



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](#)

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.: **18-8069 CA**

Current Cycle Start Date: **18-JAN-2019**

Certificate Revised Date: **N/A**

Effective Date:

06-FEB-2019 / ed. 1

Valid Until:

17-JAN-2022

Bradley Chen
Director, Medical Products Division
TUV USA, Inc.



Annex 1, page 1 of 1
(Annex 1 MUST be displayed with the main certificate)

Certificate Registered No. : **19-1612-Q / ed. 1**
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
Ultradent Products Inc. / OraTech LLC 11075 South Jordan Gateway South Jordan, Utah 84095, USA	Design, Manufacturing, Distribution and Servicing of Dental Products.

---End of list---

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

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