TECHNICAL DATA SHEET

Lectroflex

220.150

Dated : 13-09-2023

1 Administrative information relating to the company

1.1	**Name** : Vygon	
1.2	**Address :** 5 rue Adeline - 95440 Ecouen, France	**Fax :** + 33 (0)1 34 29 19 34 **E-mail :** questions@vygon.com **Website :** www.vygon.com
1.3	**Medical Device vigilance Representative :** Laurent GUILLARDEAU	**Tel :** +33 (0)1 39 92 65 69 **Fax :** +33 (0)1 39 92 64 82 **E-mail :** quality@vygon.com

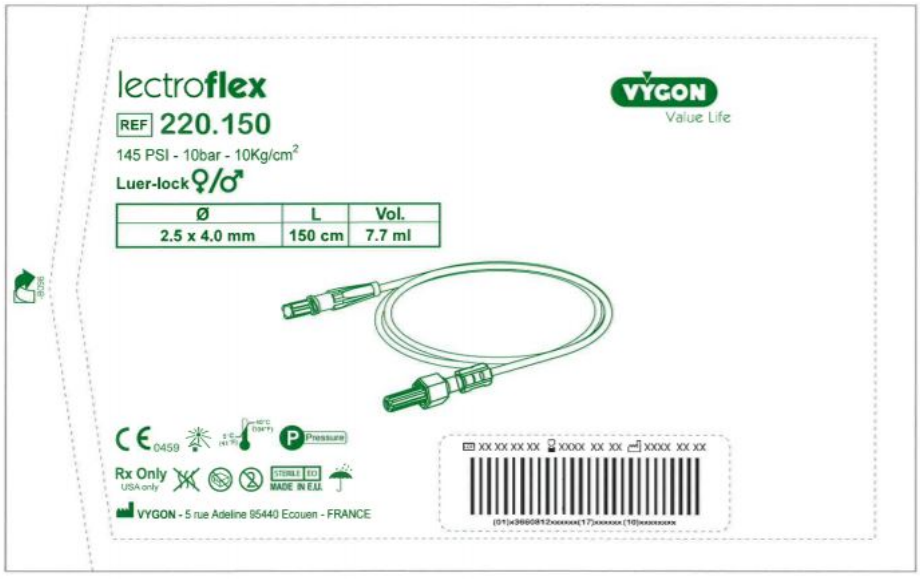
2 Information about the device or equipment

2.1	**Generic name :** Extension tube for I.V. catheters
2.2	**Commercial name :** Lectroflex
2.3	**GMDN code :** 12170
2.4	**Medical Device Class :** IIa **Applicable regulation :** 93/42/CEE **in accordance with Appendix n° :** II **Notified body N° :** 0459 **Medical Device Manufacturer :** Vygon
2.5	**Description of the device :** Triple-layer extension tube (PVC/EVA/PE)* for IV catheters with 1 male Luer-lock end and 1 female Luer-lock end. Diameter: 2,5 x 4,0 mm - Pressure tested at 10 kg/cm2 (145 PSI) Available in 7 lengths : 13.5 cm (code 220.010), 25 cm (code 220.020), 50 cm (code 220.050), 70 cm (code 220.070), 100 cm (code 220.100), 150 cm (code 220.150) and 200 cm (code 220.200). *See additional information.

