

ATTESTATION CE / EC CERTIFICATE

Approbation du Système d'assurance Qualité de la Production / Approval of Production Quality Assurance System

ANNEXE V point 3 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX V section 3 DIRECTIVE 93/42/EEC concerning medical devices

Pour les dispositifs de classe IIb ou III, un certificat CE de type est requis

For class IIb or III devices, a EC type certificate is required

Fabricant / Manufacturer

SEPTODONT

58 rue du Pont de Créteil

94107 SAINT MAUR DES FOSSES CEDEX FRANCE

Catégorie du(des) dispositif(s) / Device(s) category

Dispositif d'injection sécurisé stérile à usage unique

Sterile single use secured injection medical device

Voir détails sur addendum

See attachment for additional information

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P600252 - P600936, le système d'assurance qualité - pour la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe V point 3 de la Directive 93/42/CEE.


GMED certifies that, on the basis of the results contained in the file referenced P600252 - P600936, the quality system - for manufacturing and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex V section 3.

La validité du présent certificat est soumise à une vérification périodique ou imprévue

The validity of the certificate is subject to periodic or unexpected verification

Début de validité / Effective date : July 31st, 2020 (included)

Valable jusqu'au / Expiry date : May 26th, 2024 (included)

Signed by:

EF33BDA9BAA04A3...

On behalf of the President

Béatrice LYS

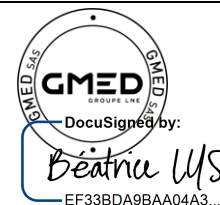
Technical Director

Identification des dispositifs / Identification of devices

GAMME « ULTRA SAFETY PLUS »

Nom/Désignation du dispositif	Référence commerciale du dispositif ou code article ^(a)
ULTRA SAFETY PLUS 0.3 x 10 mm_1.8ml	336S-342S/0.3x10_1.8
ULTRA SAFETY PLUS 0.3 x 12 mm_1.8ml	336S-342S/0.3x12_1.8
ULTRA SAFETY PLUS 0.3 x 16 mm_1.8ml	336S-342S/0.3x16_1.8
ULTRA SAFETY PLUS 0.3 x 21 mm_1.8ml	336S-342S/0.3x21_1.8
ULTRA SAFETY PLUS 0.3 x 25 mm_1.8ml	336S-342S/0.3x25_1.8
ULTRA SAFETY PLUS 0.4 x 8 mm_1.8ml	336S-342S/0.4x08_1.8
ULTRA SAFETY PLUS 0.4 x 16 mm_1.8ml	336S-342S/0.4x16_1.8
ULTRA SAFETY PLUS 0.4 x 21 mm_1.8ml	336S-342S/0.4x21_1.8
ULTRA SAFETY PLUS 0.4 x 25 mm_1.8ml	336S-342S/0.4x25_1.8
ULTRA SAFETY PLUS 0.4 x 35 mm_1.8ml	336S-342S/0.4x35_1.8
ULTRA SAFETY PLUS 0.5 x 35 mm_1.8ml	336S-342S/0.5x35_1.8
ULTRA SAFETY PLUS 0.3 x 10 mm_2.2ml	336S-342S/0.3x10_2.2
ULTRA SAFETY PLUS 0.3 x 12 mm_2.2ml	336S-342S/0.3x12_2.2
ULTRA SAFETY PLUS 0.3 x 16 mm_2.2ml	336S-342S/0.3x16_2.2
ULTRA SAFETY PLUS 0.3 x 21 mm_2.2ml	336S-342S/0.3x21_2.2
ULTRA SAFETY PLUS 0.3 x 25 mm_2.2ml	336S-342S/0.3x25_2.2
ULTRA SAFETY PLUS 0.4 x 8 mm_2.2ml	336S-342S/0.4x08_2.2
ULTRA SAFETY PLUS 0.4 x 16 mm_2.2ml	336S-342S/0.4x16_2.2

GMED	0459
-------------	-------------



On behalf of the President
Béatrice LYS
Technical Director

ULTRA SAFETY PLUS 0.4 x 21 mm_2.2ml	336S-342S/0.4x21_2.2
ULTRA SAFETY PLUS 0.4 x 25 mm_2.2ml	336S-342S/0.4x25_2.2
ULTRA SAFETY PLUS 0.4 x 35 mm_2.2ml	336S-342S/0.4x35_2.2
ULTRA SAFETY PLUS 0.5 x 35 mm_2.2ml	336S-342S/0.5x35_2.2

