

## TECHNICAL FILE

### Single valve for thoracic drainage


669.10

Dated : 03-01-2022

### 1 Administrative information relating to the company

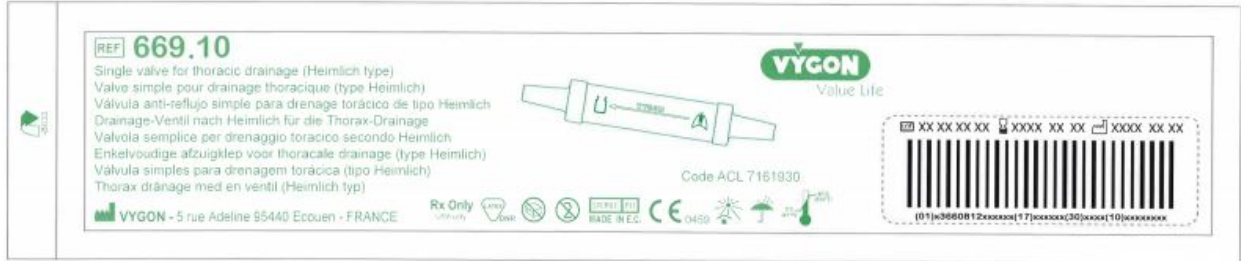
<b>1.1</b>	<b>Name :</b> Vygon	
<b>1.2</b>	<b>Address :</b> 5 rue Adeline - 95440 Ecoen, France	<b>Fax :</b> + 33 (0)1 34 29 19 34 <b>E-mail :</b> questions@vygon.com <b>Website :</b> www.vygon.com
<b>1.3</b>	<b>Medical Device vigilance Representative :</b> Laurent GUILLARDEAU	<b>Tel :</b> +33 (0)1 39 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> Single valve for thoracic drainage
<b>2.4</b>	<b>Medical Device Class :</b> I <b>Applicable regulation :</b> 93/42/CEE <b>in accordance with Appendix n° :</b> Vs <b>Notified body N° :</b> 0459 <b>Medical Device Manufacturer :</b> Vygon
<b>2.5</b>	<p><b>Description of the device :</b> Non-return valve for thoracic drainage (Heimlich type).</p> <p>Valve body in flexible and transparent polyurethane with flat natural rubber sleeve acting as a non-return valve. Note: This flat rubber sleeve never comes in direct or indirect contact with the patient or the user. Any allergic risk due to the presence of rubber can thus be excluded.</p> <p>This device is connected directly onto the patient's pleural or thoracic drain (adult, paediatric), or indirectly, using connector code 800.01 and an extension tube for neonates and infants.</p> <p>This product allows thoracic drainage to continue without risk to the patient even when transported, as the non-return valve means that the drain does not have to be clamped.</p>
	

<b>2.6</b>	<b>Packaging / Containers</b>				
	Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
	669.10	1 (Supple blister )	25 (Carton box )	25 (Carton box )	150 (Case box )

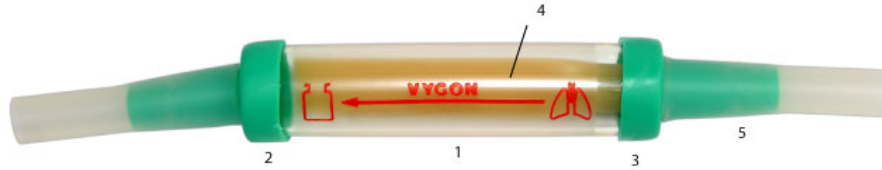
**Single unit packaging**



**Box**



<b>2.7</b>	<b>Composition of the device and Accessories :</b>		
	COMPONENTS	MARKER	MATERIALS
	Tube	1	PU-PVC
	Proximal end adaptor	2	PVC
	Distal end adaptor	3	PVC
	Internal tube (valve)	4	DNR
	Proximal and distal connector	5	Si



**For components which are likely to come into contact with the patient and/or administered products, additional points :**

- Contains latex
- DEHP-free
- Does not contain any products of animal or biological origin

**2.8 Indications :**  
Non-return valve for thoracic drainage

### 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 :**  
Non-return valve for thoracic drainage

**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



Value Life

8 Additional information relating to the product