

Déclaration CE de conformité EC declaration of conformity

Conformément à la Directive 93/42/CEE et au titre 1^{er} du livre II de la partie V du
Code de Santé Publique, sa transcription en droit français
*According to Directive 93/42/EEC and to first title of book II of part V of the French
public health code, its transcription into French law*

Fabricant : <i>Manufacturer</i>	VYCON 5, rue Adeline - 95440 Ecouen FRANCE
Gamme de produit : <i>Product group</i>	Prolongateurs souples – Accessoires de cathétérisme Flexible extension lines – IV Accessories Voir la liste de produits jointe / <i>See attached product list</i>
Classe : <i>Class</i>	IIa
Code GMDN : <i>GMDN code</i>	12170 Nécessaire d'extension de tubes d'administration intraveineuse / <i>Intravenous administration tubing extension set</i> 35072 Filtre de ligne intraveineuse / <i>Intravenous line filter</i>
Evaluation de la conformité : <i>Conformity assessment</i>	Annexe II excluant le point 4 Directive 93/42/CEE Annex II excluding section 4 Directive 93/42/EEC
Attestation CE : <i>EC Certificate</i>	9556 rev.11
Organisme Notifié : <i>Notified Body</i>	GMED - 0459 1, rue Gaston Boissier – 75015 Paris – France
Dossier Technique <i>Technical File</i>	DT078

Nous, Société Vygon, déclarons sous notre seule responsabilité que la gamme de produit mentionnée ci-dessus, satisfait aux dispositions de la directive européenne 93/42/CEE et du titre 1^{er} du livre II de la partie V du code de la santé publique, sa transcription en droit français, qui lui sont applicables.

We, Vygon, declare under our sole responsibility that the above-mentioned product group, complies with the european directive 93/42/EEC and the first title of book II of part V of the French public health code, its transcription into French law, which are applicable.

Par / by	Christophe FLUTEAUX Directeur R&D et Affaires Réglementaires <i>R&D and Regulatory Affairs Director</i>
Date	17/08/2022
Version/Revision	B3

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Références Produits / Product references

REFERENCE	DESIGNATION	Quantité par boîte / Quantity per box
Prolongateurs PE/PVC / PE/PVC Extension lines		
Classe / Class : IIa – Règle / rule : 2 – GMDN : 12170		
140.00	Connect-A-set 3 - Ø2.5×4.0mm - L.25cm - Vol.1.8ml Connect-A-set 3 - Ø2.5×4.0mm - L.25cm - Vol.1.8ml	50
140.80	Connect-A-set 3 - Ø2.5×4.0mm - L.80cm - Vol.4.5ml Connect-A-set 3 - Ø2.5×4.0mm - L.80cm - Vol.4.5ml	25
141.00	Connect-A-set 3 - Ø2.5×4.0mm - L.25cm - Vol.1.7ml Connect-A-set 3 - Ø2.5×4.0mm - L.25cm - Vol.1.7ml	50
141.01	Connect-A-set 3 - Ø2.5×4.0mm - L.13.5cm - Vol.1.2ml Connect-A-set 3 - Ø2.5×4.0mm - L.13.5cm - Vol.1.2ml	
141.80	Connect-A-set 3 - Ø2.5×4.0mm - L.80cm - Vol.4.4ml Connect-A-set 3 - Ø2.5×4.0mm - L.80cm - Vol.4.4ml	25
70141.00	Connect-A-set 3 - Ø2.5×4.0mm - L.25cm - Vol.1.7ml Connect-A-set 3 - Ø2.5×4.0mm - L.25cm - Vol.1.7ml	50
70141.01	Connect-A-set 3 - Ø2.5×4.0mm - L.13.5cm - Vol.1.1ml Connect-A-set 3 - Ø2.5×4.0mm - L.13.5cm - Vol.1.1ml	
70141.05	Connect-A-set 3 - Ø2.5×4.0mm - L.50cm - Vol.2.9ml Connect-A-set 3 - Ø2.5×4.0mm - L.50cm - Vol.2.9ml	
70141.10	Connect-A-set 3 - Ø2.5×4.0mm - L.100cm - Vol.5.3ml Connect-A-set 3 - Ø2.5×4.0mm - L.100cm - Vol.5.3ml	25
70141.80	Connect-A-set 3 - Ø2.5×4.0mm - L.80cm - Vol.4.4ml Connect-A-set 3 - Ø2.5×4.0mm - L.80cm - Vol.4.4ml	
5140.00	Connect-A-set 3 + bionector - Ø3.0×4.2mm - L.14cm - Vol.1.4ml Connect-A-set 3 + bionector - Ø3.0×4.2mm - L.14cm - Vol.1.4ml	50
5141.00	Connect-A-set 3 + bionector - Ø2.5×4.0mm - L.25cm - Vol.1.7ml Connect-A-set 3 + bionector - Ø2.5×4.0mm - L.25cm - Vol.1.7ml	
5141.01	Connect-A-set 3 + bionector - Ø2.5×4.0mm - L.13.5cm - Vol.1.1ml Connect-A-set 3 + bionector - Ø2.5×4.0mm - L.13.5cm - Vol.1.1ml	
5141.10	Connect-A-set 3 + bionector - Ø2.5×4.0mm - L.100cm - Vol.5.4ml Connect-A-set 3 + bionector - Ø2.5×4.0mm - L.100cm - Vol.5.4ml	25
5141.001	Connect-A-set 3 + bionector - Ø2.5×4.0mm - L.25cm - Vol.1.7ml Connect-A-set 3 + bionector - Ø2.5×4.0mm - L.25cm - Vol.1.7ml	50
5141.011	Connect-A-set 3 + bionector - Ø2.5×4.0mm - L.13.5cm - Vol.1.1ml Connect-A-set 3 + bionector - Ø2.5×4.0mm - L.13.5cm - Vol.1.1ml	
5141.005	Connect-A-set 3 + vadsite - Ø2.5×4.0mm - L.25cm - Vol.1.7ml Connect-A-set 3 + vadsite - Ø2.5×4.0mm - L.25cm - Vol.1.7ml	
5141.015	Connect-A-set 3 + vadsite - Ø2.5×4.0mm - L.13.5cm - Vol.1.1ml Connect-A-set 3 + vadsite - Ø2.5×4.0mm - L.13.5cm - Vol.1.1ml	

