

# 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. / 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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