



septodont

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**DECLARATION DE CONFORMITE / DECLARATION OF CONFORMITY**  
**(conformément à l'annexe VII de la Directive 93/42/CEE amendée par la Directive 2007/47/CE**  
**according to annex VII of the Directive 93/42/EEC amended by Directive 2007/47/CE)**

**dispositifs médicaux de classe IIa sous la responsabilité de SEPTODONT**  
**class IIa medical devices under SEPTODONT responsibility)**

Je soussigné, Anne Lecoq, Directeur Qualité - Pharmacien Responsable des :  
*I, the undersigned, Anne Lecoq, the Quality Director - Pharmacist Responsible of:*

Laboratoires SEPTODONT  
58, Rue du Pont de Créteil  
94107 SAINT MAUR DES FOSSES Cédex - FRANCE

déclare sous notre entière responsabilité les produits listés en annexe.  
*declare under our full responsibility the medical devices listed in the enclosure.*

Conformément aux dispositions du CSP (Code de la Santé Publique / Titre I, Livre II, Partie V)  
(transposition dans le droit français de la Directive 93/42/CEE du 14 juin 1993), ces dispositifs  
médicaux appartiennent à la **classe IIa** et satisfont aux exigences essentielles de l'annexe I.  
*According to the provisions of the CSP (French Code of Public Health / Title I, Book II, Part V)*  
*(transposition of Directive 93/42/EEC of 14 June 1993 in the French legislation), these medical*  
*devices are classified as **class IIa** and meet the essential requirements of annex I.*

Cette déclaration est fondée sur l'Attestation CE n° 9054 d'approbation du Système Qualité de la  
Production suivant l'Annexe V point 3. de la directive 93/42/CEE et sur l'Attestation CE  
n° 8297 d'approbation du Système Complet d'Assurance Qualité suivant l'Annexe II.3 de la  
directive 93/42/CEE délivrées par le G-Med (organisme notifié n° 0459)  
*This declaration is based on EC Certificate n° 9054 of approval of Production Quality*  
*Assurance System according to Annex V section 3 of Directive 93/42/EEC and on EC*  
*Certificate n° 8297 of approval full Quality Assurance System according to Annex II section 3 of*  
*Directive 93/42/EEC issued by G-Med (notified body n° 0459).*

Saint Maur,  
Date : 22 Novembre 2012 / November 22, 2012

Anne Lecoq,  
Directeur Qualité - Pharmacien Responsable  
*Quality Director - Pharmacist Responsible*



## ANNEXE / ANNEX

### dispositifs médicaux de classe IIa sous la responsabilité de SEPTODONT medical devices of class IIa under SEPTODONT responsibility

NOM DU DISPOSITIF MEDICAL MEDICAL DEVICE NAME	Evaluation conformité Conformity assessment procedure	GMDN code	Réf. Doc. Technique / Ref. Technical Doc. DTE IIa	Règle/ Rule (Annexe IX/ Annex IX)	Date 1 <sup>ère</sup> déclaration Date of 1 <sup>st</sup> declaration	Révision Revision	
						Date	Rev
ACROSEAL	Ann. V.3.	36095 – Dental material, root canal sealing	ACROS 02	8	14/12/2001	22/03/2010	2
ALVEOXYL	Ann. II.3.	35573 – Haemostatic alveolar dressing	ALVEO 55	7	16/03/2010	27/12/2010	1
APEX DSP	Ann. V.3.	16355 - Apex locator, endodontic	DTE 047	6	14/11/2005	22/03/2010	2
ASEPTOL S.A.	Ann. V.3.	38784 – Disinfectant dental	DTE 006	15	30/12/1998	22/03/2010	2
CALCIPULPE	Ann. V.3.	16182 – Cavity liner, calcium hydroxide	CALCI 05	8	02/10/1998	22/03/2010	2
CANAL +	Ann. V.3.	45233 – Dental solution, reaming aid	CANAL 06	6	02/10/1998	22/03/2010	2
CHELASOLV	Ann. V.3.	34524 – Dental solution, cleansing	LARGA 26	6	28/01/2004	22/03/2010	2
CIMPAT	Ann. V.3.	38778 – Dental material, filling, temporary	CIMPA 07	7	02/10/1998	22/03/2010	2
CIMPAT L.C.	Ann. V.3.	38778 – Dental material, filling, temporary	DTE 007	7	30/12/1998	22/03/2010	2
COMPOFILL ULTRA HYBRIDE	Ann. II.3.	35875 – Dental material, filling/restorative, polymer based	DTE 001	8	30/12/1998	22/03/2010	3
COMPOLUX (seringues / syringes)	Ann. II.3.	35876 – Dental material kit, composite restorative	DTE 001	8	30/12/1998	22/03/2010	3
COMPOLUX (pots / jars)	Ann. V.3.	35876 – Dental material kit, composite restorative	DTE 018	8	30/12/1998	22/03/2010	2
COMPOLUX 5	Ann. V.3.	35876 – Dental material kit, composite restorative	DTE 018	8	30/12/1998	22/03/2010	2
COMPOLUX MOIGNONS	Ann. II.3.	35876 – Dental material kit, composite restorative	DTE 001	8	30/12/1998	22/03/2010	3