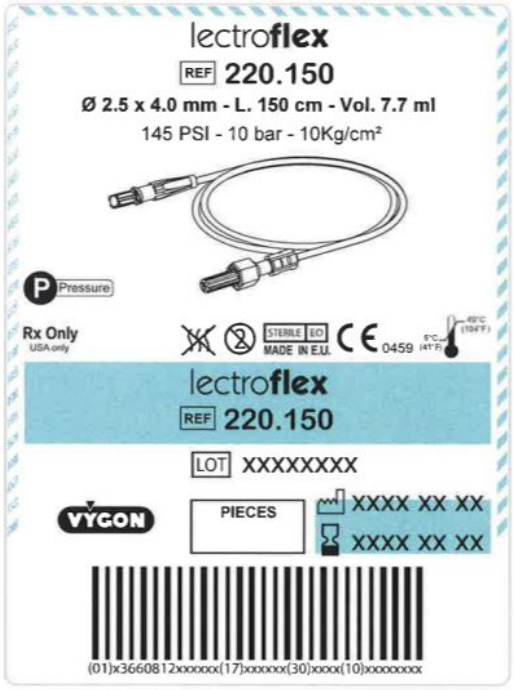
2.6 Packaging / Containers

Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
220.150	1 (Supple blister)	25 (Carton box)	25 (Carton box)	150 (Case)

Single unit packaging



Box

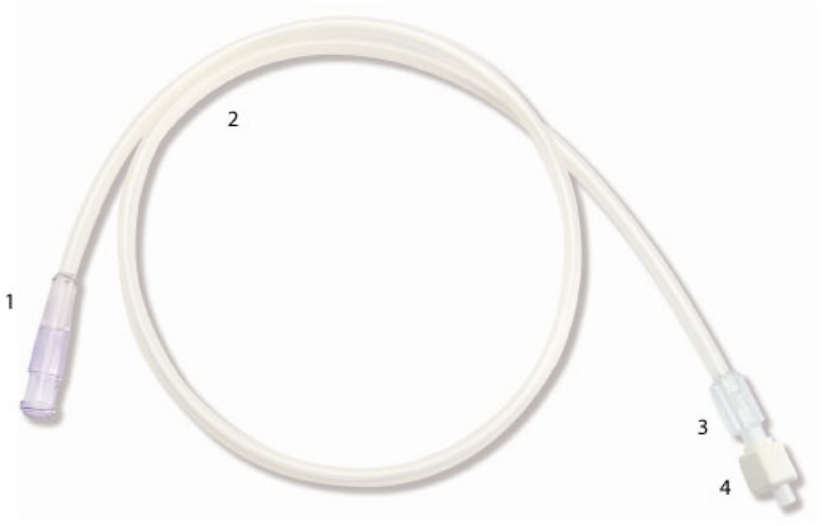


Technical features :

Code	Extension tube			
	Length cm	Int. Ø mm	Ext. Ø ml/min	Priming volume ml
220.150	150	2.5	4.0	7.7

2.7 Composition of the device and Accessories :

COMPONENTS	MARKER	MATERIALS
Female end	1	PC
Tube	2	PE / EVA / PVC
Male end	3	PC
Male locking device	4	PC
Cap		PE
Protector		PE

	 **For components which are likely to come into contact with the patient and/or administered products, additional points :** Latex-free DEHP-free Does not contain any products of animal or biological origin Pyrogen-free
2.8	**Indications :** Add-on device for IV catheters: extension tube.

3 Accessories

4 Sterilization process

	Sterile Medical Device : YES **Sterilization made for the device :** Ethylene oxide

5 Conditions of conservation and storage

5.1	**Normal conservation and storage conditions :** Storage environment temperature: between 5 and 40°C. Store protected from moisture and sunlight.
5.2	
5.3	**Duration of product validity :** 60 months

6 Security of use

7 Instructions for use

7.1	
7.2	**Indications :** Add-on device for IV catheters: extension tube.
7.3	**Precautions :** Re-use of this device may change its mechanical or biological features and may cause device failure, allergic reaction or bacterial infections.
7.4	

8 Additional information relating to the product

	PE lined PVC extension tube. This extension tube is made of 3 layers. The outer layer is in PVC, the inner layer is in Polyethylene without additives, material presenting a high chemical inertness and the intermediate layer is Ethyl Vinyl Acetate, material linking the inner and the outer layers. This structure allows to minimize interations with drugs and leaching of plasticizers from the PVC into the administered solutions.

