

## TECHNICAL DATA SHEET

### VY-P Nutrisafe2 reusable enteral syringe

1012.054

Dated : 08-08-2024

### 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>Generic name :</b> VY-P Nutrisafe2 reusable enteral syringe
<b>2.2</b>	<b>Commercial name :</b> VY-P Nutrisafe2 reusable enteral syringe
<b>2.3</b>	
<b>2.4</b>	<b>Medical Device Class :</b> 1SM <b>Applicable regulation :</b> 745/2017 <b>in accordance with Appendix n° :</b> VIII <b>Notified body N° :</b> 0051 <b>Medical Device Manufacturer :</b> Pentaferte Italia

**2.5 Description of the device :**

These Nutrisafe2 VY-P enteral syringes are intended for drug and feed administration at home. They can be re-used up to 30 cycles on a single patient only (for the cleaning process, please refer to the IFU).

These syringes feature the safety Nutrisafe2 connection, compliant with ISO 80369-1. Consequently, accidental misconnections between Nutrisafe2 connectors and other small-bore connectors intended for other clinical applications (venous access, limb cuff, urology, respiratory? as described in ISO80369) are mitigated and the right administration route is respected.

6 volumes are available: 1ml (code 1012.014), 2.5ml (code 1012.024), 5ml (code 1012.054), 10ml (code 1012.104), 20ml (code 1012.204) and 60ml (code 1012.604).

The Nutrisafe2 syringes are fitted with a purple-colored plunger and a 'VY-P Nutrisafe2 VYGON ENTERAL' marking, enabling instant identification for Nutrisafe2 enteral use.

NB: The 1ml marking doesn't include 'VY-P' due to the lack of space on the barrel.

The Nutrisafe2 connection is centered for the syringe codes: 1012.014 (1ml), 1012.024 (2.5ml), 1012.054 (5ml), 1012.104 (10ml), 1012.204 (20ml).

The Nutrisafe2 connection is offset for the syringe code: 1012.604 (60ml).

The graduation is:

- Every 0.01ml for the 1ml syringes (code 1012.014),
- Every 0.1ml for the 2.5ml syringes (code 1012.024),
- Every 0.2ml for the 5ml and 10 ml syringes (codes 1012.054, 1012.104),
- Every 0.5ml for the 20ml syringes (code 1012.204),
- Every 1ml for the 60ml syringes (code 1012.604).

For reminder, the Nutrisafe2 syringes can only be used with Nutrisafe2 feeding tubes or with any device featuring a male Nutrisafe2 connection.

Caution:

- As these syringes are re-usable, they cannot be used on a syringe-driver.
- These syringes are delivered sterile, but they become not sterile after their first use.



2.6	<b>Packaging / Containers</b>				
	Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
	1012.054	1 (Supple blister )	100 (Carton box )	100 (Carton box )	1600 (Case box )
	<p style="text-align: center;"><b>Single unit packaging</b></p> <div style="display: flex; justify-content: space-between;"> <div style="width: 30%;"> <p><b>nutrisafe2 VY-P</b>  <b>VYGON</b>                      5 rue Adeline 95440 Ecouem - FRANCE                      Tel: +33 (0)1 39 92 64 15                      Fax: +33 (0)1 34 29 19 34                      www.vygon.com                      questions@vygon.com</p> <p><b>PENTAFERTE ITALIA s.r.l.</b>                      Viale Plane Nocella, 23                      64012 CAMPLI (TE) - ITALY                      www.pentaferte.com</p> </div> <div style="width: 30%; text-align: center;"> <p>610026409 - Rev.01                        - 1 -</p> </div> <div style="width: 35%;"> <p>ENTERAL SYRINGE · ENTERALSPRITZE · SERINGUE ENTÉRALE · SIRINGA ENTERALE ·                      JERINGA ENTERAL · ENTERALE SPUIT · SERINGA ENTÉRICA ·                      STRZYKAWKA ENTERALNA · ЕНТЕРАЛНА СПРИНЦОВКА · ENTERÁLNÍ STRÍKAČKA ·                      ENTERAL SPRØYTE · ΕΝΤΕΡΙΚΗ ΣΥΡΙΓΓΑ · ΤΟΙΤΜΙΣΣÚΤΑΛ · ENTERAALINEN RUISKU ·                      ENTERALNA ŠTRCALJKA · ENTERÁLIS FECSKENDŐ · ENTERINIS ŠVIRKŠTAS ·                      ENTERĀLĀ ŠĪRCE · ENTERAL SPRØYTE · SERINGĀ ENTERĀLĀ ·                      ENTERĀLNA STRIEKAČKA · NTERALNA BRIZGALKA · ENTERALNI ŠPRIC ·                      ENTERAL SPRUTA · ENTERAL ŠIRINGA · ЭНТЕРАЛЬНЫЙ ШПРИЦ · محقنة للتغذية المعوية ·</p> </div> </div> <div style="text-align: center; margin-top: 10px;"> <p><b>REF 1012.054      5 ml</b></p> <p>(01) 08015262031367    </p> <div style="display: flex; align-items: center;"> <div style="margin-right: 10px;"> <p><b>UDI</b> </p> </div> <div> <p>2022-05-01                      2027-05-01                      LOT 22B03</p> </div> <div style="margin-left: 10px;"> <p> 0051  </p> </div> </div> </div>				
	<p style="text-align: center;"><b>Box</b></p> <div style="text-align: center;"> </div>				
	<p style="text-align: center;"><b>Case labelling</b></p> <div style="text-align: center;"> </div>				
	<b>Technical features :</b>				
	Code	Syringe			
		Volume ml	Graduation (every) ml		
	1012.054	5	0.2		

2.7	<b>Composition of the device and Accessories :</b>		
	COMPONENTS	MARKER	MATERIALS
	Body		PP
	Plunger		PP
	Seal		Synthetic isoprene
	<b>For components which are likely to come into contact with the patient and/or administered products, additional points :</b> Latex-free DEHP-free Does not contain any products of animal or biological origin		
2.8	<b>Indications :</b> These syringes are intended to be used in homecare settings and for enteral use only. They can be re-used up to 30 cycles, according with the validated cleaning process stated in the IFU. These syringes are for single-patient use only; they must be re-used on the same patient only.		

### 3 Accessories

### 4 Sterilization process

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

5.1	<b>Normal conservation and storage conditions :</b> Keep the product away from direct exposure to sunlight, in dry and clean environments, and away from extreme temperatures and extreme humidity. Storage environment temperature: between 0 and 45°C.
5.2	<b>Special precautions :</b> Please refer to the IFU in the packaging.
5.3	<b>Duration of product validity :</b> 60 months

### 6 Security of use

	<b>Technical security :</b> Please refer to the IFU in the packaging.
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### 7 Instructions for use

7.1	<b>Instructions :</b> Please refer to the IFU in the packaging.
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7.2	<b>Indications :</b> These syringes are intended to be used in homecare settings and for enteral use only. They can be re-used up to 30 cycles, according with the validated cleaning process stated in the IFU. These syringes are for single-patient use only; they must be re-used on the same patient only.
7.3	<b>Precautions :</b> Please refer to the IFU in the packaging.
7.4	<b>Contra indications :</b> Please refer to the IFU in the packaging.

## 8 Additional information relating to the product

	Latex, DEHP or products of animal/biological origin are not intentionally added in the materials used for the production of the device.
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