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COMPOLUX MOLAIRE	Ann. II.3.	35876 – Dental material kit, composite restorative	DTE 001	8	30/12/1998	22/03/2010	3
DENTIBOND L.C.	Ann. V.3.	42483 – Adhesive, dentine	DTE 001	8	30/12/1998	22/03/2010	2
DETARTRINE POWDRE	Ann. II.3.	31857 – Polishing agent, abrasive, oral cavity	DTE 034	5	19/07/2002	22/03/2010	3
DETARTROL ULTRA	Ann. V.3.	45235 – Dental solution, scaling	DETUL 11	6	02/10/1998	22/03/2010	2
DICABOND	Ann. II.3.	42483 – Adhesive, dentine	DTE 001	8	27/12/2010	-	0
DIMENOL	Ann. V.3.	38784 – Disinfectant dental	DIMEN 12	15	02/10/1998	22/03/2010	2
ENDOBTUR	Ann. V.3.	36095 – Dental material, root canal sealing	ENDOB 13	8	02/10/1998	22/03/2010	2
ENDOCAL	Ann. V.3.	34524 – Dental solution, cleansing	ENDOC 14	7	02/10/1998	22/03/2010	2
ENDOCONCEPT	Ann. V.3.	Kit d'endodontie / Endodontic Kit	CONCE 50	8	14/12/2001	22/03/2010	2
ENDOMET PLAIN ENDOMETHASONE +	Ann. V.3.	36095 – Dental material, root canal sealing	ENDOP 15	8	02/10/1998 20/07/2005	22/03/2010	2
ENDOMETHASONE LIQUIDE / LIQUID	Ann. V.3.	16709 –Cement, dental, zinc oxide eugenol	ENDOL 16	8	02/10/1998	22/03/2010	2
ENDOMETHASONE SP	Ann. II.3.	36095 – Dental material, root canal sealing	ENDOSP 56	8	22/11/2012	-	0
ENDOPEROX Poudre / Powder KIT ENDOPEROX Poudre + glycérine / Powder + glycerol	Ann. II.3.	38785 – Dental bleaching agent	ENDOX 54P	6	21/08/2003	22/03/2010	3
ENDOSOLV E et R	Ann. V.3.	45234 – Dental solution, root filling solvent	ENDOLS 17	6	02/10/1998	22/03/2010	2
ETCHING GEL 37	Ann. V.3.	36153 – Dental etching composite	ETCHG 18	6	02/10/1998	22/03/2010	2
EUGENOL OXYZINC Liquid (Export)	Ann. V.3.	16709 –Cement, dental, zinc oxide eugenol	EUGEN 19	8	02/10/1998	22/03/2010	2
FORFENAN	Ann. V.3.	36095 – Dental material, root canal sealing	FORFE 21	8	02/10/1998	22/03/2010	2
GUTTASOLV	Ann. V.3.	45234 – Dental solution, root filling solvent	GUTTA 52	6	19/07/2002	22/03/2010	2