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Prolongateurs PE/PVC / PE/PVC Extension lines		
Classe / Class : IIa – Règle / rule : 2 – GMDN : 12170		
220.010	Lectroflex - Ø2.5×4.0mm - L.13.5cm - Vol.1.0ml - Luer-lock ♀/♂ Lectroflex - Ø2.5×4.0mm - L.13.5cm - Vol.1.0ml - Luer-lock ♀/♂	25
220.020	Lectroflex - Ø2.5×4.0mm - L.25cm - Vol.1.6ml - Luer-lock ♀/♂ Lectroflex - Ø2.5×4.0mm - L.25cm - Vol.1.6ml - Luer-lock ♀/♂	
220.050	Lectroflex - Ø2.5×4.0mm - L.50cm - Vol.2.8ml - Luer-lock ♀/♂ Lectroflex - Ø2.5×4.0mm - L.50cm - Vol.2.8ml - Luer-lock ♀/♂	
220.070	Lectroflex - Ø2.5×4.0mm - L.70cm - Vol.3.8ml - Luer-lock ♀/♂ Lectroflex - Ø2.5×4.0mm - L.70cm - Vol.3.8ml - Luer-lock ♀/♂	
220.100	Lectroflex - Ø2.5×4.0mm - L.100cm - Vol.5.2ml - Luer-lock ♀/♂ Lectroflex - Ø2.5×4.0mm - L.100cm - Vol.5.2ml - Luer-lock ♀/♂	
220.150	Lectroflex - Ø2.5×4.0mm - L.150cm - Vol.7.7ml - Luer-lock ♀/♂ Lectroflex - Ø2.5×4.0mm - L.150cm - Vol.7.7ml - Luer-lock ♀/♂	
220.200	Lectroflex - Ø2.5×4.0mm - L.200cm - Vol.10ml - Luer-lock ♀/♂ Lectroflex - Ø2.5×4.0mm - L.200cm - Vol.10ml - Luer-lock ♀/♂	
221.050	Lectroflex - Ø2.5×4.0mm - L.50cm - Vol.2.8ml - Luer-lock ♂/♂ Lectroflex - Ø2.5×4.0mm - L.50cm - Vol.2.8ml - Luer-lock ♂/♂	
221.100	Lectroflex - Ø2.5×4.0mm - L.100cm - Vol.5.2ml - Luer-lock ♂/♂ Lectroflex - Ø2.5×4.0mm - L.100cm - Vol.5.2ml - Luer-lock ♂/♂	
221.150	Lectroflex - Ø2.5×4.0mm - L.150cm - Vol.7.7ml - Luer-lock ♂/♂ Lectroflex - Ø2.5×4.0mm - L.150cm - Vol.7.7ml - Luer-lock ♂/♂	
221.200	Lectroflex - Ø2.5×4.0mm - L.200cm - Vol.10ml - Luer-lock ♂/♂ Lectroflex - Ø2.5×4.0mm - L.200cm - Vol.10ml - Luer-lock ♂/♂	
222.020	Lectroflex - Ø1.5×2.5mm - L.25cm - Vol.0.59ml - Luer-lock ♀/♂ Lectroflex - Ø1.5×2.5mm - L.25cm - Vol.0.59ml - Luer-lock ♀/♂	
222.050	Lectroflex - Ø1.5×2.5mm - L.50cm - Vol.1.0ml - Luer-lock ♀/♂ Lectroflex - Ø1.5×2.5mm - L.50cm - Vol.1.0ml - Luer-lock ♀/♂	
222.100	Lectroflex - Ø1.5×2.5mm - L.100cm - Vol.1.9ml - Luer-lock ♀/♂ Lectroflex - Ø1.5×2.5mm - L.100cm - Vol.1.9ml - Luer-lock ♀/♂	
222.150	Lectroflex - Ø1.5×2.5mm - L.150cm - Vol.2.8ml - Luer-lock ♀/♂ Lectroflex - Ø1.5×2.5mm - L.150cm - Vol.2.8ml - Luer-lock ♀/♂	
222.200	Lectroflex - Ø1.5×2.5mm - L.200cm - Vol.3.7ml - Luer-lock ♀/♂ Lectroflex - Ø1.5×2.5mm - L.200cm - Vol.3.7ml - Luer-lock ♀/♂	
70222.021	Lectroflex - Ø1.0×2.5mm - L.25cm - Vol.0.5ml - Luer-lock ♀/♂ Lectroflex - Ø1.0×2.5mm - L.25cm - Vol.0.5ml - Luer-lock ♀/♂	
70222.051	Lectroflex - Ø1.0×2.5mm - L.50cm - Vol.0.6ml - Luer-lock ♀/♂ Lectroflex - Ø1.0×2.5mm - L.50cm - Vol.0.6ml - Luer-lock ♀/♂	

