

TECHNICAL FILE

Straight double taper connector and adaptor

881.66

Dated : 23-02-2023

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	

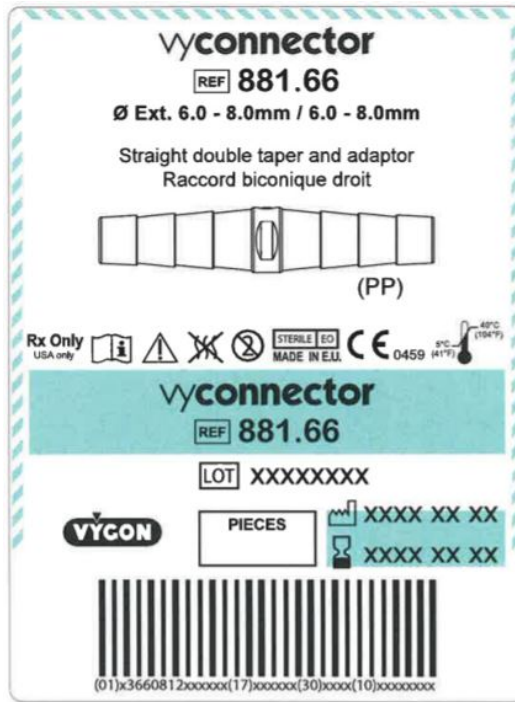
2 Information about the device or equipment

2.1					
2.2	Commercial name : Straight double taper connector and adaptor				
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 : Double taper connectors in polypropylene (codes 881.11/13/30/31/33/35/47/51/53/57/66/71/77), in polyamide (codes 881.37/44) and in ABS (code 881.00).				
					
2.6	Packaging / Containers				
	Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
	881.66	1 (Supple blister)	30 (Carton box)	30 (Carton box)	2880 (Case box)

Single unit packaging



Box



Technical features :

Code	Connector
	Ext.Ø mm
881.66	6-8 / 6-8

2.7 Composition of the device and Accessories :

COMPONENTS	MARKER	MATERIALS
Connecto(Except code 881.00 : ABS)		PP



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 :
The straight double taper connectors allow the connection of 2 tubes of same diameter, or 2 tubes of different diameter.

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 Special precautions :
Please refer to the IFU.

5.3 Duration of product validity : 60 months

6 Security of use

Technical security :
Please refer to the IFU.

7 Instructions for use

7.1 Instructions :
Please refer to the IFU.

7.2	Indications : The straight double taper connectors allow the connection of 2 tubes of same diameter, or 2 tubes of different diameter.
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. Please refer to the IFU.
7.4	Contra indications : Please refer to the IFU.

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Additional information relating to the product