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, manufacture of dental and medical products, including finishing and polishing instrument and pastes, preventative treatment materials, hygiene and perio accessories and pastes, cleaners and cleaning agents, products for endodontic and restorative procedures, dental instruments, products for infection control, rotary devices, prosthetic and tissue management devices, electrosurgical electrodes and accessories, gynecologic instrumentation, otorhinolaryngeal instruments and devices. The design and development, manufacture and service cryosurgery devices. Distribution of diamond instruments, diamond podiatry burs, diamond dermabrader burs, diamond dental burs, evacuator system and accessories, luminescence, compo discs, sterilization cassettes, and endodontic accessories.

Certificate Number:
0088326-03

Initial Certification Date:
2019-03-14

Date of Certification Decision:
2022-03-08

Certification Effective Date:
2022-03-13

Certification Expiry Date:
2025-03-13

Calin Moldovean
President, Business Assurance

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