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CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Premier Dental Products Company

Main Site: 1710 Romano Drive, Plymouth Meeting, Pennsylvania 19462, United States (FIN F000929)

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 cleaners and cleaning agents; products and instruments for endodontic procedures; finishing and polishing discs; hygiene and preventative pastes, gels, varnish, and accessories including handpiece and periodontal and diagnostic instruments; dental operative instruments; prosthetic devices such as trays, hemostatic agents, retraction products and accessories; restorative primers, cements, composites, core build-up material, matrices, bonding agents, and etches; rotary diamond burs; disposable biopsy punches; otorhinolaryngeal instruments and devices; gynecologic instruments; and electrosurgical electrodes.

The design and development, manufacture, and service of cryosurgery devices and glass bead mirror warmers.

The Distribution of dental finishing/polishing pastes; preventative dental varnish; hinged medical and dental instruments including dental retractors and dental sharpeners; infection control barriers; restorative core build-up material; cosmetic veneers, and rotary devices including diamond instruments, diamond podiatry burs, diamond dermabrader burs, and diamond dental burs; sterilization cassettes; endodontic accessories; dermatological instruments; electrosurgical accessories; gynecologic devices and instrumentation.

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Revision Level: 05

Initial Certification Date:
2019-03-14

Certification Effective Date:
2025-03-13

Certification Expiry Date:
2028-03-13

ISO 13485:2016 CERTIFICATION TM intertek

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

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