# 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.: 44911220477
Certification decision report No.: 35357179

| | |
|---|---|
| Edition: | 1 |
| Issue date: | 2023-12-05 |
| First issued: | 2023-12-05 |
| Valid until: | 2028-12-04 |

Essen, 2023-12-05

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

TÜVNORDGROUP

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Annex IX, Chapters I and III

Reg. No. 44911220477 Section 2, List of Products

**Class IIa**

| Product name | Category of device (MDx) | Technical documentation assessment report number |
|---|---|---|
| Provisorisches Zahnmaterial Dentamid | MDN 1103 | 35339774 |
| Abformsilikon Dentamid<br>Bissregistrat Dentamid<br>Dentales Schienungsmaterial (langzeit)<br>Dentales Schienungsmaterial 3D-Druck<br>Elasto-Positioner Dentamid<br>FotoDent Kunststoffe Bohrschablone 3D-Druck Klasse IIa (chirurgisch)<br>FotoDent Kunststoffe Prothesenbase 3D-Druck<br>Lichthärtende Lacke Klasse IIa Dentamid<br>Prothesengießkunststoff Dentamid<br>Unterfütterungssilikon Dentamid | MDN 1209 | 35339777 |



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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 | 35357179 |



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