

# ***DECLARATION of CONFORMITY***

**Manufacturer Name and Address:** *Pulpdent Corporation*  
80 Oakland Street  
Watertown, Massachusetts 02472 USA  
Tel: (617) 926-6666 Fax: (617) 926-6262

**Products:** **CLASS I MEDICAL DEVICES**

## **Declaration of Conformity:**

I, the undersigned, hereby declare that the medical devices specified above conform to the requirements of the United States Food and Drug Administration, the Australian TGA Regulations, the Canadian Medical Devices Regulations, the Japanese MHLW and the Pulpdent Quality Management System including all Quality Control Testing.

This Declaration is supported by:

Certificate of Registration No. 34640 rev 1, issued by GMED S.A.S., effective 16 July 2020, for compliance with the requirements of ISO 13485:2016;

Certificate of Registration No. 34641-1, issued by GMED S.A.S., effective 21 July 2020, for compliance with the requirements of Australian TGA Regulations, 2002, Schedule 3 Part 1; Canadian Medical Devices Regulations, Part 1, SOR 98/282; Japanese MHLW MO 169 and the PMD Act; and United States 21 CFR 820, 803, 806, and 807 subparts A through D.

Signed:



Date: *21 July 2020*

Marjorie Coté

*Director of Quality Assurance and Regulatory Affairs, Pulpdent Corporation*

## **Authorized European Representative:**

Advena Limited  
Tower Business Centre, 2nd Floor,  
Tower Street,  
Swatar, BKR 4013  
Malta.

## CLASS I CE MARKED DEVICES

<u>PRODUCT</u>	<u>PRODUCT CODES</u>
Articulating Paper / Film / Liquid	ARP-S, ARP-H,
Bowls	B-MS3, B-MM2, B-ML, B-MA
Brush Tips, Handle, Long Handle Brushes	BR, BRL, HAN, BR2, BR2L
Code Rings	CR-AS, CR*, CR*-50, CR-ASL, CR*-60L (* Indicates color: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, or 11)
Core Forms	HCF-* (1, 2, 3, 4, AS)
Dam Frame	RDF
Dispenser, ACTIVA-SPENSER™	DS05
Dispenser, for 1:1 Automix Cartridge	DS50, DS24
Dry-Rite (Drying Agent)	DRY
Flecta Disposable Mirror	FLEC, S-FLEC
Flexible Scaler	FLEX
Instruments, reusable, hand- operated	PCR, CRP* (* Indicates size: 1,2,3), RDF, AC2-RE, AC2-MR, PL-M, PL-E, RS-D* (* Indicates size: 2, 4, 6), SCCB-S, USCI-C, USCI-S, RST-R
KOOL-DAM Light Cure, Heatless Liquid Dam	PD, PDB, S-PD
Matrix Strips	M-DS, M-TP, SPL-P, SPL-C, SPL-F
Mixing Wells	MW-2, MW-4
Needles, endodontic irrigation, blunt	TE20N, TE50N, TE100N
Needles, Pressure Syringe, blunt	PSN-*, PSN-*A, PSN-*H (* Indicates gauge: 18, 22, 25, 30)
Pic-N-Stic	PIC
Pins	PIN
Porcelain Etch Gel	PEG, PEG-3, S-PEG
Pressure Syringe, Instrument for delivery of Root Canal Sealer	PS-O
Sparkle porcelain polishing paste	SPARK, SPARK-3
Syringes, Empty	SY-ET3, SY-ER3
Syringe Stand	STAND, D-ST
T-Band Matrix Band	BT*S/N, BT*S/W, BT*S/A, BT*C/N, BT*C/W, BT*C/A (* Indicates B for Brass or S for Stainless Steel)
Tips – Applicator / Dispensing / Mixing, blunt	30F50, 30F100, 25B20, 25B50, 25B100, 23R20, 23R100, 22D20, 22D100, 22K20, 22K100, 22DR15, 22DR75, 22KK15, 22KK75, 20L20, 20L100, 19K20, 19K100, 18G20, 18G100, A20, A50, A20N1, A50N1, AD20T, AD50T, AD20R, AD50R, AS20, AS50, FD20, F20N2, FSB20, P2520, P25100
Tray Adhesive	DTA2
Wedges	W, W-* (* Indicates size B, G, Y, W), FIN, PIN
Wonder Orange	WO-8