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HEXIDIS PLUS	Ann. V.3	38784 – Disinfectant dental	HEXID 22	15	02/10/1998	22/03/2010	2
HYDROL	Ann. V.3	34524 – Dental solution, cleansing	HYDRO 23	6	02/10/1998	22/03/2010	2
HYDROXYDE DE CALCIUM	Ann. V.3	16182 – Cavity liner, calcium hydroxide	HYDCA 24	8	02/10/1998	22/03/2010	2
IMAGE (Export) IMAGE ETCH GEL	Ann. II.3.	36153 – Dental etching composite	DTE 018	8	25/08/2003	22/03/2010	3
IMAGE FLOWABLE COMPOSITE	Ann. II.3.	35876 – Dental material kit, composite restorative	DTE 018	8	25/08/2003	22/03/2010	3
IMAGE MICROHYBRID COMPOSITE	Ann. II.3.	35875 – Dental material, filling/restorative, polymer based	DTE 018	8	25/08/2003	22/03/2010	3
IMAGE MICROHYBRID COMPOSITE KIT	Ann. II.3.	35876 – Dental material kit, composite restorative	DTE 018	8	25/08/2003	22/03/2010	3
IMAGE SEALANT KIT	Ann. II.3.	35876 – Dental material kit, composite restorative	DTE 018	8	25/08/2003	22/03/2010	3
IMAGE SINGLE COMPONENT BOND	Ann. II.3.	34782 – Dental bonding agent, polymer based	DTE 018	8	25/08/2003	22/03/2010	3
IMAGE	Ann. V.3	35875 – Dental material, filling/restorative, polymer based	DTE 001	8	12/01/2000	22/03/2010	2
IMAGE FLUIDE	Ann. V.3	35876 – Dental material kit, composite restorative	DTE 018	8	19/07/2002	22/03/2010	2
IMAGE INLAY-CORE	Ann. V.3.	35876 – Dental material kit, composite restorative	DTE 004	8	30/11/2004	22/03/2010	2



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INSTRUMENTATION MECANISEE gamme TECHNO - foret / drill, - bourre-pâte / paste carrier, - fraise diamantée / diamond bur - fraise carbure de tungstène / carbide bur -Technogire, Omnitri / rasp	Ann. II.3.	31876 – Enlarger, endodontic 41539 – Carrier, dental, endodontic paste, powered 16670 – Bur, dental diamond 16668 – Bur, dental carbide 40529 – Rasp, endodontic, powered	DTE 008	6	30/12/1998	22/03/2010	3
IONOSCELL	Ann. V.3.	16704 – Cement, dental, glass ionomer	DTE 017	8	30/12/1998	22/03/2010	2
ISODAN	Ann. V.3.	45232 – Dental material, desensitizing resin	ISODA 48	5	12/01/2000	22/03/2010	2
KIT DE PROPHYLAXIE FLUOPASTEL	Ann. V.3.	35702 – Abrasive strip, dental	DTE 041	5	21/08/2003	22/03/2010	2
LARGAL ULTRA	Ann. V.3.	45233 – Dental solution, reaming aid	LARGA 26	6	02/10/1998	22/03/2010	2
N'DURANCE DIMER CORE	Ann. II.3.	35875 – Dental material, filling/restorative, polymer based	N'DDC 57	8	20/01/2012	-	0
NEUTROCIM	Ann. V.3.	38776 – Cement, dental, zinc sulphate	NEUTRO 28	8	02/10/1998	22/03/2010	2
OXYDE DE ZINC	Ann. V.3.	36095 – Dental material, root canal sealing	ZnO 30	8	02/10/1998	22/03/2010	2
KIT PARCAN AIGUILLES PARCAN	Ann. V.3.	35970 – syringe, dental, irrigating	PARCAK 32	6	02/10/1998	22/03/2010	2
PHARMAETHYL	Ann. V.3.	38787 – Cryogenic spray, dental	PHARM 33	6	02/10/1998	22/03/2010	2
PROPHYLUX	Ann. V.3.	31780 – Dental material, pit/fissure sealing, polymer based	DTE 018	5	30/12/1998	22/03/2010	2
PROVICROWN Cartouches /Cartridges	Ann. II.3.	31783– Crown/bridge, temporary, polymer based	DTE 001	7	30/03/2001	22/03/2010	3
PROVICROWN Poudre + Liquide / Powder +Liquid	Ann. V.3.	31783– Crown/bridge, temporary, polymer based	DTE 004	7	30/12/1998	22/03/2010	2



