

# Certificate

acc. to **ISO 13485:2016**

Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

Certificate Registration No.: **19-1612-Q**

TUV USA, Inc. hereby certifies that the quality management system of the company mentioned below is in conformance with **ISO 13485:2016** for Medical Devices-Quality Management Systems-Requirements for Regulatory Purposes.

**ULTRADENT**  
PRODUCTS, INC.

**Ultradent Products, Inc. / OraTech LLC**  
**505 West Ultradent Drive (10200 South)**  
**South Jordan, Utah 84095, USA**

Additional sites covered by QM System: [See Annex 1](#)

Scope:

**Design, Manufacturing, Distribution, and Servicing of Dental 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)



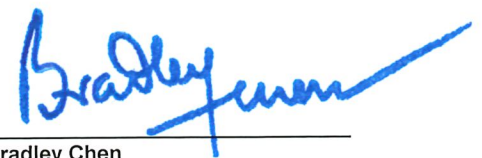
Audit Report Reference No.: **21-3982 RC-SA3**

Initial Certification Date: **2019-01-18**

Current Cycle Start Date: **2023-02-16**

Effective Date:  
**2023-02-16 / ed. 6**

Valid Until:  
**2026-02-15**



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

**Annex 1, page 1 of 1**

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

**Certificate Registration No. :** 19-1612-Q / ed. 6  
**Company Name:** Ultradent Products, Inc. / OraTech LLC  
**Central Office Address:** 505 West Ultradent Drive (10200 South)  
South Jordan, Utah 84095, USA



**Additional Sites covered by the QM System:**

<b>Location</b>	<b>Scope of Certification</b>
<b>Headquarters</b> <b>Ultradent Products, Inc.</b> 505 West Ultradent Drive (10200 South) South Jordan, Utah 84095, USA	Design, Manufacturing, and Distribution
<b>Site 1</b> <b>OraTech LLC</b> 10075 South Jordan Gateway South Jordan, Utah 84095, USA	Manufacturing and Servicing
<b>Site 2</b> <b>Ultradent Products, Inc. (The Tower)</b> 10235 South Jordan Gateway South Jordan, Utah 84095, USA	Sales, Marketing, IT Support, and Software Validation
<b>Site 3</b> <b>Ultradent Products, Inc.</b> <b>(Checker Warehouse)</b> 6620 West 2100 South Suite D (Unit 4) West Valley City, Utah 84128, USA	Warehousing

---End of list---

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