified, Attesté

5. in **Karlsruhe**
at, à

6. am **23. Januar 2024**
the, le

7. durch **Regierungspräsidium Karlsruhe**
by, par

8. unter Nr. **232/2024**
N°, sous N°

9. Siegel/Stempel:
Seal/Stamp, Sceau/timbre

10. Unterschrift:
Signature

Schlump
(Beschäftigte)



Devices:

Product:
nickel-chromium dental alloys

Risk class: IIa

Product:
nickel-chromium joining materials

Risk class: IIa

Product:
cobalt-chromium dental alloys

Risk class: IIa

Product:
cobalt-chromium joining materials

Risk class: IIa

Product:
titanium for prosthetics

Risk class: IIa

Product:
titanium expansion screws, stainless steel expansion screws

Risk class: IIa

Product:
titanium brackets, ceramic brackets, stainless steel brackets

Risk class: IIa

Product:
titanium buccal tubes, stainless steel buccal tubes

Risk class: IIa

Product:
accessories for brackets made of titanium and stainless steel

Risk class: IIa

Product:
pre-welded parts

Risk class: IIa

Product:
bands

Risk class: IIa

Product:
class II appliances

Risk class: IIa

Product:
accessories for class II appliances

Risk class: IIa

Product:
distalization appliances

Risk class: IIa

Product:
accessories for distalization appliances

Risk class: IIa

Notes:

The certificate is based on the previous certificate D1002600042 dated 03.02.2023 with the following changes:

Supplemented by the products:

- nickel-chromium joining materials
- cobalt-chromium joining materials
- titanium expansion screws, stainless steel expansion screws (TD 6)
- titanium brackets, ceramic brackets, stainless steel brackets (TD 6)
- titanium buccal tubes, stainless steel buccal tubes (TD 5)
- accessories for brackets made of titanium and stainless steel (TD 6)
- pre-welded parts (TD 6)
- bands (TD 6)
- class II appliances (TD 7)
- accessories for class II appliances (TD 7)
- distalization appliances (TD 7)
- accessories for distalization appliances (TD 7)

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