



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
ALVEOGL	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 POUDRE	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, Omniti / 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	SELF 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 (verniss + 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