

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>	VYRON 5, rue Adeline - 95440 Ecouen FRANCE
Gamme de produit : <i>Product group</i>	Raccords / Connectors Voir la liste de produits jointe / See attached product list
Classe : <i>Class</i>	IIa
Code GMDN : <i>GMDN code</i>	64466 Non-ISO80369-standardized small-bore linear connector, single use
Evaluation de la conformité : <i>Conformity assessment</i>	Annexe II excluant le point 4 de la Directive 93/42/CEE Annex II excluding section 4 of the 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>	DT126 rev.3

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 R&D and Regulatory Affairs Director
Date	02/08/2021
Version/Revision	A1



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Références Produits / Product references

REFERENCE	DESIGNATION	Quantité par boîte / Quantity per box
Vyconnector		
Classe / Class : IIa – Règle / rule : 2 – GMDN : 64466		
881.00	Vyconnector – Raccord biconique droit – Ø Ext. 7.8-15.7mm / 7.8-15.7mm Vyconnector – Straight double taper and adaptor – Ø Ext. 7.8-15.7mm / 7.8-15.7mm	30
881.11	Vyconnector – Raccord biconique droit – Ø Ext. 10.0-13.0mm / 10.0-13.0mm Vyconnector – Straight double taper and adaptor – Ø Ext. 10.0-13.0mm / 10.0-13.0mm	
881.11 D	Vyconnector – Raccord biconique droit – Ø Ext. 10.0-13.0mm / 10.0-13.0mm Vyconnector – Straight double taper and adaptor – Ø Ext. 10.0-13.0mm / 10.0-13.0mm	50
881.13	Vyconnector – Raccord biconique droit – Ø Ext. 13.5-16.0mm / 13.5-16.0mm Vyconnector – Straight double taper and adaptor – Ø Ext. 13.5-16.0mm / 13.5-16.0mm	30
881.30	Vyconnector – Raccord biconique droit – Ø Ext. 13.5-15.5mm / 10.0-12.0mm Vyconnector – Straight double taper and adaptor – Ø Ext. 13.5-15.5mm / 10.0-12.0mm	
881.31	Vyconnector – Raccord biconique droit – Ø Ext. 3.0-5.0mm / 10.0-13.0mm Vyconnector – Straight double taper and adaptor – Ø Ext. 3.0-5.0mm / 10.0-13.0mm	
881.31 D	Vyconnector – Raccord biconique droit – Ø Ext. 3.0-5.0mm / 10.0-13.0mm Vyconnector – Straight double taper and adaptor – Ø Ext. 3.0-5.0mm / 10.0-13.0mm	50
881.33	Vyconnector – Raccord biconique droit – Ø Ext. 3.0-5.0mm / 3.0-5.0mm Vyconnector – Straight double taper and adaptor – Ø Ext. 3.0-5.0mm / 3.0-5.0mm	30
881.33 D	Vyconnector – Raccord biconique droit – Ø Ext. 3.0-5.0mm / 3.0-5.0mm Vyconnector – Straight double taper and adaptor – Ø Ext. 3.0-5.0mm / 3.0-5.0mm	50
881.35	Vyconnector – Raccord biconique droit – Ø Ext. 13.5-15.5mm / 5.5-7.0mm Vyconnector – Straight double taper and adaptor – Ø Ext. 13.5-15.5mm / 5.5-7.0mm	30
881.37	Vyconnector – Raccord biconique droit – Ø Ext. 7.0-10.0mm / 3.0-5.0mm Vyconnector – Straight double taper and adaptor – Ø Ext. 7.0-10.0mm / 3.0-5.0mm	
881.37 D	Vyconnector – Raccord biconique droit – Ø Ext. 3.0-5.0mm / 7.0-10.0mm Vyconnector – Straight double taper and adaptor – Ø Ext. 3.0-5.0mm / 7.0-10.0mm	50
881.44	Vyconnector – Raccord biconique droit – Ø Ext. 4.0-6.0mm / 4.0-6.0mm Vyconnector – Straight double taper and adaptor – Ø Ext. 4.0-6.0mm / 4.0-6.0mm	30
881.44 D	Vyconnector – Raccord biconique droit – Ø Ext. 4.0-6.0mm / 4.0-6.0mm Vyconnector – Straight double taper and adaptor – Ø Ext. 4.0-6.0mm / 4.0-6.0mm	50
881.47	Vyconnector – Raccord biconique droit – Ø Ext. 7.0-10.0mm / 4.0-6.0mm Vyconnector – Straight double taper and adaptor – Ø Ext. 7.0-10.0mm / 4.0-6.0mm	30
881.47 D	Vyconnector – Raccord biconique droit – Ø Ext. 4.0-7.0mm / 7.0-10.0mm Vyconnector – Straight double taper and adaptor – Ø Ext. 4.0-7.0mm / 7.0-10.0mm	50
881.51	Vyconnector – Raccord biconique droit – Ø Ext. 5.0-7.0mm / 10.0-13.0mm Vyconnector – Straight double taper and adaptor – Ø Ext. 5.0-7.0mm / 10.0-13.0mm	30
881.51 D	Vyconnector – Raccord biconique droit – Ø Ext. 5.0-7.0mm / 10.0-13.0mm Vyconnector – Straight double taper and adaptor – Ø Ext. 5.0-7.0mm / 10.0-13.0mm	50