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PROVICROWN Seringues / Syringes	Ann. V.3.	31783- Crown/bridge, temporary, polymer based	DTE 001	7	23/11/2005	22/03/2010	2
PROVISCELL Base + Catalyseur / Base + Catalyst	Ann. V.3.	38778 - Dental material, filling, temporary	DTE 007	7	30/12/1998	22/03/2010	2
PROVISCELL Seringue s/ Syringes	Ann. V.3.	38778 - Dental material, filling, temporary	DTE 001	7	23/11/2005	22/03/2010	2
QUICKSET	Ann. V.3.	38778 - Dental material, filling, temporary	QUICK 34	7	02/10/1998	22/03/2010	2
RESORCELL boulettes / pellets	Ann. V.3.	35895 - Sponge, haemostatic, absorbable	RESOR 35B	6	02/10/1998	22/03/2010	2
SECURALLOY capsules	Ann. II.3.	35791 - Dental amalgam, capsule	DTE 046	8	20/07/2005	22/03/2010	2
SELFFAST	Ann. V.3	16705 - Cement, dental, polycarboxylate	SELFA 37	8	02/10/1998	22/03/2010	2
SELFFAST Décapant	Ann. V.3	35871 - Denture cleanser	SELFD 38	8	02/10/1998	22/03/2010	2
SEPTALLOY NG 50 poudre / powder SEPTALLOY NG 70 poudre / powder (Hors France)	Ann. II.3.	34836 - Dental amalgam, alloy	DTE 046	8	20/07/2005	22/03/2010	2
SEPTALLOY NG 50 capsules SEPTALLOY NG 70 capsules	Ann. II.3.	35791 - Dental amalgam, capsule	DTE 046	8	20/07/2005	22/03/2010	2
SEPTOBOND S.E. SEPTOBOND S.E. Activateur/Activator	Ann. V.3	42483 - Adhesive, dentine	DTE 040	8	21/08/2003	22/03/2010	2
SEPTOCAL L.C.	Ann. V.3	16182 - Cavity liner, calcium hydroxide	DTE 028	8	30/12/1998	22/03/2010	2
SEPTOCALCINE ULTRA	Ann. V.3	16182 - Cavity liner, calcium hydroxide	SEPTU 39	8	02/10/1998	22/03/2010	2
SEPTOCIM	Ann. V.3.	16704 - Cement, dental, glass ionomer	DTE 001	8	23/11/2005	22/03/2010	2
SEPTOJECT	Ann. II.3.	12740 - Needle,dental	DTE 011	6	30/12/1998	22/03/2010	3
SEPTOJECT Evolution	Ann. II.3.	12740 - Needle,dental	DTE 011	6	27/12/2010	-	0
SEPTOJECT XL	Ann. II.3.	12740 - Needle,dental	DTE 011	6	12/01/2000	22/03/2010	3



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SEPTO-PACK	Ann. V.3	35573 – Dressing, dental, periodontal	SEPPA 40	7	02/10/1998	22/03/2010	2
SEPTOPOINTES ACRYLIQUE	Ann. V.3	34791 – Root canal obturating point, dental	DTE 012	8	30/12/1998	22/03/2010	2
SEPTOPOINTES GUTTA SEPTOPOINTES GUTTA condensation	Ann. V.3	31872 – Dental material, root filling, gutta percha	DTE 032	8	30/12/1998	22/03/2010	2
SEPTOPOINTES PAPIER / PAPIER GRADUE	Ann. V.3	38777 – Absorbent point, dental	DTE 032	6	30/12/1998	22/03/2010	2
SEPTOSCELL	Ann. V.3	16710 – Cement, dental, zinc phosphate	DTE 018	8	30/12/1998	22/03/2010	2
SILCOT (vernis + solvant / varnish + solvent)	Ann. V.3	35698 – Cavity varnish solution, dental	SILCO 41	7	02/10/1998	22/03/2010	2
SURFASEPT S.A.	Ann. V.3	38784 – Disinfectant dental	SURFA 42	15	02/10/1998	22/03/2010	2
TEMPOSCCELL	Ann. V.3	16709 –Cement, dental, zinc oxide eugenol	DTE 001	7	23/11/2005	22/03/2010	2
TRAY-NET	Ann. V.3	33162 – Detergent	TRAYN 43	7	02/10/1998	22/03/2010	2
UNIBOND	Ann. II.3.	42483 – Adhesive, dentine	DTE 001	8	30/12/1998	22/03/2010	3
VAPOSEPT 29	Ann. V.3.	38784 – Disinfectant dental	DTE 006	15	12/10/2004	22/03/2010	2