GAMME « ULTRA SAFETY PLUS PART A »

Nom/Désignation du dispositif	Référence commerciale du dispositif ou code article ^(a)
ULTRA SAFETY PLUS Part A 0.3 x 10 mm_1.8ml	336S/0.3x10_1.8
ULTRA SAFETY PLUS Part A 0.3 x 12 mm_1.8ml	336S/0.3x12_1.8
ULTRA SAFETY PLUS Part A 0.3 x 16 mm_1.8ml	336S/0.3x16_1.8
ULTRA SAFETY PLUS Part A 0.3 x 21 mm_1.8ml	336S/0.3x21_1.8
ULTRA SAFETY PLUS Part A 0.3 x 25 mm_1.8ml	336S/0.3x25_1.8
ULTRA SAFETY PLUS Part A 0.4 x 8 mm_1.8ml	336S/0.4x8_1.8
ULTRA SAFETY PLUS Part A 0.4 x 16 mm_1.8ml	336S/0.4x16_1.8
ULTRA SAFETY PLUS Part A 0.4 x 21 mm_1.8ml	336S/0.4x21_1.8
ULTRA SAFETY PLUS Part A 0.4 x 25 mm_1.8ml	336S/0.4x25_1.8
ULTRA SAFETY PLUS Part A 0.4 x 35 mm_1.8ml	336S/0.4x35_1.8
ULTRA SAFETY PLUS Part A 0.5 x 35 mm_1.8ml	336S/0.5x35_1.8
ULTRA SAFETY PLUS Part A 0.3 x 10 mm_2.2ml	336S/0.3x10_2.2
ULTRA SAFETY PLUS Part A 0.3 x 12 mm_2.2ml	336S/0.3x12_2.2
ULTRA SAFETY PLUS Part A 0.3 x 16 mm_2.2ml	336S/0.3x16_2.2
ULTRA SAFETY PLUS Part A 0.3 x 21 mm_2.2ml	336S/0.3x21_2.2

GMED 0459



DocuSigned by:

Béatrice LYS

EF33BDA9BAA04A3...

**On behalf of the President
 Béatrice LYS
 Technical Director**

ULTRA SAFETY PLUS Part A 0.3 x 25 mm_2.2ml	336S/0.3x25_2.2
ULTRA SAFETY PLUS Part A 0.4 x 8 mm_2.2ml	336S/0.4x8_2.2
ULTRA SAFETY PLUS Part A 0.4 x 16 mm_2.2ml	336S/0.4x16_2.2
ULTRA SAFETY PLUS Part A 0.4 x 21 mm_2.2ml	336S/0.4x21_2.2
ULTRA SAFETY PLUS Part A 0.4 x 25 mm_2.2ml	336S/0.4x25_2.2
ULTRA SAFETY PLUS Part A 0.4 x 35 mm_2.2ml	336S/0.4x35_2.2
ULTRA SAFETY PLUS Part A 0.5 x 35 mm_2.2ml	336S/0.5x35_2.2

GAMME « ULTRA SAFETY PLUS XL »

Nom/Désignation du dispositif	Référence commerciale du dispositif ou code article ^{a)}
ULTRA SAFETY PLUS XL 0.3 x 10 mm_1.8ml	337S-342S/0.3x10_1.8
ULTRA SAFETY PLUS XL 0.3 x 12 mm_1.8ml	337S-342S/0.3x12_1.8
ULTRA SAFETY PLUS XL 0.3 x 16 mm_1.8ml	337S-342S/0.3x16_1.8
ULTRA SAFETY PLUS XL 0.3 x 21 mm_1.8ml	337S-342S/0.3x21_1.8
ULTRA SAFETY PLUS XL 0.3 x 25 mm_1.8ml	337S-342S/0.3x25_1.8
ULTRA SAFETY PLUS XL 0.4 x 8 mm_1.8ml	337S-342S/0.4x08_1.8
ULTRA SAFETY PLUS XL 0.4 x 16 mm_1.8ml	337S-342S/0.4x16_1.8
ULTRA SAFETY PLUS XL 0.4 x 21 mm_1.8ml	337S-342S/0.4x21_1.8
ULTRA SAFETY PLUS XL 0.4 x 25 mm_1.8ml	337S-342S/0.4x25_1.8
ULTRA SAFETY PLUS XL 0.4 x 35 mm_1.8ml	337S-342S/0.4x35_1.8
ULTRA SAFETY PLUS XL 0.5 x 35 mm_1.8ml	337S-342S/0.5x35_1.8
ULTRA SAFETY PLUS XL 0.3 x 10 mm_2.2ml	337S-342S/0.3x10_2.2



