

TECHNICAL FILE

Nutrisafe2 bottle cap

820.18

Dated : 23-08-2024

1 Administrative information relating to the company

1.1	Name : Vygon	
1.2	Address : 5 rue Adeline - 95440 Ecouen, 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 : Nutrisafe2 bottle cap
2.3	GMDN code : 60539
2.4	Medical Device Class : I Applicable regulation : 93/42/CEE Medical Device Manufacturer : Vygon
2.5	Description of the device : Lockable cap for drug vials (for oral / enteral administration) with male lockable Nutrisafe2 connection (onto which the female port of a Nutrisafe2 syringe must be connected) with integral stopper. This device is available in 4 sizes: - code 820.18 for 18mm vials - code 820.20 for 20mm vials - code 820.22 for 22mm vials - code 820.28 for 28mm vials Manufactured according to NF H 35-49 standard.



2.6 Packaging / Containers

Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
820.18	1 (Individual blister)	20 (Carton box)	20 (Carton box)	480 (Carton box)

Single unit packaging



	Box 		
	Technical features :		
	Code		Cap
	820.18		Ø mm 18
2.7	Composition of the device and Accessories :		
	COMPONENTS	MARKER	MATERIALS
	Cap	1	LDPE



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 :**
Lockable cap for drug samplings with a Nutrisafe2 syringe. The drug is then administered either orally or through a Nutrisafe2 feeding tube.

3 Accessories

4 Sterilization process

Sterile Medical Device : NO

Sterilization made for the device : Non sterile

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

	Technical security : EN 1615 EN 868
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7 Instructions for use

7.1	
7.2	Indications : Lockable cap for drug samplings with a Nutrisafe2 syringe. The drug is then administered either orally or through a Nutrisafe2 feeding tube.
7.3	
7.4	

8 Additional information relating to the product