

DECLARATION of CONFORMITY

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

SRN: US-MF-000004897

Products: **CLASS I MEDICAL DEVICES** *[list follows]*

EU Declaration of Conformity:

I, the undersigned, as representative of Pulpdent Corporation, hereby declare that the medical devices specified above conform to the requirements of the Medical Devices Regulation (EU) 2017/745 and the Pulpdent Quality Management System including all Quality Control Testing. This declaration is issued under the sole responsibility of the manufacturer.

Signed: 

Date: *September 14, 2021*

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.

All of the Medical Devices listed below are used by the dental professional in the operatory

CLASS I MEDICAL DEVICE	GMDN Code	Part/Catalog Number	UDI	BUDI
Applicator tips and needles, blunt single use, for dispensing materials	60366	30F50	D70130F502	++D701APPLAS
	60366	30F100	D70130F1002	++D701APPLAS
	60366	25B20	D70125B202	++D701APPLAS
	60366	25B50	D70125B502	++D701APPLAS
	60366	25B100	D70125B1002	++D701APPLAS
	60366	23R20	D70123R202	++D701APPLAS
	60366	23R100	D70123R1002	++D701APPLAS
	60366	22D20	D70122D202	++D701APPLAS
	60366	22D100	D70122D1002	++D701APPLAS
	60366	22K20	D70122K202	++D701APPLAS
	60366	22K100	D70122K1002	++D701APPLAS
	60366	22DR15	D70122DR152	++D701APPLAS
	60366	22DR75	D70122DR752	++D701APPLAS
	60366	22KK15	D70122KK152	++D701APPLAS
	60366	22KK75	D70122KK752	++D701APPLAS
	60366	20L20	D70120L202	++D701APPLAS
	60366	20L100	D70120L1002	++D701APPLAS
	60366	19K20	D70119K202	++D701APPLAS
	60366	19K100	D70119K1002	++D701APPLAS
	60366	18G20	D70118G202	++D701APPLAS
	60366	18G100	D70118G1002	++D701APPLAS
	60366	FRN-TOP	D701FRNTOP2	++D701APPLAS
	60366	P2520	D701P25202	++D701APPLAS
	60366	P25100	D701P251002	++D701APPLAS
	60366	PSN-18	D701PSN182	++D701APPLAS
	60366	PSN-22	D701PSN222	++D701APPLAS
	60366	PSN-25	D701PSN252	++D701APPLAS
	60366	PSN-30	D701PSN302	++D701APPLAS

CLASS I MEDICAL DEVICE	GMDN Code	Part/Catalog Number	UDI	BUDI
	60366	PSN-A	D701PSNA2	++D701APPLAS
	60366	PSN-H	D701PSNH2	++D701APPLAS
	60366	PSYN	D701PSYN2	++D701APPLAS
Applicators – Mixing tips, single use, for dispensing materials from two- chambered receptacles	58399	A20	D701A202	++D701APPLAS
	58399	A50	D701A502	++D701APPLAS
	58399	A20N1	D701A20N12	++D701APPLAS
	58399	A50N1	D701A50N12	++D701APPLAS
	58399	ACEM20, F670002	D701ACEM202	++D701APPLAS
	58399	ACEM50, F67005	D701ACEM502	++D701APPLAS
	58399	AD20T	D701AD20T2	++D701APPLAS
	58399	AD50T	D701AD50T2	++D701APPLAS
	58399	AD20R	D701AD20R2	++D701APPLAS
	58399	AD50R	D701AD50R2	++D701APPLAS
	58399	APRC20, B580002	D701APRC202	++D701APPLAS
	58399	AS20	D701AS202	++D701APPLAS
	58399	AS50	D701AS502	++D701APPLAS
	58399	FD20	D701FD202	++D701APPLAS
	58399	F20N2	D701F20N22	++D701APPLAS
	58399	FD20AP, F806802	D701FD20AP2	++D701APPLAS
	58399	FD50AP, F80685	D701FD50AP2	++D701APPLAS
	58399	FSB20, FSB20AP, F673002	D701FSB202	++D701APPLAS
	58399	FSB50AP, F67305	D701FSB50AP2	++D701APPLAS
Brush tips, Long Handle Brushes, single use, for applying materials	35697	BR	D701BR2	++D701BR9Q
	35697	BR2	D701BR22	++D701BR9Q
	35697	BR2L	D701BR2L2	++D701BR9Q

