

## TECHNICAL FILE

### Dual valve for thoracic drainage


668.00

Dated : 03-01-2022

### 1 Administrative information relating to the company

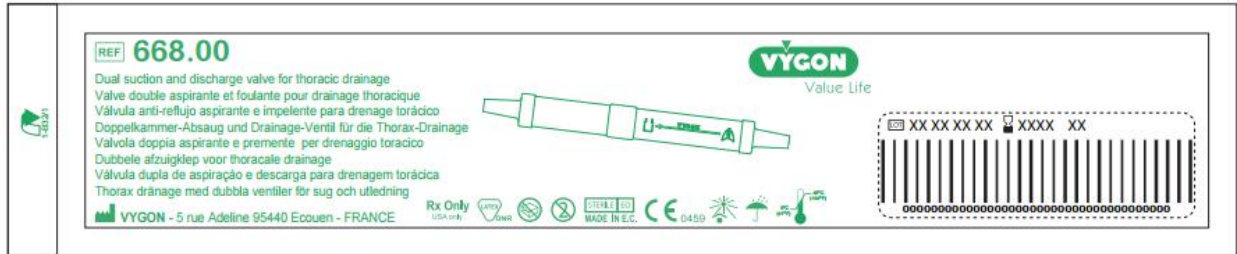
<b>1.1</b>	<b>Name :</b> Vygon	
<b>1.2</b>	<b>Address :</b> 5 rue Adeline - 95440 Ecouen, France	<b>Fax :</b> + 33 (0)1 34 29 19 34 <b>E-mail :</b> questions@vygon.com <b>Website :</b> www.vygon.com
<b>1.3</b>	<b>Medical Device vigilance Representative :</b> Laurent GUILLARDEAU	<b>Tel :</b> +33 (0)1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

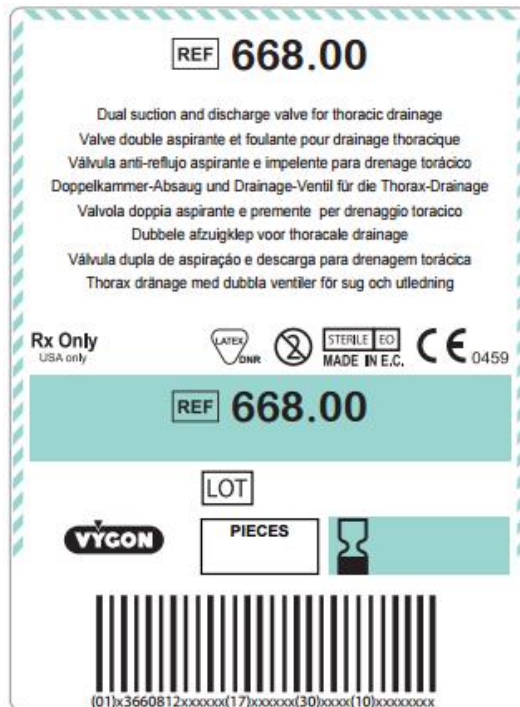
<b>2.1</b>	
<b>2.2</b>	<b>Commercial name :</b> Dual valve for thoracic drainage
<b>2.4</b>	<b>Medical Device Class :</b> I <b>Applicable regulation :</b> 93/42/CEE <b>in accordance with Appendix n° :</b> V <b>Notified body N° :</b> 0459 <b>Medical Device Manufacturer :</b> Vygon
<b>2.5</b>	<p><b>Description of the device :</b> Double-chamber valve for thoracic drainage.</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 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. 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> <p>Code 668.00: this two chamber device differs from the single valve code 669.10 in that it is possible to apply suction by manual compression of the compartment marked with an arrow (vacuum approximately 150 mbar).</p>
	

2.6	<b>Packaging / Containers</b>				
	Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
	668.00	1 (Supple blister)	20 (Carton box)	20 (Carton box)	120 (Case box)

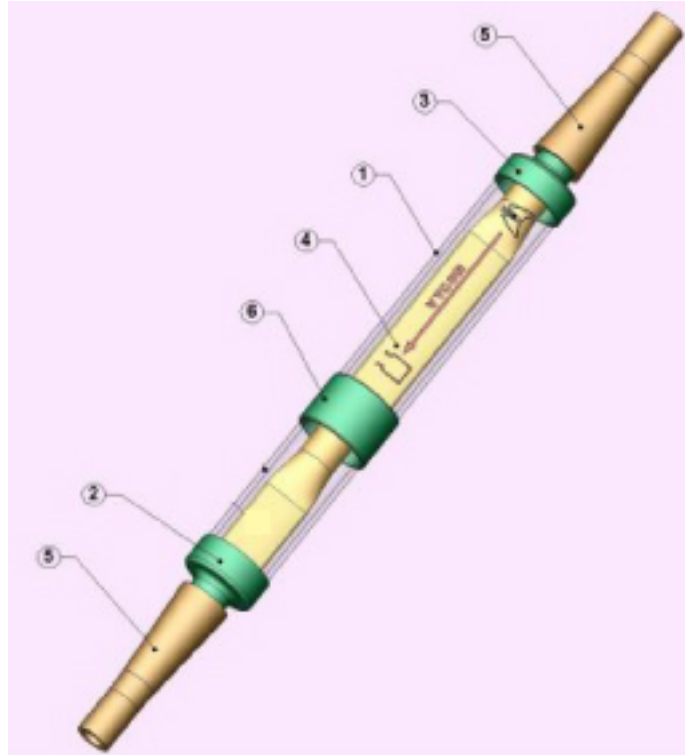
**Single unit packaging**



**Box**



2.7	<b>Composition of the device and Accessories :</b>		
	COMPONENTS	MARKER	MATERIALS
	Body of the valve	1	PU-PVC
	Distal end adaptor	2	PVC
	Proximal end adaptor	3	PVC
	Connector	6	PVC
	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 double chamber 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	<b>Indications :</b> Non-return double chamber valve for thoracic drainage
7.3	<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.
7.4	

8 Additional information relating to the product