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septodont



**DECLARATION DE CONFORMITE / DECLARATION OF CONFORMITY**  
**(conformément à la Directive 93/42/CEE / according to Directive 93/42/EEC)**

Nous / We,

SEPTODONT  
58 rue du Pont de Créteil  
94107 Saint-Maur-des-Fossés Cedex - FRANCE

fabricant, assurons et déclarons sous notre entière responsabilité que les dispositifs médicaux de classe IIa listés en annexe satisfont aux exigences de la Directive 93/42/CEE et du Code de la Santé Publique Français (Titre I, Livre II, Partie V), sa transcription en droit français.

*manufacturer, assure and declare under our sole responsibility that the Class IIa medical devices listed in appendix meet the provisions of the Directive 93/42/EEC and French Public Health Code (Title I, Book II, Part V), its transcription into French law.*

Cette déclaration est basée sur les éléments suivants:

*This declaration is based on the following documents:*

- Documentation technique démontrant la conformité de ces produits aux exigences essentielles suivant l'Annexe I de la Directive 93/42/CEE,  
*Technical documentation demonstrating the conformity of these products to the essential requirements according to Annex I of Directive 93/42/EEC,*

- Attestation CE N° 36719 (date d'expiration : 26 mai 2024) d'approbation du Système d'Assurance Qualité de la Production suivant l'Annexe V.3 de la Directive 93/42/CEE délivrée par le GMED\* (Organisme notifié n°0459).

*EC Certificate N° 36719 (expiry date: May 26<sup>th</sup>, 2024) for the approval of Production Quality Assurance System according to Annex V.3 of Directive 93/42/EEC issued by GMED\* (Notified body n°0459).*

Saint-Maur-des-Fossés,

Date : 20/07/2020

Myriam BOUSQUET BEDU,  
Directeur Assurance Qualité – Pharmacien Responsable Intérimaire  
*Quality Assurance Director – Pharmacist Responsible Deputy*

\*GMED – 1 rue Gaston Boissier - 75724 Paris Cedex 15

Nom du produit/ Product name	REF	Diamètre x Longueur Diameter x Length (mm)	Format cartouche Cartridge format (mL)	Code GMDN GMDN code	Dossier Technique Technical file	Classification (Règle/ Rule)
<b>Ultra Safety Plus</b>	336S-342S/0.3x10_1.8	0.3x10	1.8	<b>45152</b> Dental anaesthesia injection kit	DTE Ila 011/S/Z-USP	6
	336S-342S/0.3x12_1.8	0.3x12				
	336S-342S/0.3x16_1.8	0.3x16				
	336S-342S/0.3x21_1.8	0.3x21				
	336S-342S/0.3x25_1.8	0.3x25				
	336S-342S/0.4x08_1.8	0.4x8				
	336S-342S/0.4x16_1.8	0.4x16				
	336S-342S/0.4x21_1.8	0.4x21				
	336S-342S/0.4x25_1.8	0.4x25				
	336S-342S/0.4x35_1.8	0.4x35				
	336S-342S/0.5x35_1.8	0.5x35				
	336S-342S/0.3x10_2.2	0.3x10	2.2			
	336S-342S/0.3x12_2.2	0.3x12				
	336S-342S/0.3x16_2.2	0.3x16				
	336S-342S/0.3x21_2.2	0.3x21				
	336S-342S/0.3x25_2.2	0.3x25				
	336S-342S/0.4x08_2.2	0.4x8				
	336S-342S/0.4x16_2.2	0.4x16				
	336S-342S/0.4x21_2.2	0.4x21				
	336S-342S/0.4x25_2.2	0.4x25				
336S-342S/0.4x35_2.2	0.4x35					
336S-342S/0.5x35_2.2	0.5x35					