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Core Forms	16730	HCF-* 1, 2, 3, 4, AS, HCF-AP, F80690	D701HCF12	++D701HCFPX
Dispenser	60885	DS05	D701DS052	++D701DS9Y
	60885	DS50	D701DS502	++D701DS9Y
	60885	DS24	D701DS242	++D701DS9Y
Dry-Rite Drying Agent	45116	DRY	D701DRY2	++D701DRYRW
Endodontic needles, blunt applicators	60366	TE20N	D701TE20N2	++D701TEAL
	60366	TE50N	D701TE50N2	++D701TEAL
	60366	TE100N	D701TE100N2	++D701TEAL
FLECTA Disposable Dental Mirror	31776	FLEC	D701FLEC2	++D701FLEC9N
	31776	S-FLEC	D701SFLEC2	++D701FLEC9N
KOOL-DAM Light- cure Liquid Dam	45004	PD	D701PD2	++D701PDA6
	45004	PDB	D701PDB2	++D701PDA6
	45004	S-PD	D701SPD2	++D701PDA6
	45004	PD-TOP	D701PDTOP2	++D701PDA6
	45004	PD3NL	D701PD3NL2	++D701PDA6
Mixing Wells- disposable 2 or 4 well mixing tray	44999	MW-2	D701MW22	++D701MWB3
	44999	MW-4	D701MW42	++D701MWB3
Porcelain Etch Gel (dental etchant for porcelain prostheses)	36153	PEG	D701PEG2	++D701PEGRF
	36153	PEG-3	D701PEG32	++D701PEGRF
	36153	S-PEG	D701SPEG2	++D701PEGRF
	36153	PEG-TOP	D701PEGTOP2	++D701PEGRF

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	36153	PEG-3-NL	D701PEG3NL2	++D701PEGRF
Sparkle Porcelain Polishing Paste for prostheses	45407	SPARK	D701SPARK2	++D701SPARK5U
	45407	SPARK-3	D701SPARK32	++D701SPARK5U
Syringes, oral, empty	47017	SY-ET3	D701SYET32	++D701SYBR
	47017	SY-ER3	D701SYER32	++D701SYBR
	47017	SYET3-TOP	D701SYET3TOP2	++D701SYBR
T-Bands - Matrix Bands for forming restorations	38786	BT*S/N =BTBSN	D701BTBSN2	++D701BT9U
	38786	BTSSN	D701BTSSN2	++D701BT9U
	38786	BT*S/W = BTBSW	D701BTBSW2	++D701BT9U
	38786	BTSSW	D701BTSSW2	++D701BT9U
	38786	BT*S/A = BTBSA	D701BTBSA2	++D701BT9U
	38786	BTSSA	D701BTSSA2	++D701BT9U
	38786	BT*C/N = BTBCN	D701BTBCN2	++D701BT9U
	38786	BTSCN	D701BTSCN2	++D701BT9U
	38786	BT*C/W = BTBCW	D701BTBCW2	++D701BT9U
	38786	BTSCW	D701BTSCW2	++D701BT9U
	38786	BT*C/A = BTBCA	D701BTBCA2	++D701BT9U
	38786	BTSCA	D701BTSCA2	++D701BT9U
Tray Adhesive	16658	DTA2	D701DTA22	++D701DTA2
Wedges	45007	W	D701W2	++D701WXF
	45007	W-B	D701WB2	++D701WXF
	45007	W-G	D701WG2	++D701WXF
	45007	W-Y	D701WY2	++D701WXF
	45007	W-W	D701WW2	++D701WXF

END OF LIST

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