ATTESTATION / *CERTIFICATE* **N° 9556 rev. 11**

Délivrée à Paris le 10 mai 2021

Issued in Paris on May 10th, 2021

ATTESTATION CE / *EC CERTIFICATE*

Approbation du Système Complet d'assurance Qualité/ *Approval of full Quality Assurance System*

ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices

Pour les dispositifs de classe III, un certificat CE de conception est requis
For class III devices, a EC design certificate is required

Fabricant / *Manufacturer*

VYGON
5 rue Adeline
95440 ECOUEN FRANCE

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

Cathéters, sondes, tubes, accessoires et dispositifs pour perfusion, anesthésie, réanimation, nutrition, gastro-entérologie, urologie, chirurgie, drainage, voies respiratoires et hémodialyse. Chambres à cathéter implantable et accessoires.

Catheters, probes, tubes, accessories and devices for infusion, anesthesia, reanimation, enteral feeding, gastro-enterology, urology, surgery, drainage, respiratory tract and haemodialysis. Implantable vascular access systems and accessories.

Voir document complémentaire GMED / See GMED additional document

n° 37945

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P177278 - P600786, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced P177278 - P600786, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4.

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 :* **May 10th, 2021 (included)**

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

GMED SAS GMED SAS
DocuSigned by: Béatrice Lys EF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director

GMED_b2p3_new2020-V0-04-

GMED - 9556 rev. 11
Modifie le certificat 9556-10

Certificate

Full Quality Assurance System Approval

Annex II excluding (4) of the Directive on Medical Devices

ECM, Bismarckstr. 106, 52066 Aachen, notified to EC under 0481 hereby declares that an examination of the under mentioned quality assurance system has been carried out following the requirements of annex II excluding (4) of the Directive 93/42/EEC.

This certificate is issued on behalf of:

Manufacturer

Vygon GmbH & Co. KG
Prager Ring 100, 52070 Aachen, Germany

ECM certifies that the full quality assurance system under which the products listed in annex I to this certificate are manufactured conforms with the requirements of annex II excluding (4) of the Directive 93/42/EEC on medical devices.

The approved quality assurance system is subject to periodic surveillance as defined by annex II excluding (4), section 5.

This Certificate is only valid for the products mentioned above. Special terms of validity are described in annex I to this certificate.

Any substantial changes of the quality assurance system or the listed products which might affect conformity to annex II of the Directive 93/42/EEC have to be notified to ECM and are subject to a separate assessment.

Audit Report Number	Registered under	Valid until
001-17-1127	**Z/17/04150E**	**December 19th, 2022**

Aachen, December 19th, 2017

Certification Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-240.10.12

Annex I of Certificate Z/17/04150E

Date of revision: May 25th, 2020

ecm
Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH

This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code*
Single use devices	Adhesive, liquid -- siliconeglue	10-036
Single use devices	Catheter Introducers -- specanula -- splitneedle -- peelable cannula -- microsite	10-678
Single use devices	Catheters, Arterial Micro-Flow -- leaderflex	10-691
Single use devices	Catheters, Vascular, Embolectomy / Thrombectomy -- embolectoball	10-714
Single use devices	Catheters, Spinal, Epidural -- peristyl -- peripur	10-717
Single use devices	Catheters, Vascular, Umbilical -- umbilicalcath expert -- umbilicalcath2 expert -- umbilicalcath3	10-759
Single use devices	Fittings / Adapters, Luer -- easylock -- transadapt	11-729
Single use devices	Guide Wires -- guide	11-925

* UMDS Code is optional

Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH

This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code[1]
Single use devices	Tubing, Polyvinyl Chloride -- Extension line -- Verlängerungs-Katheter	14-247
Single use devices	Catheter Hemodialysis -- dualysecath -- trilysecath -- dualysecathexpert -- trilysecathexpert -- lifecath twin	15-022
Single use devices / Non active implantable products	Catheter Hemodialysis -- lifecath apheresis+ -- lifecath apheresis	15-022
Single use devices	Catheters, others -- repairset lifecath	15-209
Single use devices	Guides, Other -- introducath desilet -- desivalve	15-224
Single use devices	Cables/Leads, ECG -- combcard	15-754

