

## TECHNICAL FILE

### Straight double taper connector and adaptor

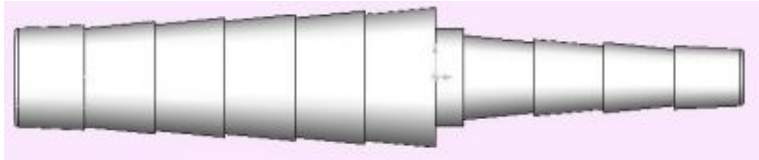
881.47

Dated : 23-02-2023

#### 1 Administrative information relating to the company

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

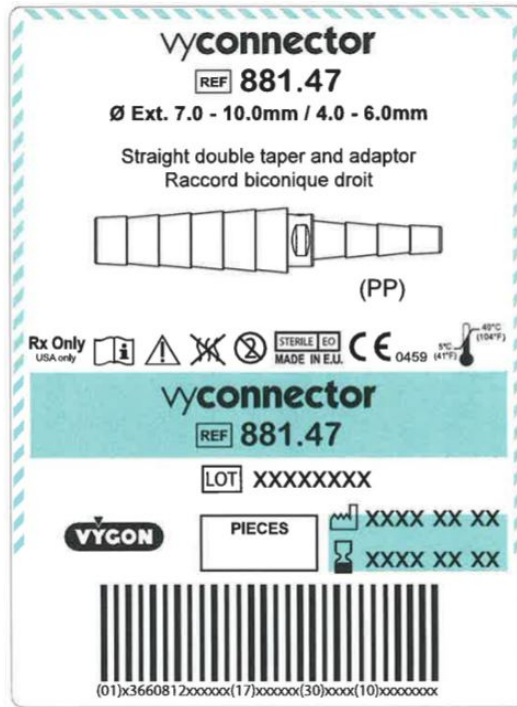
#### 2 Information about the device or equipment

2.1					
2.2	<b>Commercial name :</b> Straight double taper connector and adaptor				
2.4	<b>Medical Device Class :</b> IIa <b>Applicable regulation :</b> 93/42/CEE <b>in accordance with Appendix n° :</b> II <b>Notified body N° :</b> 0459 <b>Medical Device Manufacturer :</b> Vygon				
2.5	<b>Description of the device :</b> 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	<b>Packaging / Containers</b>				
	Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
	881.47	1 (Supple blister)	30 (Carton box)	30 (Carton box)	2880 (Case box)

Single unit packaging



Box

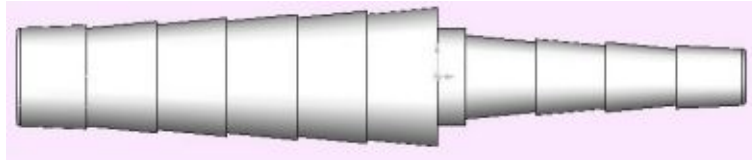


Technical features :

Code	Connector
	Ext.Ø mm
881.47	7-10 / 4-6

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.

<b>7.3</b>	<b>Precautions :</b> 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.
<b>7.4</b>	<b>Contra indications :</b> Please refer to the IFU.

**8** Additional information relating to the product