

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](#)

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

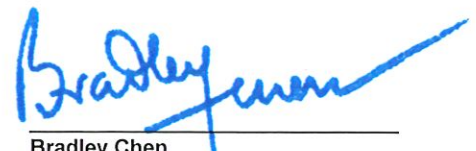
Tel: 001-603-870-8023, Fax: 001-603-870-8026, Email: medical-usa@tuv-nord.com



Audit Report Reference No.: **19-8064 RC**
Certificate Initial Issue Date: **18-JAN-2019**
Current Cycle Start Date: **03-AUG-2020**
Certificate Revised Date: **02-SEPT-2020**

Effective Date:
02-SEPT-2020 / ed. 5

Valid Until:
02-AUG-2023



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. 5
Company Name: **Ultradent Products Inc. / OraTech LLC**
Central Office Address: **505 West Ultradent Drive (10200 South), South Jordan, Utah 84095, USA**

Additional Site(s) covered by the QM System:

Location	Scope of Certification
Head Office: Ultradent Products Inc. 505 West Ultradent Drive (10200 South) South Jordan, Utah 84095, USA	Design, Manufacturing, and Distribution of Dental Products
Site 1: OraTech LLC 10075 South Jordan Gateway South Jordan, Utah 84095, USA	Manufacturing and Servicing of Dental Products
Site 2: Ultradent Products Inc. (The Towers) 10255 South Jordan Gateway South Jordan, Utah 84095, USA	Sales, Marketing, IT Support, and Software Validation

---End of List---

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

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