

## TECHNICAL FILE

### Control suction tube

535.08

Dated : 12-08-2019

### 1 Administrative information relating to the company

<b>1.1</b>	<b>Name :</b> Vygon SA	
<b>1.2</b>	<b>Address :</b> 5 rue Adeline - 95440 Ecouen, France	<b>Fax :</b> + 33 (0)1 34 29 19 34 <b>E-mail :</b> questions@vygon.com <b>Website :</b> www.vygon.com
<b>1.3</b>	<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

<b>2.1</b>	
<b>2.2</b>	<b>Commercial name :</b> Control suction tube
<b>2.4</b>	<b>Medical Device Class :</b> IIa <b>Applicable EU Directive :</b> 93/42/CEE <b>in accordance with Appendix n° :</b> II <b>Notified body N° :</b> 0459 <b>Medical Device Manufacturer :</b> Vygon
<b>2.5</b>	<b>Description of the device :</b> Tracheal and bronchial suction catheter. Open tip. Proximal connector with lateral eye for finger tip control (with integral closing cap). Fr 4 – 5 – 6 – 7 – 8 – 10: with 2 lateral eyes Centimetre graduations from 5 to 20 cm. Length 29 cm Fr 12 – 14 – 16 – 18: no lateral eyes Centimetre graduations from 5 to 20 cm. Length 42 cm



**2.6 Packaging / Containers**

Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
535.08	1 (Supple blister)	50 (Carton box)	50 (Carton box)	450 (Case box)

**Single unit packaging**

	<p>REF <b>535.08</b> <b>Ø2.5 mm - 08Fr - L.290 mm</b> PVC - ORX / XRO / RXC          Control suction catheter / Sonde pour aspiration contrôlée Code ACL          Sonda para aspiración controlada / Absaugkatheter mit Sogregulierung 7161462          Sonda per aspirazione controllata / Regelbare aspirationsonde          Sonda para aspiração controlada / Sugkateter med reglerbart sug</p> <p><b>VYRON</b> - 5 rue Adeline 95440 Ecoeur - FRANCE</p>	<p><b>VYRON</b> Value Life</p> <p>Rx Only USA only</p> <p>STERILE EO MADE IN E.C. CE 0459</p>
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**Box**

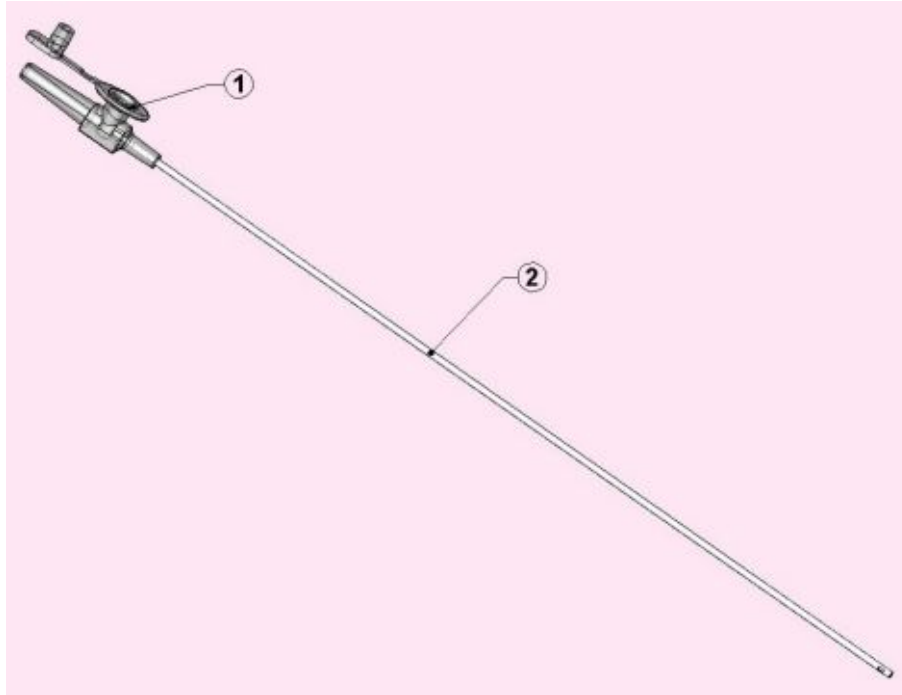


**Technical features :**

Code	Tube	
	Length cm	Ext. Ø Fr
535.08	29	8

**2.7 Composition of the device and Accessories : 535.08**

COMPONENTS	MARKER	MATERIALS
Connector	1	PVC
Tube	2	PVC



**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

**2.8 Indications :**  
Tracheal and bronchial suction catheter with connector for finger-tip suction control

### 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

<b>7.1</b>	
<b>7.2</b>	<b>Indications :</b> Tracheal and bronchial suction catheter with connector for finger-tip suction control
<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.
<b>7.4</b>	

**8** Additional information relating to the product