

Certificate

acc. to ISO 13485:2016

Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

Certificate Registration No.: **19-1613-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. 16/2013; RDC ANVISA n. 23/2012; 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.



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

DUNS number: **01-336-9913**

Additional sites covered by QM System: **See Annex 1**

List of Products: **See Annex 2**

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

TUV USA, Inc. is an MDSAP Recognised Auditing Organization



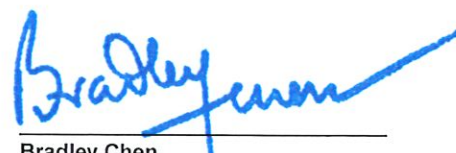
Audit Report Reference No.: **19-8064 RC**

Current Cycle Start Date: **2020-08-03**

Certificate Revised Date: **2020-09-02**

Effective Date:
2020-09-02 / ed. 3

Valid Until:
2023-08-02



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)



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Company Name: **Ultradent Products Inc. / OraTech LLC**

Central Office Address: **505 West Ultradent Drive (10200 South), South Jordan, Utah 84095, USA**

Location

Scope of Certification

Head Office:

Ultradent Products Inc.
505 West Ultradent Drive
(10200 South)
South Jordan, Utah 84095, USA
DUNS number: 01-336-9913

**Design, Manufacturing, and
Distribution of Dental Products**

Site 1:

OraTech LLC
10075 South Jordan Gateway
South Jordan, Utah 84095, USA
DUNS number: 01-336-9913

**Manufacturing and Servicing of
Dental Products**

Site 2:

**Ultradent Products Inc. (The
Towers)**
10255 South Jordan Gateway
South Jordan, Utah 84095, USA
DUNS number: 01-336-9913

**Sales, Marketing, IT Support, and
Software Validation**

---End of List---

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Annex 2, page 1 of 4

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Company Name: **Ultradent Products Inc. / OraTech LLC**

Central Office Address: **505 West Ultradent Drive (10200 South), South Jordan, Utah 84095, USA**

Products	UMDNS	GMDN
Lubricating Jellies (Dental)	12-401	45233
Cavity Liners	16-182	16704, 47232
Cavity Varnish	16-183	34524, 64794, 64795
Root Canal Posts	16-202	38609
Cement, Dental, Resin Composite	16-707	35870
Restorative Materials Kits, Dental; Crown and Bridge	16-733	45236
Composite Restorative Materials Kits, Light-Cured	16-734	34782, 36153, 64164
Composite Restorative Materials, Light-Cured	16-736	35870, 34771, 34782
Composite Restorative Material	16-740	35870, 34782

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Company Name: **Ultradent Products Inc. / OraTech LLC**

Central Office Address: **505 West Ultradent Drive (10200 South), South Jordan, Utah 84095, USA**

Products	UMDNS	GMDN
Endodontic Filling, Materials	17-611	31872, 36095
Restorative Materials, Dental, Other	17-619	34771, 38785, 60408
Dental Etching Liquids	17-737	36153, 63592
Cement, Orthodontic	17-943	16704, 31750
Hemostatic Media	17-944	34771, 46423
Cement, Dental	11-150	34771, 60510
Bur, Dental Carbide	16-668	16668
Bur, Dental Diamond	16-670	16668
Restorative Materials, Dental Unfilled	16-736, 16-740	34782
Bur, Dental	10-521	43311

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Central Office Address: **505 West Ultradent Drive (10200 South), South Jordan, Utah 84095, USA**

Products	UMDNS	GMDN
Syringe, Plastic	13-938	63696, 58894
Tips	11-160, 16-671	60366, 37434, 62154, 63614, 63696, 35768, 35970, 17977, 35697, 63953
Impression Material, Dispensing Gun	16-679	35866, 58106
Impression Material	16-679	35866, 58106
Disinfection Solution / Scrub	N/A	34524
Prophy Paste	16-699	11168
Dental Wax	16-189	45251
Tongue Depressor	14-066	36311
Disk, Abrasive	16-470	16668

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Products	UMDNS	GMDN
Saws, Other	15-244	63358
Matrix Band, Dental	16-195	38786, 16195, 62764
Tooth Pick	33-208	33208
Mouth Trays	16-350	43025
Brush, Bur Cleaning	10-502	35768
Gingival Retraction Kit	16-352	35861
Prophylaxis Cups	16-184	16184
Eye Glasses	N/A	N/A
Light, Dental Activator	16-386	35775

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