

VITAL SIGNS® PRESSURE INFUSOR BAG

LATEX FREE | SINGLE USE | DISPOSABLE | NON-STERILE | DEHP FREE

DEVICE MANUFACTURING SPECIFICATIONS

Reference Number	IN8000xx; IN9000xx
Manufacturer	Vyaire Medical 26125 N. Riverwoods Blvd Mettawa, IL 60045 USA
Classification – US	Class 1, Exempt
FDA Product Code	KZD – Infusor, Pressure for IV Bags
Classification – CA	Rule 7, Class I
Classification – AU	Rule 2, Class I
Classification – BR	Class I
Classification – JA	Class I
Classification – UK	Rule 1, Class I
Classification – EU	Rule 1, Class I
CE Mark	CE
EU Authorized Representative	Emergo Europe
EMDN Code	A0599, Disposable Infusion Mechanical Systems - Accessories
GMDN Code	13100, Pressure Infusor, Manual
UMDNS Code	13100, Pressure Infusor
UNSPSC Code	42221704 Intravenous or Arterial Pressure Infusion Bags
Made In	China
Usage	Single Use
Sterility	Non-Sterile
Patient Population	Neonate, Pediatric, Adult
Packaging	6/Case, 12/Case, 20/Case, 48/Case
Storage Conditions	Storage Temperature -20°C to 50°C, Humidity Limitation 0% to 50%
Shelf Life	2 Years
Disposable Instructions	Dispose of Device per Local and State Environmental Regulations

Description: The Pressure Infusor consists of an air bladder, netting or PVC sleeve, a stopcock, a gauge for indicating pressure of the infusor air bladder, hanging hook, and pump bulb. The Pressure Infusor is placed around the IV bag, and the air bladder is inflated with the pump bulb. As the bladder is inflated, the Pressure Infusor begins to surround and squeeze the IV bag applying pressure on the solution. They are disposable, single-patient use.

Intended Purpose: This pressure infusor is a device consisting of an inflatable cuff which is placed around an IV bag. When the device is inflated, it increases the pressure on the IV bag to assist in the infusion of the fluid.

Area of Use: Pre-hospital, Hospitals, Surgery Centers, Medical Centers.

Contraindications: None known.

Compatibility: Pressure Infusor are designed to only be used in combination with 500 mL, 1000 mL, 3000 mL IV bags.

DEVICE SPECIFICATIONS

Description	Specification		
Size	500 mL	1000 mL	3000 mL
Gauge Accuracy	± 10%	± 10%	± 10%
Gauge Pressure Range	0-400 mmHg	0-400 mmHg	0-400 mmHg
Length	11.25 ± 0.25 cm	14.75 ± 0.25 cm	22.50 ± 0.25 cm
Width	6.0 ± 0.25 cm	6.0 ± 0.25 cm	9.25 ± 0.25 cm
Storage Conditions	Storage Temperature -20°C to 50°C, Humidity Limitation 0% to 50%		



DEVICE MATERIAL

Component	Netted Backing	Clear Backing
Netted Sleeve	150 Denier Polyester	Clear, Polyvinyl Chloride (PVC)
Hanger/Loop	Polyester/ Thermoplastic Elastomer (TPE)	Thermoplastic Elastomer (TPE)
Bladder	Nylon Polyurethane	Nylon Polyurethane
Gauge Diaphragm	Polyisoprene, Latex-Free	Polyisoprene, Latex-Free
Gauge Assembly	High Impact Polystyrene (HIPS)	High Impact Polystyrene
Gauge Flange	Thermoplastic Polyurethane (TPU)	Thermoplastic Polyurethane (TPU)
Inflation/ Pump Bulb	Polyvinyl Chloride (PVC)	Polyvinyl Chloride (PVC)
Bulb Check Valves	Low-Density Polyethylene (LDPE)	Low-Density Polyethylene (LDPE)
Bulb Ball	Stainless Steel	Stainless Steel
Tubing	Polyvinyl. Chloride (PVC), White	Polyvinyl. Chloride (PVC), White
Stopcock	Polycarbonate (PC), High Density Polyethylene (HDPE)	Polycarbonate (PC), High Density Polyethylene (HDPE)

Latex: The devices do not contain natural rubber latex.

Phthalates: The devices do not contain DEHP or BPA.

Biocompatible: Per EN ISO 18562-1:2020, the pressure infusor bag does not come in contact with the patient, is not part of the fluid/airway pathway, nor does it contact any medicinal drugs, fluid, or blood products. These devices are REACH compliant and do not contain 3TG conflict minerals. These devices do not contain blood derivatives or materials derived from animal or human tissue.

Part Number	UOM	GTIN	UOM	GTIN
IN800048	Each	10190752133747	48/Case	50190752133745
IN800012	Each	10190752133723	12/Case	50190752133721
IN900012	Each	10190752133754	12/Case	50190752133752
IN900048	Each	10190752133778	48/Case	50190752133776
IN950006	Each	10190752133785	6/Case	50190752133783
IN950012	Each	10190752133792	12/Case	50190752133790
IN900020	Each	10190752133761	20/Case	50190752133769
IN800020	Each	10190752133730	20/Case	50190752133738

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