

TECHNICAL DATA SHEET

Neosafe

214.06

Dated : 23-08-2024

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	Generic name : Blood sampling needle
2.2	Commercial name : Neosafe
2.3	GMDN code : 35209
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 : Neosafe is intended for collection of small volumes of blood (<2 mL) for neonatology via the venous circulatory system. The collected blood is then used for analysis. It includes: - a stainless steel needle, siliconized to facilitate its insertion in the vein - a wing which ensures a good hold of the device and indicates the bevel orientation of the needle Blood sampling on the back of the hand of the baby is less painless than when carried out on the heel of the child. Neo-Safe is available in 3 sizes: 21G, 22G and 23G.



2.6 Packaging / Containers


Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
214.06	1 (Rigid blister pack)	50 (Carton box)	50 (Carton box)	600 (Carton box)

Single unit packaging



Box



Technical features :				
Code		Needle		
	Length mm	Int. Ø mm	Ext. Ø mm	Gauge G
214.06	17	0.40	0.60	23
2.7	Composition of the device and Accessories :			
	COMPONENTS	MARKER		MATERIALS
	Wing	1		PVC
	Needle	2		Stainless steel
Protector			PP	
				
<p>For components which are likely to come into contact with the patient and/or administered products, additional points :</p> <ul style="list-style-type: none"> Latex-free DEHP-free Does not contain any products of animal or biological origin Pyrogen-free 				
2.8	<p>Indications : Needle for blood sampling of small volumes of blood in neonates and infants.</p>			

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	Duration of product validity : 60 months
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6 Security of use

7 Instructions for use

7.1	
7.2	Indications : Needle for blood sampling of small volumes of blood in neonates and infants.
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.
7.4	

8 Additional information relating to the product