[1] UMDS Code is optional

Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH

This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code*
Single use devices	Transfer Sets, Fluid -- Taky-Spike - Plus -- Transfer-Set -- Iectrocath	16-610
Single use devices	Catheterization Kits, Central Venous -- seldipur -- multicath2 -- multicath3 -- multicath4 -- multicath5 -- multicath7 -- leadercathexpert -- multicath2expert -- multicath3expert -- multicath4expert -- multicath5expert -- multicath7expert -- lifecath broviac -- lifecath hickman -- lifecath biflux -- lifecath triple -- lifecath broviac expert -- lifecath hickman expert -- lifecath biflux expert -- multistar2 -- multistar3 -- multistar4 -- multistar5 -- multistar7	16-615

* UMDS Code is optional

ecm
Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH

This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code*
Single use devices	Catheters, Cardiac, Flotation Balloon, Pacing Electrodes -- bipacingball	16-654
Single use devices	Catheter Introducers -- aseptcath	17-578
Single use devices	Catheter, Central Venous, Peripherally Inserted -- premicath -- epicutaneo cava pur -- lifecath PICC expert -- epicutaneo2expert -- epicutaneo cava expert -- epicutaneo cava -- epicutaneo2 -- epicutaneostar -- epicutaneo2star -- premistar -- lifecath PICC silicone -- nutriline -- nutriline twinflo -- nutristar -- nutristar twinflo	18-017

* UMDS Code is optional

Annex I of Certificate Z/17/04150E

Date of revision: May 25th, 2020

ecm
Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH

This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code[1]
Single use devices / Non active implantable products	Catheter, Central Venous, Peripherally Inserted -- lifecath PICC pur -- lifecath PICC easy -- lifecath CT PICC easy -- maxflo -- maxfloexpert	18-017
Single use devices	Intravenous Line Connectors, Needleless -- repairset epicutaneo cava	18-066
Single use devices	Catheters, Vascular, Infusion, Peripheral --seldipur smartmidline -- homecarecathexpert -- lifecath midline pur	10-727
Single use devices	Cables/Leads, ECG vygocard	15-754

Special terms of validity:

None.

[1] UMDS Code is optional

Déclaration CE de conformité
EC declaration of conformity

Conformément à la Directive 93/42/CEE et au titre 1er 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 : *Manufacturer*	**VYGON** **5, rue Adeline - 95440 Ecouen** FRANCE
Gamme de produit : *Product group*	**Prolongateurs souples – Accessoires de cathétérisme** ***Flexible extension lines – IV Accessories*** Voir la liste de produits jointe / *See attached product list*
Classe : *Class*	**IIa**
Code GMDN : *GMDN code*	12170 Nécessaire d'extension de tubes d'administration intraveineuse / *Intravenous administration tubing extension set* 35072 Filtre de ligne intraveineuse / *Intravenous line filter*
Evaluation de la conformité : *Conformity assessment*	**Annexe II excluant le point 4 Directive 93/42/CEE** ***Annex II excluding section 4 Directive 93/42/EEC***
Attestation CE : *EC Certificate*	**9556 rev.11**
Organisme Notifié : *Notified Body*	**GMED - 0459** **1, rue Gaston Boissier – 75015 Paris – France**
Dossier Technique *Technical File*	**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 1er 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 *17/08/2022*

Version/Revision B3

Déclaration CE de conformité
EC declaration of conformity

Références Produits / *Product references*

REFERENCE	DESIGNATION	Quantité par boite / 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*	

CF

Déclaration CE de conformité
EC declaration of conformity

REFERENCE	DESIGNATION	Quantité par boite / Quantity per box
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 ♀/♂*	