Nom du produit/ Product name	REF	Diamètre x Longueur Diameter x Length (mm)	Format cartouche Cartridge format (mL)	Code GMDN GMDN code	Dossier Technique Technical file	Classification (Règle/ Rule)	
<b>Ultra Safety Plus Part A</b>	336S/0.3x10_1.8	0.3x10	1.8	12740 Dental syringe needle, single-use	DTE Ila 011/S/Z-USP	6	
	336S/0.3x12_1.8	0.3x12					
	336S/0.3x16_1.8	0.3x16					
	336S/0.3x21_1.8	0.3x21					
	336S/0.3x25_1.8	0.3x25					
	336S/0.4x8_1.8	0.4x8					
	336S/0.4x16_1.8	0.4x16					
	336S/0.4x21_1.8	0.4x21					
	336S/0.4x25_1.8	0.4x25					
	336S/0.4x35_1.8	0.4x35					
	336S/0.5x35_1.8	0.5x35					
	336S/0.3x10_2.2	0.3x10					2.2
	336S/0.3x12_2.2	0.3x12					
	336S/0.3x16_2.2	0.3x16					
	336S/0.3x21_2.2	0.3x21					
	336S/0.3x25_2.2	0.3x25					
	336S/0.4x8_2.2	0.4x8					
	336S/0.4x16_2.2	0.4x16					
	336S/0.4x21_2.2	0.4x21					
	336S/0.4x25_2.2	0.4x25					
336S/0.4x35_2.2	0.4x35						
336S/0.5x35_2.2	0.5x35						

Nom du produit/ Product name	REF	Diamètre x Longueur Diameter x Length (mm)	Format cartouche Cartridge format (mL)	Code GMDN GMDN code	Dossier Technique Technical file	Classification (Règle/ Rule)
<b>Ultra Safety Plus XL</b>	337S-342S/0.3x10_1.8	0.3x10	1.8	45152 Dental anaesthesia injection kit	DTE IIa 011/SIZ-USP	6
	337S-342S/0.3x12_1.8	0.3x12				
	337S-342S/0.3x16_1.8	0.3x16				
	337S-342S/0.3x21_1.8	0.3x21				
	337S-342S/0.3x25_1.8	0.3x25				
	337S-342S/0.4x08_1.8	0.4x8				
	337S-342S/0.4x16_1.8	0.4x16				
	337S-342S/0.4x21_1.8	0.4x21				
	337S-342S/0.4x25_1.8	0.4x25				
	337S-342S/0.4x35_1.8	0.4x35				
	337S-342S/0.5x35_1.8	0.5x35				
	337S-342S/0.3x10_2.2	0.3x10	2.2			
	337S-342S/0.3x12_2.2	0.3x12				
	337S-342S/0.3x16_2.2	0.3x16				
	337S-342S/0.3x21_2.2	0.3x21				
	337S-342S/0.3x25_2.2	0.3x25				
	337S-342S/0.4x08_2.2	0.4x8				
	337S-342S/0.4x16_2.2	0.4x16				
	337S-342S/0.4x21_2.2	0.4x21				
	337S-342S/0.4x25_2.2	0.4x25				
337S-342S/0.4x35_2.2	0.4x35					
337S-342S/0.5x35_2.2	0.5x35					

Nom du produit/ Product name	REF	Diamètre x Longueur Diameter x Length (mm)	Format cartouche Cartridge format (mL)	Code GMDN GMDN code	Dossier Technique Technical file	Classification (Règle/ Rule)
<b>Ultra Safety Plus XL Part A</b>	337S/0.3x10_1.8	0.3x10	1.8	12740 Dental syringe needle, single-use	DTE Ila 011/S/Z-USP	6
	337S/0.3x12_1.8	0.3x12				
	337S/0.3x16_1.8	0.3x16				
	337S/0.3x21_1.8	0.3x21				
	337S/0.3x25_1.8	0.3x25				
	337S/0.4x8_1.8	0.4x8				
	337S/0.4x16_1.8	0.4x16				
	337S/0.4x21_1.8	0.4x21				
	337S/0.4x25_1.8	0.4x25				
	337S/0.4x35_1.8	0.4x35				
	337S/0.5x35_1.8	0.5x35				
	337S/0.3x10_2.2	0.3x10	2.2			
	337S/0.3x12_2.2	0.3x12				
	337S/0.3x16_2.2	0.3x16				
	337S/0.3x21_2.2	0.3x21				
	337S/0.3x25_2.2	0.3x25				
	337S/0.4x8_2.2	0.4x8				
	337S/0.4x16_2.2	0.4x16				
	337S/0.4x21_2.2	0.4x21				
	337S/0.4x25_2.2	0.4x25				
337S/0.4x35_2.2	0.4x35					
337S/0.5x35_2.2	0.5x35					

