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CE

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
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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

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(annule et remplace version October 2017)

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 1ère déclaration *Date of 1st 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 - Platinium +	N047	35866 – Silicone dental impression material	5	30/12/1998
PERFEXIL - Platinium +		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 1ère déclaration *Date of 1st 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