



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,

Date : 14 Novembre 2019 / November 14, 2019



Anne LECOQ,
Directeur Qualité Europe – Pharmacien Responsable
Europe Quality Director – Pharmacist Responsible



ANNEXE / APPENDIX

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

NOM DU DISPOSITIF MEDICAL MEDICAL DEVICE NAME	REF	GMDN code	Règle/ Rule (Annexe IX/ Annex IX)	Date 1 ^{ère} déclaration Date of 1 st declaration
CALYPSO - Framboise - Menthe - Orange	263S 264S 265S	42345 – Dental mouthwash	5	08/12/1997
CONDENSIL		35866 – Silicone dental impression material	5	30/12/1998
- Fluide bleu	N129/FB			
- Fluide vert	N129/FV			
- Lourd	N129/L			
- Catalyseur	N129/C			
DETARTRINE Tube: - Detartrine 150 Z - Detartrine 100 ZF	274S 275S	11168 – Toothpaste	5	26/07/2012
DETARTRINE Pot / Jar: - Detartrine - Detartrine Z	323S 324S	11168 – Toothpaste	5	24/10/1995
PERFEXIL BITE - Platinum +	N047	35866 – Silicone dental impression material	5	30/12/1998
PERFEXIL - Platinum +		35866 – Silicone dental impression material	5	30/12/1998
- 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	24/10/1995
PLASTALGIN FAST (ex Ortho)	238S	35863 – Alginate dental impression material	5	24/10/1995



NOM DU DISPOSITIF MEDICAL MEDICAL DEVICE NAME	REF	GMDN code	Règle/ Rule (Annexe IX/ Annex IX)	Date 1 ^{ère} déclaration Date of 1 st declaration
PULPOFLUORANE	290S	38787 – Cryogenic spray dental	5	08/12/1997
RACEGEL - 1 seringue / syringe - 5 seringues / syringes	287S/1 287S/5	16352 – Gingival retraction kit	5	11/02/2009
RACESTYPTINE Solution - 13 ml - 45ml	196S/13 196S/45	46423 – Gingival retraction solution	5	08/06/1999
RACESTYPTINE CORD N (ex SEPTOCORD) - N°0 - N°1	210S/0 210S/1	35861 – Gingival retraction cord, non medicated	5	24/10/1995
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	20/06/2001
TRAY-NET	222S	38773 - Instrument cleaning agent	5	31/10/2017