

TECHNICAL FILE

Nutrisafe2 bottle cap 820.18

Dated: 23-08-2024

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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: 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.		





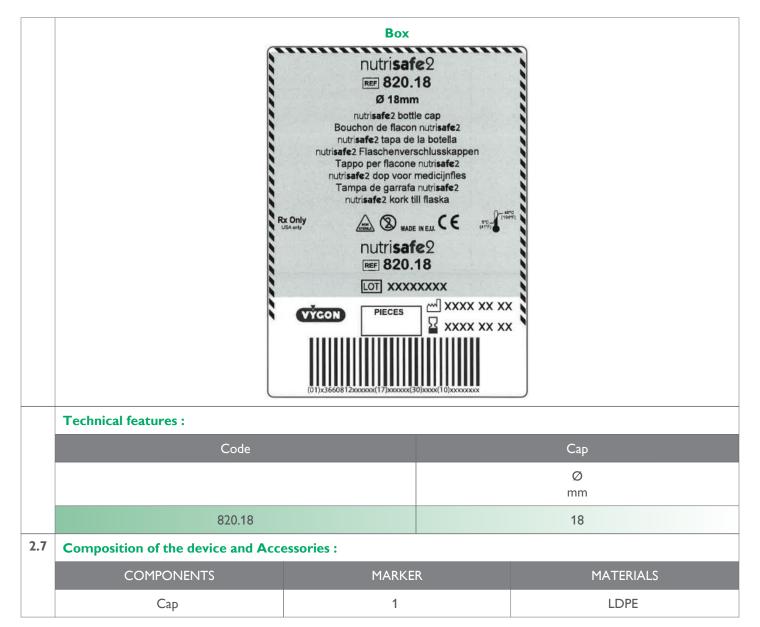
2.6 Packaging / Containers

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











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

- 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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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