TÜVNORD

EU-Quality Management System Certificate

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX, Chapters I and III

The Notified Body of TÜV NORD CERT GmbH certifies that the manufacturer

Dreve Dentamid GmbH
Max-Planck-Straße 31
59423 Unna
Germany

has established, documented and implemented a quality management system in accordance with Article 10, paragraph 9 of Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The conformity assessment has been carried out and successfully completed in accordance with Annex IX, Chapters I and III. The result of the assessment, references to investigations carried out, relevant common specifications and test reports are summarised in the report mentioned below. The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The validity of this certificate is based on the maintenance of the quality management system in accordance with the requirements of the Regulation and its regular surveillance by the Notified Body in accordance with Annex IX, Chapter I, Section 3. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.

In addition to the CE marking, the identification number of the Notified Body must be affixed to the devices.

For the placing on the market of class III and Class IIb implantable devices an additional EU technical documentation assessment certificate according to Annex IX, Chapter II is required.

Single Registration Number of the Manufacturer (SRN):	DE-MF-000005452
Authorised Representative:	--
The validity of this EU Certificate depends on conditions and / or is limited to the following:	--
List of Products, Risk Classification and Details:	see Section 2
Certificate history:	see Section 3

Reg.-No.: 44 911 220477
Certification decision report No.: 3536 9216

Edition:	2
Issue date:	2023-04-19
First issued:	2023-12-05
Valid until:	2028-12-05

Essen, 2024-04-19

TÜV NORD CERT GmbH is a Notified Body with identification number 0044

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TÜV®

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-095

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Reg. No. 44 911 220477 Section 2, List of Products

Class IIa

Product name	Category of device (MDx)	Technical documentation assessment report number
Temporary dental teeth material / *Provisorisches Zahnmaterial Dentamid*	MDN 1103	3533 9774
Impression silicones / *Abformsilikon* Bite registrates / *Bissregistrat* Dental splinting material (long-term) / *Dentales Schienungsmaterial (langzeit)* Dental splinting material 3D printing / *Dentales Schienungsmaterial 3D-Druck* Elasto-positioner / *Elasto-Positioner* FotoDent® resins 3D printing drill guides (surgical) / *FotoDent® Kunststoffe Bohrschablone 3D-Druck* FotoDent® resins 3D printing denture base / *FotoDent® Kunststoffe Prothesenbase 3D-Druck* Light-curing lacquers / *Lichthärtende Lacke* Denture base pouring resins / *Prothesengießkunststoff* Relining silicones / *Unterfütterungssilikon*	MDN 1209	3533 9777

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Reg. No. 44 911 220477 Section 3, Certificate History

Certificate History

Edition	Date	Action leading to revision	Certification decision report number
1	2023-12-05	Initial Issuance	3535 7179
2	2023-04-19	Notification Change 001 (Product extension) / Amendment of the English product group names	3536 9216

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