CF

Déclaration CE de conformité
EC declaration of conformity

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

cf

Déclaration CE de conformité
EC declaration of conformity

REFERENCE	DESIGNATION	Quantité par boite / Quantity per box
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 *Extension tube coiled presentation with anti-siphon valve* - Luer-lock ♀-♂ - Ø1.5×2.5mm - L.400cm - Vol.7.3ml	15
834.70	Prolongateur spiralé avec valve anti-siphon - Luer-lock ♀-♂ - Ø1.0×2.5mm - L.200cm - Vol.1.8ml *Extension tube coiled presentation with anti-siphon valve* - Luer-lock ♀-♂ - Ø1.0×2.5mm - L.200cm - Vol.1.8ml	
834.80	Prolongateur spiralé avec valve anti-siphon - Luer-lock ♀-♂ - Ø1.0×2.5mm - L.300cm - Vol.2.6ml *Extension tube coiled presentation with anti-siphon valve* - Luer-lock ♀-♂ - Ø1.0×2.5mm - L.300cm - Vol.2.6ml	
834.90	Prolongateur spiralé avec valve anti-siphon - Luer-lock ♀-♂ - Ø1.0×2.5mm - L.400cm - Vol.3.4ml *Extension tube coiled presentation with anti-siphon valve* - Luer-lock ♀-♂ - Ø1.0×2.5mm - L.400cm - Vol.3.4ml	

REFERENCE	DESIGNATION	Quantité par boite / 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 *Filter-a-line - Vol.4.4ml - Ø1.00x2.45mm - L.10cm*	10
807.02	Filter-a-line - Vol.3.6ml - Ø1.00x2.45mm - L.24cm *Filter-a-line - Vol.3.6ml - Ø1.00x2.45mm - L.24cm*	
807.102	Filter-a-line - Vol.3.6ml - Ø1.00x2.45mm - L.24cm *Filter-a-line - Vol.3.6ml - Ø1.00x2.45mm - L.24cm*	

CF

Vygon GmbH & Co.KG

Prager Ring 100

Aachen Nordrhein-Westfalen

52070 Germany

2024-10-09

Notified Body Confirmation Letter

Reference: EU2023-607/969561

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Vygon GmbH & Co.KG

Prager Ring 100

Aachen Nordrhein-Westfalen

52070 Germany

SRN Number (if available): DE-MF-000005305, DE-PR-000034160

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive

93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
nutriline nutriline twinflo premicath	Class III	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19
multicath2 multicath3 multicath4 multicath5 multicath7	Class III	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19
lifecath broviac lifecath hickman lifecath biflux lifecath triple	Class III	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19 Certificate Z/16/03966E; NB0481 expiry 2021-11-15
repairsets lifecath	Class I device placed on the market in sterile condition	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19
silicone glue	Class I device placed on the market in sterile condition	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19
seldipur smartmidline	Class IIa	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19
leaderflex	Class III	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19
combcard vygocard	Class I device placed on the market in sterile condition	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19
lifecath PICC PUR lifecath PICC easy lifecath CT PICC easy	Class III	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19 Certificate Z/18/04325E; NB0481 expiry 2023-10-27 Certificate Z/20/04654E; NB0481 expiry 2021-05-22
epicutaneo cava epicutaneo2	Class III	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
epicutaneo cava pur			Certificate Z/18/04202E; NB0481 expiry 2023-03-26
lifecath midline pur	Class IIb implantable non-WET	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19
dualysecath trilysecath	Class III	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19
umbilicalcath3	Class III	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19
bipacingball	Class III	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19 Certificate Z/19/04554E; NB0481 expiry 2024-06-05
microsite splitneedle peelable cannula introducath desilet	Class IIa	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19
desivalve	Class IIa	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19
leadercathexpert multicath3expert multicath2expert multicath4expert multicath5expert multicath7expert	Class III	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19
dualysecathexpert trilysecathexpert	Class III	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19
maxfloexpert	Class III	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19 Certificate Z/18/04325E; NB0481 expiry 2023-03-26
umbilicalcath expert umbilicalcath2 expert	Class III	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19
multistar2 multistar3 multistar4 multistar5	Class III	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19 Certificate Z/20/04654E; NB0481 expiry 2021-05-22

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
multistar7			
premistar	Class III	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19 Certificate Z/20/04654E; NB0481 expiry 2021-05-22

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2024/10/07	Initial issue
2024/10/09	Amended – Change 'Vygocard' to 'vygoncard'