

# Certificate

acc. to **ISO 13485:2016**

**Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes**

**Certificate Registration No.: 19-1633-M**

TUV USA, Inc. hereby certifies that the quality management system of the company mentioned below is in conformance with ISO 13485:2016 under MDSAP for Medical Devices Requirements under the following jurisdictions:

**Australia:** Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure. **Brazil:** RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021, RDC ANVISA n. 67/2009. **Canada:** Medical Devices Regulations – Part 1- SOR/98-282. **Japan:** MHLW Ministerial Ordinance 169, Article 4 to Article 68. **USA:** United States: 21 CFR 803; 21 CFR 806; 21 CFR 807 – Subparts A to D; 21 CFR 820.

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

Facility ID: **F005234**

Additional sites covered by QM System: **N/A**

List of Products: **See Annex 1**

Scope: **s**

**Design and development, manufacture and distribution of medical devices for dental applications (3D printing, thermoforming technique, silicones, resins, light polymerization, cleaning products)**

The validity of this certification document can be obtained by contacting the TUV USA, Inc. Office.

**TUV USA, Inc. (a Member of the TÜV NORD Group)**

**215 Main Street, Suite 1, Salem, NH 03079, USA**

**Tel: 001-603-870-8023, Fax: 001-603-870-8026, Email: [medical-usa@tuv-nord.com](mailto:medical-usa@tuv-nord.com)**

*TUV USA, Inc. is an MDSAP Recognised Auditing Organization*



**Audit Report Reference No.: 21-3967 RC-SA3**

**Initial Certification Date: 2019-12-15**

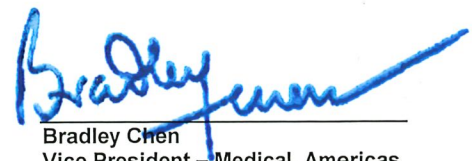
**Current Cycle Start Date: 2022-12-15**

**Effective Date:**

**2022-12-15 / ed. 2**

**Valid Until:**

**2025-12-14**



**Bradley Chen**  
Vice President – Medical, Americas  
Medical Products Division  
TUV USA, Inc.

**Annex 1, page 1 of 2**

*(Annex 1 MUST be displayed with the main certificate)*

**Certificate Registration No. :** 19-1633-M / ed. 2  
**Company Name:** Dreve Dentamid GmbH  
**Central (HQ) Office Address:** Max-Planck-Straße 31, 59423 Unna, Germany



<b>Products</b>	<b>UMDNS</b>	<b>GMDN</b>
Dentures, partial (Dental acrylic resin)	17-845	63591
Dental impression material, silicone	16-679	35866
Bite registration material	16-679	38602
Dental material mixing nozzle, non-sterile	19-671	58399
Denture, Varnish (Dental restorative material varnish)	17-845	45294
Restorative material kits, dental crown and bridge (Dental crown bridge polymer, temporary)	16-733	45236
Denture relining hard (Denture reliner, hard)	17-609	17609
Denture relining soft (Denture reliner, soft, professional)	17-610	17610
Cleaner, denture (Orthodontic appliance cleaner)	16-715	44736
Dental splinting materials (Dental appliance fabrication material, thermoplastic)	16-697	58288

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<b>Products</b>	<b>UMDNS</b>	<b>GMDN</b>
Prosthesis implantation instrument, dental (Dental appliance fabrication material, cured)	17-992	16730
Dental hand instruments, orthodontic (Orthodontic appliance positioning mould, basic)	16-664	63997
Dental impression tray material	16350	58106
Universal dental resins and equipment (dental laboratory use) [JMDN: 70750010, 70891000, 70682000, 35761000, 34811000]	N/A	N/A

---End of list---

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