GMED 0459

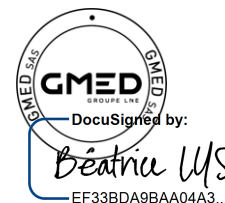
**On behalf of the President
 Béatrice LYS
 Technical Director**

ULTRA SAFETY PLUS XL 0.3 x 12 mm_2.2ml	337S-342S/0.3x12_2.2
ULTRA SAFETY PLUS XL 0.3 x 16 mm_2.2ml	337S-342S/0.3x16_2.2
ULTRA SAFETY PLUS XL 0.3 x 21 mm_2.2ml	337S-342S/0.3x21_2.2
ULTRA SAFETY PLUS XL 0.3 x 25 mm_2.2ml	337S-342S/0.3x25_2.2
ULTRA SAFETY PLUS XL 0.4 x 8 mm_2.2ml	337S-342S/0.4x08_2.2
ULTRA SAFETY PLUS XL 0.4 x 16 mm_2.2ml	337S-342S/0.4x16_2.2
ULTRA SAFETY PLUS XL 0.4 x 21 mm_2.2ml	337S-342S/0.4x21_2.2
ULTRA SAFETY PLUS XL 0.4 x 25 mm_2.2ml	337S-342S/0.4x25_2.2
ULTRA SAFETY PLUS XL 0.4 x 35 mm_2.2ml	337S-342S/0.4x35_2.2
ULTRA SAFETY PLUS XL 0.5 x 35 mm_2.2ml	337S-342S/0.5x35_2.2

GAMME « ULTRA SAFETY PLUS XL Part A »

Nom/Désignation du dispositif	Référence commerciale du dispositif ou code article ^(a)
ULTRA SAFETY PLUS XL Part A 0.3 x 10 mm_1.8ml	337S/0.3x10_1.8
ULTRA SAFETY PLUS XL Part A 0.3 x 12 mm_1.8ml	337S/0.3x12_1.8
ULTRA SAFETY PLUS XL Part A 0.3 x 16 mm_1.8ml	337S/0.3x16_1.8
ULTRA SAFETY PLUS XL Part A 0.3 x 21 mm_1.8ml	337S/0.3x21_1.8
ULTRA SAFETY PLUS XL Part A 0.3 x 25 mm_1.8ml	337S/0.3x25_1.8
ULTRA SAFETY PLUS XL Part A 0.4 x 8 mm_1.8ml	337S/0.4x8_1.8
ULTRA SAFETY PLUS XL Part A 0.4 x 16 mm_1.8ml	337S/0.4x16_1.8
ULTRA SAFETY PLUS XL Part A 0.4 x 21 mm_1.8ml	337S/0.4x21_1.8
ULTRA SAFETY PLUS XL Part A 0.4 x 25 mm_1.8ml	337S/0.4x25_1.8

