

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Premier Dental Products Company

(FIN F000929)

Main Site: 1710 Romano Drive

Plymouth Meeting, Pennsylvania 19462, United States

has been registered by Intertek, an MDSAP recognized auditing organization,
as conforming to the requirements of:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

Canada: Medical Devices Regulations – Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68; PMD Act

The management system is applicable to:

The design and development and manufacture of dental and medical products, including perio-hygiene instruments, restorative materials, dental cements, dental varnishes, endoinstruments, implantable RC post, polishing-finishing material, sterile and non-sterile burs, Tracheostomy / Laryngectomy Tubes and Hemostatic Agent/Astringent.

Certificate Number:

0088326

Initial Certification Date:

2019-03-14

Certification Effective Date:

2019-03-14

Certification Expiry Date:

2022-03-13



Calin Moldovean

President, Business Assurance

Intertek Testing Services NA, Inc.
900 Chelmsford Street
Lowell, MA, USA 01851

