

**Ce document complémentaire GMED n°37870 rev 2 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 2 attests to the validity of CE certificate n°9101 rev 14 with regard to the information listed below.*

**Fabricant / Manufacturer:**

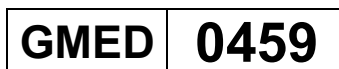
**Pulpdent Corporation**  
80 Oakland Street  
Watertown MA 02472 UNITED STATES

### **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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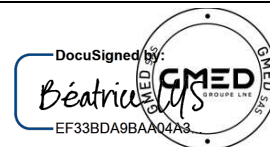


**On behalf of the President**  
**Béatrice LYS**  
**Technical Director**

### 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, 5028537EU, 5028540EU	Ila
ACTIVA BioACTIVE-CEMENT	VC1A2, VC2A2, VC1T, VC2T, S-VCA2, S-VCT VTC1A2, VTC2A2, VTC1T, VTC2T, S-VTCA2, S-VTCT	Ila
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	Ila
ACTIVA KIDS BioACTIVE-RESTORATIVE	VKP, VK1P, VK2P, VTK1P, VTK2P, VTKP	Ila
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 VPFCA1, VPFCA2, VPFCA3, VPFCA35, VPFCA4, VPFCA6, VPFCB1, VPFCBW, VPFCOS	Ila
ACTIVA PRONTO	VNF1A1, VNF1A2, VNF1A3, VNF1A35, VNF1A4, VNF1A6, VNF1B1, VNF1BL, VNF1BW, VNF1OS	Ila

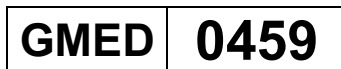
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Technical Director**

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	VNF3A1, VNF3A2, VNF3A3, VNF3A35, VNF3A4, VNF3A6, VNF3B1, VNF3BL, VNF3BW, VNF3OS S-VNFA1, S-VNFA2, S-VNFA3, S-VNFA35, S-VNFA4, S-VNFA6, S-VNFB1, S-VNFB1, S-VNFB1, S-VNFBW, S-VNFOS VNFA1, VNFA2, VNFA3, VNFCA35, VNFCA4, VNFCA6, VNFCB1, VNFCBW, VNFCOS	Ila
DenTASTIC Dental Adhesive System	DAS-C1, DASP-A, DASP-B, DASP-C, DASP-1, DASP-2, CDUR, CDURE	Ila
DenTASTIC DUO Dual Cure Catalyst for UNO	DUO, CDDUO, CDDUOE	Ila
DenTASTIC UNO Single Component Dental Adhesive	UNO, UNO-R, S-UNO, CDUNO, CDUNOE	Ila
DenTASTIC UNO-DUO	UNDO	Ila
Dentin Conditioning Gel	DEN	Ila
Dentin Desensitizer	DES	Ila
EDTA Solution, 17%	EDTA-30, EDTA-60, EDTA-120, EDTA480	Ila
Embrace Esthetic Opaquer	EMO1, EMO2, EMO3, EMO4, EMO5, E4200	Ila
Embrace Varnish	FV50, FV200, FVT, FVX100, S-FV, ZG-FV1	Ila
Embrace Wet Bond Pit & Fissure Sealant, Natural Shade	EMS, EMS3, EMSB, S-EMS, E2000, E2100	Ila
Embrace Wet Bond Pit & Fissure Sealant, Off-white Shade	EMSW, EMSW3, EMSWB, S-EMSW, E2200, E2300	Ila
Embrace WetBond Class V Cervical Restorative Resin	EMVA2, EMVA35, E5100, E5400	Ila
Embrace WetBond First Coat	EMFC, E4100	Ila
Embrace WetBond Low Fill Pit & Fissure Sealant	EMSWLF, EMSWLFB	Ila
Embrace WetBond Resin Cement / Low Viscosity	EMCA, EMCAR, EMCAR2, E1000, E1100, E1200, URC7L, GK027	Ila



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<b>Description du Dispositif Médical</b> <i>Medical Device Description</i>	<b>Référence Commerciale du Dispositif Médical</b> <i>Medical Device Commercial Reference Number</i>	<b>Classe du Dispositif Médical</b> <i>Medical Device Class</i>
Embrace WetBond Resin Cement / Medium Viscosity	EMCM, EMCMR, EMCMR2, E1300, E1400, E1500, ACEM7, F67000, ICEM, 66036084, ICEMPV, 66037633, URC7M, GK028	IIa
Embrace WetBond Restoration & PFM Repair Kit	EMPFM, E4000	IIa
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

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Ortho-Choice Ortho-Coat	OC	Ila
Ortho-Choice Orthodontic Bracket Adhesive (OBA)	OCBA, OCBAS	Ila
PerioCare Periodontal Dressing	PC	Ila
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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**On behalf of the President  
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Technical Director**

## Sites couverts et Activités / Locations and Activities

Sites / Locations	Activités / Activities
<b>Pulpdent Corporation</b> 80 Oakland Street Watertown, MA 02472 USA	<b>Conception, Fabrication, Contrôle final /</b> Design, Manufacturing, Final Control
<b>Pulpdent Corporation</b> 73 Oakland Street Watertown, MA 02472 USA	<b>Fabrication / Manufacturing</b>
<b>Pulpdent Corporation</b> 46 Acton Street Watertown, MA 02472 USA	<b>Fabrication / Manufacturing</b>
<b>Pulpdent Corporation</b> 300-400 Pleasant Street Watertown, MA 02472 USA	<b>Fabrication / Manufacturing</b>

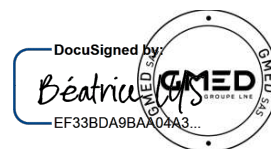
## Modifications / Modifications

### Identification des modifications apportées au certificat CE n° 9101 rev 14:

*Identification of the modifications made to the CE certificate n° 9101 rev 14:*

Modifications / Modifications	Dossier(s) / File(s) N°	Date / Date
<b>Nouvelle référence de rapport dans le cadre du maintien de la certification / New file reference in the framework of the maintenance of the certification</b>	T001152-P5-DOCR	<b>19 août 2021</b> August 19, 2021
<b>Mise à jour de la liste des références / Update of list of references</b>	T001635_P3-DOCR	<b>25 mai 2023</b> May 25, 2023

<b>GMED</b>	<b>0459</b>
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