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Prolongateurs PE/PVC / PE/PVC Extension lines		
Classe / Class : Ila – Règle / rule : 2 – GMDN : 12170		
70222.101	Lectroflex - Ø1.0×2.5mm - L.100cm - Vol.1.0ml - Luer-lock ♀/♂ <i>Lectroflex - Ø1.0×2.5mm - L.100cm - Vol.1.0ml - Luer-lock ♀/♂</i>	25
70222.151	Lectroflex - Ø1.0×2.5mm - L.150cm - Vol.1.4ml - Luer-lock ♀/♂ <i>Lectroflex - Ø1.0×2.5mm - L.150cm - Vol.1.4ml - Luer-lock ♀/♂</i>	
70222.201	Lectroflex - Ø1.0×2.5mm - L.200cm - Vol.1.8ml - Luer-lock ♀/♂ <i>Lectroflex - Ø1.0×2.5mm - L.200cm - Vol.1.8ml - Luer-lock ♀/♂</i>	
70222.301	Lectroflex - Ø1.0×2.5mm - L.300cm - Vol.2.6ml - Luer-lock ♀/♂ <i>Lectroflex - Ø1.0×2.5mm - L.300cm - Vol.2.6ml - Luer-lock ♀/♂</i>	
70222.701	Lectroflex - Ø1.0×2.5mm - L.700cm - Vol.5.8ml - Luer-lock ♀/♂ <i>Lectroflex - Ø1.0×2.5mm - L.700cm - Vol.5.8ml - Luer-lock ♀/♂</i>	
831.01	Safeguard1 - Ø1.0×2.5mm - L.160cm - Vol.1.8ml <i>Safeguard1 - Ø1.0×2.5mm - L.160cm - Vol.1.8ml</i>	20
832.01	Protect-a-line1 - Ø1.0×2.5mm - L.150cm <i>Protect-a-line1 - Ø1.0×2.5mm - L.150cm</i>	50
832.211	Protect-a-line1 - Ø1.0×2.5mm - L.200cm <i>Protect-a-line1 - Ø1.0×2.5mm - L.200cm</i>	
832.04	Protect-a-line2 - Ø2.5×4.2mm - L.15cm / Ø1.0×2.5mm - L.165cm <i>Protect-a-line2 - Ø2.5×4.2mm - L.15cm / Ø1.0×2.5mm - L.165cm</i>	
80832.01C	Protect-a-line ♂/♂ - Ø1.0×2.5mm - L.150cm <i>Protect-a-line ♂/♂ - Ø1.0×2.5mm - L.150cm</i>	
80832.01D	Protect-a-line ♂/♂ - Ø1.0×2.5mm - L.114cm <i>Protect-a-line ♂/♂ - Ø1.0×2.5mm - L.114cm</i>	
80832.01E	Protect-a-line ♂/♂ - Ø1.0×2.5mm - L.76cm <i>Protect-a-line ♂/♂ - Ø1.0×2.5mm - L.76cm</i>	
70832.01	V-green PL150 - Ø1.0×2.5mm - L.150cm - Vol.1.4ml <i>V-green PL150 - Ø1.0×2.5mm - L.150cm - Vol.1.4ml</i>	
70832.211	V-green PL200 - Ø1.0×2.5mm - L.200cm - Vol.1.8ml <i>V-green PL200 - Ø1.0×2.5mm - L.200cm - Vol.1.8ml</i>	
70832.04	V-green PL160 Y - Ø2.5×4.2mm - L.10cm - Vol.0.95ml / Ø1.0×2.5mm - L.150cm - Vol.1.9ml <i>V-green PL160 Y - Ø2.5×4.2mm - L.10cm - Vol.0.95ml / Ø1.0×2.5mm - L.150cm - Vol.1.9ml</i>	
833.80	Prolongateur spiralé avec valve anti-siphon - Luer-lock ♀-♂ - Ø1.5×2.5mm - L.300cm - Vol.5.5ml <i>Extension tube coiled presentation with anti-siphon valve - Luer-lock ♀-♂ - Ø1.5×2.5mm - L.300cm - Vol.5.5ml</i>	15

