



DECLARATION DE CONFORMITE / DECLARATION OF CONFORMITY
(conformément à l'annexe VII de la Directive 93/42/CEE consolidée
according to annex VII of the Directive 93/42/EEC consolidated)

dispositifs médicaux de classe I sous la responsabilité de SEPTODONT
medical devices of class I under SEPTODONT's responsibility

Je soussignée, Anne LECOQ, Directeur Qualité Europe – Pharmacien Responsable des :
I, the undersigned, Anne LECOQ, the Europe Quality Director – Pharmacist Responsible of:
SEPTODONT
58, Rue du Pont de Créteil
94107 SAINT MAUR DES FOSSES CEDEX
FRANCE

assure et déclare, 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), que les dispositifs médicaux listés en annexe appartiennent à la classe I et satisfont aux exigences essentielles de l'annexe I de la Directive 93/42/CEE.

certify and declare that, 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), the medical devices listed in the appendix are classified as class I and meet with essential requirements of the annex I of Directive 93/42/EEC.

Saint-Maur-des-Fossés,
Date : 28/03/20


Anne LECOQ,
Directeur AQ Corporate – Pharmacien Responsable
Corporate QA Director – Pharmacist Responsible

ANNEXE / APPENDIX

NOM DU DISPOSITIF MEDICAL MEDICAL DEVICE NAME	REF	GMDN code	Règle/ Rule (Annexe IX/ Annex IX)	Dossier Technique Technical file
CALYPSO - Framboise - Menthe - Orange	263S 264S 265S	42345 – Dental mouthwash	5	DTE I-CAL13
CONDENSIL - Fluide bleu - Fluide vert - Lourd - Catalyseur	 N129/FB N129/FV N129/L N129/C	35866 – Silicone dental impression material	5	DTE I-COND24
DETARTRINE Tube: - Detartrine 150 Z - Detartrine 100 ZF	274S 275S	11168 – Toothpaste	5	DTE I-DET 03/tube
DETARTRINE Pot / Jar: - Detartrine - Detartrine Z	323S 324S	11168 – Toothpaste	5	DTE I-DET 03
PERFEXIL BITE - Platinum +	N047	35866 – Silicone dental impression material	5	DTE I-PERF 25



NOM DU DISPOSITIF MEDICAL MEDICAL DEVICE NAME	REF	GMDN code	Règle/ Rule (Annexe IX/ Annex IX)	Dossier Technique Technical file
PERFEXIL - Platinium +		35866 – Silicone dental impression material	5	DTE I-PERF 25
- Putty Hard (gris/grey)	N046/PH			
- Putty Soft (vert/green)	N046/PS			
- Putty Soft Rapide (bleu/blue)	N046/PSR			
- Putty Super Soft Rapide Pot/Jar (turquoise/turquoise blue)	N046/PSSR/P			
- Putty Super Soft Rapide Cartouche/Cartridge (turquoise/turquoise blue)	N046/PSSR/C			
- Light (saumon/salmon pink)	N046/L			
- Regular (violet/purple)	N046/R			
- Light Rapide (orange)	N046/LR			
- Super Light (jaune/yellow)	N046/SL			
- Tray material (kaki)	N046/TM			
PLASTALGIN PN	294S	35863 – Alginate dental impression material	5	DTE I-ALG 02
PLASTALGIN FAST (ex Ortho)	238S	35863 – Alginate dental impression material	5	
PULPOFLUORANE	290S	38787 – Cryogenic spray dental	5	DTE I-PUL 08

NOM DU DISPOSITIF MEDICAL MEDICAL DEVICE NAME	REF	GMDN code	Règle/ Rule (Annexe IX/ Annex IX)	Dossier Technique Technical file
RACEGEL - 1 seringue / syringe - 3 seringues / syringes	287S/1 287S/5	16352 – Gingival retraction kit	5	DTE I-RACG 21
RACESTYPTINE Solution - 13 ml - 45ml	196S/13 196S/45	46423 – Gingival retraction solution	5	DTE I-RAS 16
RACESTYPTINE CORD N (ex SEPTOCORD) - N°0 - N°1	210S/0 210S/1	35861 – Gingival retraction cord, non medicated	5	DTE I-SEP 10
SEPTOFIL - Ultra Fin / Ultra Thin - Fin / Thin - Moyen / Medium - Gros / Thick - Assortis / Assorted	262S 259S 261S 260S 259S/260S/ 261S/262S	35861 – Gingival retraction cord, non medicated	5	DTE I-SEPF 17
TRAY-NET	222S	38773 – Instrument cleaning agent	5	DTE I-TRAYN 43
ULTRA SAFETY PLUS Twist Part B sterilisable	345S	64304 – Manual non- rotary , dental instrument handle	1	DTE I-USPTS 23