Product data sheet

Home Care Prefilled Syringe

10% Aqueous Glycerin Solution



Area of application

The syringe prefilled with 10ml sterile 10% aqueous glycerin solution is used for inflation of Silicone Foley catheter balloons. The product is for single use only.

Product range

Capacity	Packaging	Reference
Home Care Prefilled Syringe, 10% Aqueous Glycerin Solution		
10ml	10/30	45000010

Sterilization

Sterile, Sterilized by Gamma Irradiation, Shelf life: 3 years

Certifications

CE-marking	CE 2797
Product classification	Class I Sterile (EU)
Quality system certified to	ISO 13485 Medical Device Single Audit Program (MDSAP)
European Medical Device Nomenclature (EMDN)	A02010702 - PREFILLED SYRINGES WITH STERILE WATER A02010799 - PREFILLED SYRINGES - OTHER
Global Medical Device Nomenclature (GMDN)	47017

Instructions for use

Included?	Yes

Material specifications

Contains latex?	No
Contains DEHP?	No
Contains cotton?	No
Contains paper?	Packaging only
Syringe	Polypropylene
Glycerin solution	Glycerin, Water

Packaging information

Reference	Primary pack./Single peelpack		Secondary pack./Shelf box		Tertiary pack./Shipper			Gross weight kg	Pallet Qty. pcs
	Qty. pcs	Dimensions, mm (LxW)	Qty. pcs	Dimensions mm (LxWxD)	Qty. pcs	Dimensions mm (LxWxD)	Volume m^3		
45000010	1	254 x 80	10	250 x 120 x 80	30	260 x 260 x 140	0.009	1.5	5,040

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GTIN codes			
REF	**Primary package**	**Secondary package**	**Tertiary package**
45000010	06944932787490	16944932787497	26944932787494

Packaging material	
Primary package	Nylon, Film
Secondary package	Corrugated fiberboard
Tertiary package	Double-wall corrugated fiberboard

Storage and handling	
	This way up
	Keep dry
	Fragile, handle with care
	Keep away from sunlight
	Do not resterilize
	Do not re-use
	Do not use if package is damaged and consult instructions for use
	Temperature limit (-15° to 49°C)
	Consult instructions for use or consult electronic instructions for use

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