GMED 0459



**On behalf of the President
 Béatrice LYS
 Technical Director**

ULTRA SAFETY PLUS XL Part A 0.4 x 35 mm_1.8ml	337S/0.4x35_1.8
ULTRA SAFETY PLUS XL Part A 0.5 x 35 mm_1.8ml	337S/0.5x35_1.8
ULTRA SAFETY PLUS XL Part A 0.3 x 10 mm_2.2ml	337S/0.3x10_2.2
ULTRA SAFETY PLUS XL Part A 0.3 x 12 mm_2.2ml	337S/0.3x12_2.2
ULTRA SAFETY PLUS XL Part A 0.3 x 16 mm_2.2ml	337S/0.3x16_2.2
ULTRA SAFETY PLUS XL Part A 0.3 x 21 mm_2.2ml	337S/0.3x21_2.2
ULTRA SAFETY PLUS XL Part A 0.3 x 25 mm_2.2ml	337S/0.3x25_2.2
ULTRA SAFETY PLUS XL Part A 0.4 x 8 mm_2.2ml	337S/0.4x8_2.2
ULTRA SAFETY PLUS XL Part A 0.4 x 16 mm_2.2ml	337S/0.4x16_2.2
ULTRA SAFETY PLUS XL Part A 0.4 x 21 mm_2.2ml	337S/0.4x21_2.2
ULTRA SAFETY PLUS XL Part A 0.4 x 25 mm_2.2ml	337S/0.4x25_2.2
ULTRA SAFETY PLUS XL Part A 0.4 x 35 mm_2.2ml	337S/0.4x35_2.2
ULTRA SAFETY PLUS XL Part A 0.5 x 35 mm_2.2ml	337S/0.5x35_2.2

GAMME « ULTRA SAFETY PLUS Twist Part A »

Nom/Désignation du dispositif	Référence commerciale du dispositif ou code article ^(a)
ULTRA SAFETY PLUS Twist Part A 0.3 x 10 mm_1.8ml	343S/0.3x10_1.8
ULTRA SAFETY PLUS Twist Part A 0.3 x 12 mm_1.8ml	343S/0.3x12_1.8
ULTRA SAFETY PLUS Twist Part A 0.3 x 16 mm_1.8ml	343S/0.3x16_1.8
ULTRA SAFETY PLUS Twist Part A 0.3 x 21 mm_1.8ml	343S/0.3x21_1.8
ULTRA SAFETY PLUS Twist Part A 0.3 x 25 mm_1.8ml	343S/0.3x25_1.8
ULTRA SAFETY PLUS Twist Part A 0.4 x 8 mm_1.8ml	343S/0.4x8_1.8

GMED 0459



DocuSigned by:

Béatrice LYS

EF33BDA9BAA04A3...

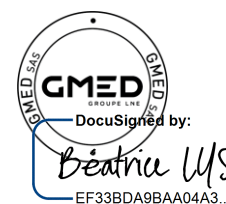
On behalf of the President
Béatrice LYS
Technical Director

ULTRA SAFETY PLUS Twist Part A 0.4 x 16 mm_1.8ml	343S/0.4x16_1.8
ULTRA SAFETY PLUS Twist Part A 0.4 x 21 mm_1.8ml	343S/0.4x21_1.8
ULTRA SAFETY PLUS Twist Part A 0.4 x 25 mm_1.8ml	343S/0.4x25_1.8
ULTRA SAFETY PLUS Twist Part A 0.4 x 35 mm_1.8ml	343S/0.4x35_1.8
ULTRA SAFETY PLUS Twist Part A 0.5 x 35 mm_1.8ml	343S/0.5x35_1.8
ULTRA SAFETY PLUS Twist Part A 0.3 x 10 mm_2.2ml	343S/0.3x10_2.2
ULTRA SAFETY PLUS Twist Part A 0.3 x 12 mm_2.2ml	343S/0.3x12_2.2
ULTRA SAFETY PLUS Twist Part A 0.3 x 16 mm_2.2ml	343S/0.3x16_2.2
ULTRA SAFETY PLUS Twist Part A 0.3 x 21 mm_2.2ml	343S/0.3x21_2.2
ULTRA SAFETY PLUS Twist Part A 0.3 x 25 mm_2.2ml	343S/0.3x25_2.2
ULTRA SAFETY PLUS Twist Part A 0.4 x 8 mm_2.2ml	343S/0.4x8_2.2
ULTRA SAFETY PLUS Twist Part A 0.4 x 16 mm_2.2ml	343S/0.4x16_2.2
ULTRA SAFETY PLUS Twist Part A 0.4 x 21 mm_2.2ml	343S/0.4x21_2.2
ULTRA SAFETY PLUS Twist Part A 0.4 x 25 mm_2.2ml	343S/0.4x25_2.2
ULTRA SAFETY PLUS Twist Part A 0.4 x 35 mm_2.2ml	343S/0.4x35_2.2
ULTRA SAFETY PLUS Twist Part A 0.5 x 35 mm_2.2ml	343S/0.5x35_2.2