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Vyconnector		
Classe / Class : Ila – Règle / rule : 2 – GMDN : 64466		
881.53	Vyconnector – Raccord biconique droit – Ø Ext. 13.5-15.5mm / 3.5-5.0mm Vyconnector – Straight double taper and adaptor – Ø Ext. 13.5-15.5mm / 3.5-5.0mm	30
881.57	Vyconnector – Raccord biconique droit – Ø Ext. 13.5-15.5mm / 7.5-9.0mm Vyconnector – Straight double taper and adaptor – Ø Ext. 13.5-15.5mm / 7.5-9.0mm	
881.66	Vyconnector – Raccord biconique droit – Ø Ext. 6.0-8.0mm / 6.0-8.0mm Vyconnector – Straight double taper and adaptor – Ø Ext. 6.0-8.0mm / 6.0-8.0mm	
881.66 D	Vyconnector – Raccord biconique droit – Ø Ext. 6.0-8.0mm / 6.0-8.0mm Vyconnector – Straight double taper and adaptor – Ø Ext. 6.0-8.0mm / 6.0-8.0mm	50
881.71	Vyconnector – Raccord biconique droit – Ø Ext. 7.0-10.0mm / 10.0-13.0mm Vyconnector – Straight double taper and adaptor – Ø Ext. 7.0-10.0mm / 10.0-13.0mm	30
881.71 D	Vyconnector – Raccord biconique droit – Ø Ext. 7.0-10.0mm / 10.0-13.0mm Vyconnector – Straight double taper and adaptor – Ø Ext. 7.0-10.0mm / 10.0-13.0mm	50
881.77	Vyconnector – Raccord biconique droit – Ø Ext. 7.0-9.5mm / 7.0-9.5mm Vyconnector – Straight double taper and adaptor – Ø Ext. 7.0-9.5mm / 7.0-9.5mm	30
881.77 D	Vyconnector – Raccord biconique droit – Ø Ext. 7.0-10.0mm / 7.0-10.0mm Vyconnector – Straight double taper and adaptor – Ø Ext. 7.0-10.0mm / 7.0-10.0mm	50

REFERENCE	DESIGNATION	Quantité par boîte / Quantity per box
Vyconnector		
Classe / Class : Ila – Règle / rule : 2 – GMDN : 64466		
882.04	Vyconnector – Raccord en T – Ø4-6mm Vyconnector – T connector – Ø4-6mm	30
882.08	Vyconnector – Raccord en T – Ø8-10mm Vyconnector – T connector – Ø8-10mm	
882.08 D	Vyconnector – Raccord en T – Ø8-10mm Vyconnector – T connector – Ø8-10mm	25
882.12	Vyconnector – Raccord en T – Ø12-14mm Vyconnector – T connector – Ø12-14mm	30
882.16	Vyconnector – Raccord en T – Ø16-18mm Vyconnector – T connector – Ø16-18mm	

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REFERENCE	DESIGNATION	Quantité par boite / Quantity per box
Vyconnector		
Classe / Class : IIa – Règle / rule : 2 – GMDN : 64466		
884.04	Vyconnector – Raccord en Y – Ø4-6mm Vyconnector – Y connector – Ø4-6mm	30
884.04 D	Vyconnector – Raccord en Y – Ø4-6mm Vyconnector – Y connector – Ø4-6mm	25
884.06	Vyconnector – Raccord en Y – Ø6-8mm Vyconnector – Y connector – Ø6-8mm	
884.08	Vyconnector – Raccord en Y – Ø8-10mm Vyconnector – Y connector – Ø8-10mm	30
884.08 D	Vyconnector – Raccord en Y – Ø8-10mm Vyconnector – Y connector – Ø8-10mm	25
884.12	Vyconnector – Raccord en Y – Ø12-14mm Vyconnector – Y connector – Ø12-14mm	30
884.16	Vyconnector – Raccord en Y – Ø16-18mm Vyconnector – Y connector – Ø16-18mm	