

ATTESTATION CE / EC CERTIFICATE

Approbation du Système Complet d'assurance Qualité / Approval of full Quality Assurance System

ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices

Pour les dispositifs de classe III, un certificat CE de conception est requis

For class III devices, a EC design certificate is required

Fabricant / Manufacturer

PULPDENT CORPORATION

80 Oakland Street

WATERTOWN, MA 02472 UNITED STATES

Catégorie du(des) dispositif(s) / Device(s) category

**Dispositifs médicaux à usage professionnel dentaire
(Cf. Addendum pour description complète de la catégorie)**

*Medical devices for professional dental use
(see Addendum for additional information)*

Voir document complémentaire GMED / See GMED additional document

n° 37870

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé T001152, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced T001152, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4.

La validité du présent certificat est soumise à une vérification périodique ou imprévue

The validity of the certificate is subject to periodic or unexpected verification

Début de validité / Effective date : January 20th, 2021 (included)

Valable jusqu'au / Expiry date : May 26th, 2024 (included)



On behalf of the President

Béatrice LYS

Technical Director

DocuSigned by:

Beatrice Lys

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Ce document complémentaire GMED n°37870 rev 0 atteste de la validité du certificat CE n°9101 rev 14 au regard des informations listées ci-dessous.

This GMED additional document N°37870 rev 0 attests to the validity of CE certificate n°9101 rev 14 with regard to the information listed below.

Fabricant / Manufacturer:

Pulpdent Corporation
80 Oakland Street
Watertown MA 02472 UNITED STATES

Catégorie des dispositifs (Description complète)

Device category (Full Description)

Dispositifs médicaux à usage professionnel dentaire: adhésifs dentaires, produits pour préparation des surfaces, produits pour comblement des puits et fissures, ciment verre ionomère et résine composite, produit pour le coiffage pulpaire, produits de comblement de fond de cavité et de canal radiculaire (non-médicinaux), pansements parodontaux, matériaux pour couronnes et bridges temporaires et matériaux fluorés et de reminéralisation

Medical devices for professional dental use: dental adhesives, surface preparation materials, pit and fissure sealants, glass ionomer and resin composite materials, pulp capping materials, cavity liners and root canal sealant (non-medicated), periodontal dressings, temporary crown and bridge materials and cements, and fluoride and remineralization materials

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Identification des dispositifs / Identification of devices

Description du Dispositif Médical <i>Medical Device Description</i>	Référence Commerciale du Dispositif Médical <i>Medical Device Commercial Reference Number</i>	Classe du Dispositif Médical <i>Medical Device Class</i>
ACTIVA BioACTIVE-BASE/LINER	VB1, VB2, S-VB, VTB1, VTB2, S-VTB	IIa
ACTIVA BioACTIVE-CEMENT	VC1A2, VC2A2, VC1T, VC2T, S-VCA2, S-VCT VTC1A2, VTC2A2, VTC1T, VTC2T, S-VTCA2, S-VTCT	IIa
ACTIVA BioACTIVE-RESTORATIVE	VRA1, VRA2, VRA3, VR1A1, VR1A2, VR1A3, VR1A35, VR2A1, VR2A2, VR2A3, VR2A35, S-VRA2 VTRA1, VTRA2, VTRA3, VTR1A1, VTR1A2, VTR1A3, VTR1A35, VTR2A1, VTR2A3, VTR2A2, VTR2A35	IIa
ACTIVA KIDS BioACTIVE-RESTORATIVE	VKP, VK1P, VK2P, VTK1P, VTK2P, VTKP	IIa
ACTIVA PRESTO	VPF1A1, VPF1A2, VPF1A3, VPF1A35, VPF1A4, VPF1A6, VPF1B1, VPF1BL, VPF1BW, VPF1OS VPF3A1, VPF3A2, VPF3A3, VPF3A35, VPF3A4, VPF3A6, VPF3B1, VPF3BL, VPF3BW, VPF3OS S-VPFA1, S-VPFA2, S-VPFA3, S-VPFA35, S-VPFA4, S-VPFA6, S-VPFB1, S-VPFBL, S-VPFBW, S-VPFOS VPFA1, VPFA2, VPFA3, VPFA35, VPFA4, VPFA6, VPFCB1, VPFCBW, VPFCOS	IIa
ACTIVA PRONTO	VNF1A1, VNF1A2, VNF1A3, VNF1A35, VNF1A4, VNF1A6, VNF1B1, VNF1BL, VNF1BW, VNF1OS VNF3A1, VNF3A2, VNF3A3, VNF3A35, VNF3A4, VNF3A6, VNF3B1, VNF3BL, VNF3BW, VNF3OS S-VNFA1, S-VNFA2, S-VNFA3, S-VNFA35,	IIa

