

TECHNICAL FILE

Adaptor Nutrisafe2 - ENFit

368.72

Dated : 08-08-2024

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

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2.2	Commercial name : Adaptor Nutrisafe2 - ENFit
2.3	GMDN code : 64461
2.4	Medical Device Class : IIa Applicable regulation : 93/42/CEE in accordance with Appendix n° : II Notified body N° : 0459 Medical Device Manufacturer : Vygon
2.5	Description of the device : The Nutrisafe2-ENFit adaptor is indicated for enteral use only. It enables the connection between an administration set equipped with a female ENFit connector at its distal end and a Nutrisafe2 feeding tube equipped with a male Nutrisafe2 connector at its proximal end. Priming volume: 0.10 ml
	

2.6	Packaging / Containers				
	Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
	368.72	1 (Supple blister)	100 (Carton box)	100 (Carton box)	1800 (Case box)
	Single unit packaging 				
	Box 				
2.7	Composition of the device and Accessories :				
	COMPONENTS	MARKER		MATERIALS	
	Adaptor			PVC	

	 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 : Adaptor for enteral nutrition

3 Accessories

4 Sterilization process

	Sterile Medical Device : YES Sterilization made for the device : Ethylene oxide
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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	Special precautions : Please refer to the IFU.
5.3	Duration of product validity : 36 months

6 Security of use

	Technical security : Please refer to the IFU.
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7 Instructions for use

7.1	Instructions : Please refer to the IFU.
7.2	Indications : Adaptor for enteral nutrition
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. Please refer to the IFU.
7.4	Contra indications : Please refer to the IFU.

8 Additional information relating to the product

	BPA free
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