

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, preweld accessoires, 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



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