

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

**Dentaurum GmbH & Co. KG
Turnstraße 31
75228 Ispringen
Germany**

for the scope

product class IIa: titanium brackets, titanium buccal tubes, titanium expansion screws, titanium for prosthetics, titanium anchorage elements, ceramic brackets, plastic brackets, stainless steel brackets, stainless steel expansion screws, stainless steel buccal tubes, mesh bases, prewelded accessories, wires, arches, wire elements, tubes, bands, bracket adhesives, dental ceramics, rotating instruments, orthodontic elements for fixed appliances, CoCr-dental alloys, NiCr-dental alloys, orthodontic and earmould based plastics,
product class IIb: orthodontic implants, orthodontic anchorage systems

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system
meets all requirements according to

Annex II – excluding Section 4 of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2020-06-03
Valid until	2023-12-17
Registration no.	D1002600038
Report no.	P19-00702-147244
Stuttgart	2020-06-03


Head of Certification Body



Certificate

mdc medical device certification GmbH
certifies that



Dentaurum GmbH & Co. KG
Turnstraße 31
75228 Ispringen
Germany

for the scope

**design, manufacture and distribution of products for
orthodontics and dental technology as well as dental implants and
products for oral maxillary**

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system
meets all requirements of the following standard

EN ISO 9001

Quality management systems –
Requirements

(ISO 9001:2015)

Valid from	2021-12-03
Valid until	2024-11-30
Registration no.	D1002600040
Report no.	P21-01352-213171
Stuttgart	2021-12-03




Head of Certification Body



Certificate

mdc medical device certification GmbH
certifies that



Dentaurum GmbH & Co. KG
Turnstraße 31
75228 Ispringen
Germany

for the scope

**design, manufacture and distribution of medical devices for
orthodontics and dental technology as well as dental implants and
products for oral maxillary**

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system
meets all requirements of the following standard

EN ISO 13485

**Medical devices – Quality management systems –
Requirements for regulatory purposes**

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Valid from	2021-12-04
Valid until	2024-12-03
Registration no.	D1002600039
Report no.	P21-01352-213169
Stuttgart	2021-12-03

Head of Certification Body



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

Turnstraße 31
75228 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	Registration No.	D1002600044
Valid until:	2028-02-02	Evaluation Report No.	P22-01165-261976

Stuttgart, 2023-03-20


Head of Notified Body

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)