

TECHNICAL FILE

Vene-K
5805.01

Dated : 12-04-2022

1 Administrative information relating to the company

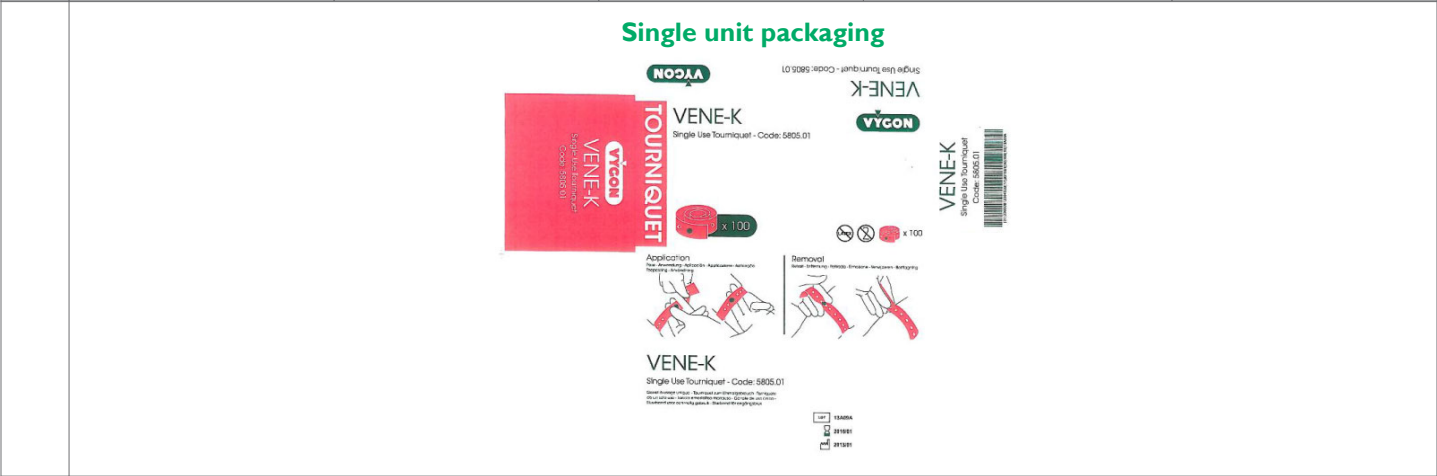
1.1	Name : Vygon	
1.2	Address : 5 rue Adeline - 95440 Ecouen, France	Fax : + 33 (0)1 34 29 19 34 E-mail : questions@vygon.com Website : www.vygon.com
1.3	Medical Device vigilance Representative : Laurent GUILLARDEAU	Tel : +33 (0)1 39 92 65 69 Fax : +33 (0)1 39 92 64 82 E-mail : quality@vygon.com

2 Information about the device or equipment

2.1	
2.2	Commercial name : Vene-K
2.4	Medical Device Class : I ns Applicable regulation : 93/42/CEE Medical Device Manufacturer : Vygon
2.5	Description of the device : Vene-K is a silicone single-use, quick-release tourniquet. Vene-K is intended to avoid cross-contamination due to the fact that a high proportion of reusable tourniquets are contaminated with blood and bacterial pathogens. Code 5802.05: standard Vene-K Code 5805.02: Vene-K paediatric



2.6	Packaging / Containers				
	Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
	5805.01	1 (Carton box)	100 (Carton box)	100 (Carton box)	1000 (Case box)



2.7	Composition of the device and Accessories :		
	COMPONENTS	MARKER	MATERIALS
	Green button	1	PP
	Tourniquet	2	Si



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 :

Single-use tourniquet

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 : 84 months

6 Security of use

7 Instructions for use

7.1	
7.2	Indications : Single-use tourniquet
7.3	
7.4	

8 Additional information relating to the product