

TECHNICAL FILE

Dualstop
9888.002

Dated : 23-05-2022

1 Administrative information relating to the company

1.1	Name : Vygon	
1.2	Address : 5 rue Adeline - 95440 Ecoen, 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

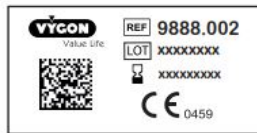
2.1	
2.2	Commercial name : Dualstop
2.4	Medical Device Class : I Applicable regulation : 93/42/CEE in accordance with Appendix n° : V.3 Notified body N° : 0459 Medical Device Manufacturer : Vygon
2.5	Description of the device : Luer-lock cap : male Luer-lock on one end, female Luer-lock on the other end. Code 9888.00 : red cap Code 9888.002 : white cap Code 9889.000 : blue cap



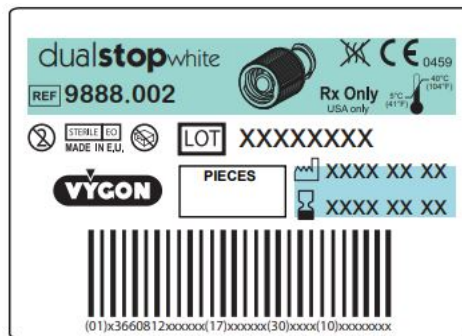
2.6 Packaging / Containers

Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
9888.002	1 (Supple blister)	100 (Carton box)	100 (Carton box)	1000 (Case box)

Single unit packaging



Box



Case labelling



Technical features :

Code	Cap
	Colour -
9888.002	White

2.7 Composition of the device and Accessories :

COMPONENTS	MARKER	MATERIALS
Cap		PE



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	<p>Indications : The male Luer-lock end of the cap can be used to obturate the female Luer-lock hub of an IV catheter, extension tube, stopcock etc ... The female Luer-lock end of the cap can be used to obturate the male cone of a syringe.</p>
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3 Accessories

4 Sterilization process

	<p>Sterile Medical Device : YES Sterilization made for the device : Ethylene oxide</p>
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5 Conditions of conservation and storage

5.1	<p>Normal conservation and storage conditions : Storage environment temperature: between 5 and 40°C. Store protected from moisture and sunlight.</p>
5.2	
5.3	<p>Duration of product validity : 60 months</p>

6 Security of use

7 Instructions for use

7.1	
7.2	<p>Indications : The male Luer-lock end of the cap can be used to obturate the female Luer-lock hub of an IV catheter, extension tube, stopcock etc ... The female Luer-lock end of the cap can be used to obturate the male cone of a syringe.</p>
7.3	<p>Precautions : Re-use of this device may change its mechanical or biological features and may cause device failure, allergic reaction or bacterial infections.</p>
7.4	

8 Additional information relating to the product