Nom du produit/ Product name	REF	Diamètre x Longueur Diameter x Length (mm)	Format cartouche Cartridge format (mL)	Code GMDN GMDN code	Dossier Technique Technical file	Classification (Règle/ Rule)
<b>Ultra Safety Plus Twist Part A</b>	343S/0.3x10_1.8	0.3 x10	1.8	<b>12740</b> Dental syringe needle, single-use	DTE Ila TWIST 61	6
	343S/0.3x12_1.8	0.3 x12				
	343S/0.3x16_1.8	0.3 x16				
	343S/0.3x21_1.8	0.3 x21				
	343S/0.3x25_1.8	0.3 x25				
	343S/0.4x8_1.8	0.4 x8				
	343S/0.4x16_1.8	0.4 x16				
	343S/0.4x21_1.8	0.4 x21				
	343S/0.4x25_1.8	0.4 x25				
	343S/0.4x35_1.8	0.4 x35				
	343S/0.5x35_1.8	0.5 x35				
	343S/0.3x10_2.2	0.3 x10	2.2			
	343S/0.3x12_2.2	0.3 x12				
	343S/0.3x16_2.2	0.3 x16				
	343S/0.3x21_2.2	0.3 x21				
	343S/0.3x25_2.2	0.3 x25				
	343S/0.4x8_2.2	0.4 x8				
	343S/0.4x16_2.2	0.4 x16				
	343S/0.4x21_2.2	0.4 x21				
	343S/0.4x25_2.2	0.4 x25				
343S/0.4x35_2.2	0.4 x35					
343S/0.5x35_2.2	0.5 x35					

Nom du produit/ Product name	REF	Diamètre x Longueur Diameter x Length (mm)	Format cartouche Cartridge format (mL)	Code GMDN GMDN code	Dossier Technique Technical file	Classification (Règle/ Rule)
Ultra Safety Plus Twist XL Part A	344S/0.3x10_1.8	0.3 x10	1.8	12740 Dental syringe needle, single-use	DTE Ila TWIST 61	6
	344S/0.3x12_1.8	0.3 x12				
	344S/0.3x16_1.8	0.3 x16				
	344S/0.3x21_1.8	0.3 x21				
	344S/0.3x25_1.8	0.3 x25				
	344S/0.4x8_1.8	0.4 x8				
	344S/0.4x16_1.8	0.4 x16				
	344S/0.4x21_1.8	0.4 x21				
	344S/0.4x25_1.8	0.4 x25				
	344S/0.4x35_1.8	0.4 x35				
	344S/0.5x35_1.8	0.5 x35				
	344S/0.3x10_2.2	0.3 x10	2.2			
	344S/0.3x12_2.2	0.3 x12				
	344S/0.3x16_2.2	0.3 x16				
	344S/0.3x21_2.2	0.3 x21				
	344S/0.3x25_2.2	0.3 x25				
	344S/0.4x8_2.2	0.4 x8				
	344S/0.4x16_2.2	0.4 x16				
	344S/0.4x21_2.2	0.4 x21				
	344S/0.4x25_2.2	0.4 x25				
344S/0.4x35_2.2	0.4 x35					
344S/0.5x35_2.2	0.5 x35					