GAMME « ULTRA SAFETY PLUS Twist XL Part A »

Nom/Désignation du dispositif	Référence commerciale du dispositif ou code article ^(a)
ULTRA SAFETY PLUS Twist XL Part A 0.3 x 10 mm_1.8ml	344S/0.3x10_1.8
ULTRA SAFETY PLUS Twist XL Part A 0.3 x 12 mm_1.8ml	344S/0.3x12_1.8

GMED 0459



**On behalf of the President
 Béatrice LYS
 Technical Director**

ULTRA SAFETY PLUS Twist XL Part A 0.3 x 16 mm_1.8ml	344S/0.3x16_1.8
ULTRA SAFETY PLUS Twist XL Part A 0.3 x 21 mm_1.8ml	344S/0.3x21_1.8
ULTRA SAFETY PLUS Twist XL Part A 0.3 x 25 mm_1.8ml	344S/0.3x25_1.8
ULTRA SAFETY PLUS Twist XL Part A 0.4 x 8 mm_1.8ml	344S/0.4x8_1.8
ULTRA SAFETY PLUS Twist XL Part A 0.4 x 16 mm_1.8ml	344S/0.4x16_1.8
ULTRA SAFETY PLUS Twist XL Part A 0.4 x 21 mm_1.8ml	344S/0.4x21_1.8
ULTRA SAFETY PLUS Twist XL Part A 0.4 x 25 mm_1.8ml	344S/0.4x25_1.8
ULTRA SAFETY PLUS Twist XL Part A 0.4 x 35 mm_1.8ml	344S/0.4x35_1.8
ULTRA SAFETY PLUS Twist XL Part A 0.5 x 35 mm_1.8ml	344S/0.5x35_1.8
ULTRA SAFETY PLUS Twist XL Part A 0.3 x 10 mm_2.2ml	344S/0.3x10_2.2
ULTRA SAFETY PLUS Twist XL Part A 0.3 x 12 mm_2.2ml	344S/0.3x12_2.2
ULTRA SAFETY PLUS Twist XL Part A 0.3 x 16 mm_2.2ml	344S/0.3x16_2.2
ULTRA SAFETY PLUS Twist XL Part A 0.3 x 21 mm_2.2ml	344S/0.3x21_2.2
ULTRA SAFETY PLUS Twist XL Part A 0.3 x 25 mm_2.2ml	344S/0.3x25_2.2
ULTRA SAFETY PLUS Twist XL Part A 0.4 x 8 mm_2.2ml	344S/0.4x8_2.2
ULTRA SAFETY PLUS Twist XL Part A 0.4 x 16 mm_2.2ml	344S/0.4x16_2.2
ULTRA SAFETY PLUS Twist XL Part A 0.4 x 21 mm_2.2ml	344S/0.4x21_2.2
ULTRA SAFETY PLUS Twist XL Part A 0.4 x 25 mm_2.2ml	344S/0.4x25_2.2
ULTRA SAFETY PLUS Twist XL Part A 0.4 x 35 mm_2.2ml	344S/0.4x35_2.2
ULTRA SAFETY PLUS Twist XL Part A 0.5 x 35 mm_2.2ml	344S/0.5x35_2.2

GMED 0459



DocuSigned by:

Béatrice LYS

EF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director

Identification des sites et activités / Identification of locations and activities


✚ 58, Rue du Pont de Créteil - 94107 SAINT MAUR DES FOSSES CEDEX – France :
Siège social, fabrication / *Headquarters, manufacturing*

✚ 58, Rue du Pont de Créteil - 94100 SAINT MAUR DES FOSSES – France :
Fabrication / *Manufacturing*

✚ 103-105 avenue Beaurepaire - 94100 SAINT MAUR DES FOSSES – France :
Conception, affaires réglementaires, vigilance / *Design, regulatory affairs, vigilance*

✚ 4 rue Ambroise Croizat – 77183 CROISSY BEAUBOURG – France :
Stockage, distribution, service clients France et export, réclamation clients, communication /
Warehouse, distribution, France and export customer services France, customer complaints, communication

GMED | **0459**


DocuSigned by:
Béatrice LYS
EF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director