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Prolongateurs PE/PVC / PE/PVC Extension lines		
Classe / Class : IIa – Règle / rule : 2 – GMDN : 12170		
833.90	Prolongateur spiralé avec valve anti-siphon - Luer-lock ♀-♂ - Ø1.5×2.5mm - L.400cm - Vol.7.3ml <i>Extension tube coiled presentation with anti-siphon valve - Luer-lock ♀-♂ - Ø1.5×2.5mm - L.400cm - Vol.7.3ml</i>	15
834.70	Prolongateur spiralé avec valve anti-siphon - Luer-lock ♀-♂ - Ø1.0×2.5mm - L.200cm - Vol.1.8ml <i>Extension tube coiled presentation with anti-siphon valve - Luer-lock ♀-♂ - Ø1.0×2.5mm - L.200cm - Vol.1.8ml</i>	
834.80	Prolongateur spiralé avec valve anti-siphon - Luer-lock ♀-♂ - Ø1.0×2.5mm - L.300cm - Vol.2.6ml <i>Extension tube coiled presentation with anti-siphon valve - Luer-lock ♀-♂ - Ø1.0×2.5mm - L.300cm - Vol.2.6ml</i>	
834.90	Prolongateur spiralé avec valve anti-siphon - Luer-lock ♀-♂ - Ø1.0×2.5mm - L.400cm - Vol.3.4ml <i>Extension tube coiled presentation with anti-siphon valve - Luer-lock ♀-♂ - Ø1.0×2.5mm - L.400cm - Vol.3.4ml</i>	

REFERENCE	DESIGNATION	Quantité par boîte / Quantity per box
Prolongateurs PVC / PVC Extension lines		
Classe / Class : IIa – Règle / rule : 2 – GMDN : 35072		
807.01	Filter-a-line - Vol.4.4ml - Ø1.00x2.45mm - L.10cm <i>Filter-a-line - Vol.4.4ml - Ø1.00x2.45mm - L.10cm</i>	10
807.02	Filter-a-line - Vol.3.6ml - Ø1.00x2.45mm - L.24cm <i>Filter-a-line - Vol.3.6ml - Ø1.00x2.45mm - L.24cm</i>	
807.102	Filter-a-line - Vol.3.6ml - Ø1.00x2.45mm - L.24cm <i>Filter-a-line - Vol.3.6ml - Ø1.00x2.45mm - L.24cm</i>	