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	S-VNFA4, S-VNFA6, S-VNFB1, S-VNFB1, S-VNFBW, S-VNFOS VNFA1, VNFA2, VNFA3, VPNA35, VNFA4, VNFA6, VNFCB1, VNFCBW, VNFCOS	IIa
DenTASTIC Dental Adhesive System	DAS-C1, DASP-A, DASP-B, DASP-C, DASP-1, DASP-2, CDUR, CDURE	IIa
DenTASTIC DUO Dual Cure Catalyst for UNO	DUO, CDDUO, CDDUOE	IIa
DenTASTIC UNO Single Component Dental Adhesive	UNO, UNO-R, S-UNO, CDUNO, CDUNOE	IIa
DenTASTIC UNO-DUO	UNDO	IIa
Dentin Conditioning Gel	DEN	IIa
Dentin Desensitizer	DES	IIa
EDTA Solution, 17%	EDTA-30, EDTA-60, EDTA-120, EDTA480	IIa
Embrace Esthetic Opaquer	EMO1, EMO2, EMO3 EMO4, EMO5, E4200	IIa
Embrace Varnish	FV50, FV200, FVT, FVX100, S-FV, ZG-FV1	IIa
Embrace Wet Bond Pit & Fissure Sealant, Natural Shade	EMS, EMS3, EMSB, S-EMS, E2000, E2100	IIa
Embrace Wet Bond Pit & Fissure Sealant, Off-white Shade	EMSW, EMSW3, EMSWB, S-EMSW, E2200, E2300	IIa
Embrace WetBond Class V Cervical Restorative Resin	EMVA2, EMVA35, E5100, E5400	IIa
Embrace WetBond First Coat	EMFC, E4100	IIa
Embrace WetBond Low Fill Pit & Fissure Sealant	EMSWLF, EMSWLF	IIa
Embrace WetBond Resin Cement / Low Viscosity	EMCA, EMCAR, EMCAR2, E1000, E1100, E1200	IIa
Embrace WetBond Resin Cement / Medium Viscosity	EMCM, EMCMR, EMCMR2, E1300, E1400, E1500, ACEM7, F67000	IIa
Embrace WetBond Restoration & PFM Repair Kit	EMPFM, E4000	IIa

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Embrace WetBond Seal-n-Shine	EMSNS, EMSNY, S-EMSNS, E3000, E3100	IIa
Etch Royale 37% Phosphoric Acid Etching Gel	ER, ER6, ER24, ER50, ER50R, S-ER	IIa
Etch-All 10 % Phosphoric Acid Etching Gel	EA, EA-5	IIa
Etch-Rite 38% Phosphoric Acid Etching Gel	ETCH, ET-TWIN, ET-6, ET-12, ET12G, ET-24, ET-144, ET-50, ET-50R, S-ETCH ET12-TOP, ET50-TOP, ET4-TOP	IIa
File-Rite EDTA Gel	FILE, S-FILE, FILET EDTA-THV, EDTA-TLV	IIa
Flows-Rite, Multi-Purpose Flowable Composite and Veneer Cement	FK1, FKA1, FKA2, FKA3, FKA35, FKS, S-FLOWS	IIa
Forendo Paste	FORE	IIa
GlassFill Glass Ionomer Filling Material	IFU	IIa
GlassLine Glass Ionomer Lining Material & Post Cement	ILI	IIa
GlassLute Glass Ionomer Cement	ILU	IIa
Kleer Veneer	KV1, KV2, KV4	IIa
Lime-Lite Enhanced, Light Cure Cavity Liner	LLE, LLE3, S-LLE	IIa
Multi-Cal	MULTI, MULTI-3, S-MULTI, MULTI-TOP	IIa
Opaquer	OP1, OP2	IIa
Ortho-Choice Glass Ionomer Band Cement	OCGI	IIa
Ortho-Choice OBA Bonding Resin	OCBAR	IIa
Ortho-Choice Ortho-Coat	OC	IIa
Ortho-Choice Orthodontic Bracket Adhesive (OBA)	OCBA, OCBAS	IIa
PerioCare Periodontal Dressing	PC	IIa

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PolyCarb WaterSet, Anhydrous Polycarboxylate Cement	CPC	Ila
Porcelain Prep Kit	PPK	Ila
Prep-Rite RC / Viscous EDTA Gel	PRC, APRC, B58000	Ila
Pressure Syringe Combo Kit (includes RK)	PSK	Ila
Pulpdent Cavity Liner	PCL, PCL-I	Ila
Pulpdent Paste	PSYK, PSY, E1300	Ila
Pulpdent Root Canal Sealer Endodontic Filling Material	RK, RSP, RSP-4, RSL, RSL-2, RK-I	Ila
Seal-Rite Low Viscosity Pit and Fissure Sealant	SEAL-LV	Ila
Seal-Rite Pit & Fissure Sealant	SEAL, SEAL-3, RITE, S-SEAL	Ila
Semi-Gel Etchant 35 % Phosphoric Acid	ET-18	Ila
Silane Bond Enhancer	SIL, SIL-3, SIL-TOP, E1400	Ila
SNOOP Caries Disclosing Agent	SNOOP	Ila
Spee-Dee Build-Up	SBU50, SBU, SBU5, SBUAP, SBUAP3, E7000 F80680, F80682, F80686	Ila
TempCanal Enhanced	TEK, TE3, TE4, S-TEK	Ila
Tuff-Temp™ Plus Provisional Veneer, Crown & Bridge Resin	TTPA1, TTPA2, TTPA3, TTPA35, TTPB1, TTPB, TTP5A1, TTP5A2, TTP5A3, TTP5A35, TTP5B1, TTP5B, TTG, S-TTPA3 TTP50A1, TTP50A2, TTP50A3, TTP50A1X, TTP50A2X, TTP50A3X TTA2AP, TTA3AP F67300, F67310	Ila

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Sites couverts et Activités / Locations and Activities

Sites / Locations	Activités / Activities
Pulpdent Corporation 80 Oakland Street Watertown, MA 02472 USA	Conception, fabrication et controle final / Design, manufacturing and final control
Pulpdent Corporation 73 Oakland Street Watertown, MA 02472 USA	Fabrication / Manufacturing
Pulpdent Corporation 46 Acton Street Watertown, MA 02472 USA	Fabrication / Manufacturing
Pulpdent Corporation 300-400 Pleasant Street Watertown, MA 02472 USA	Fabrication / Manufacturing

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