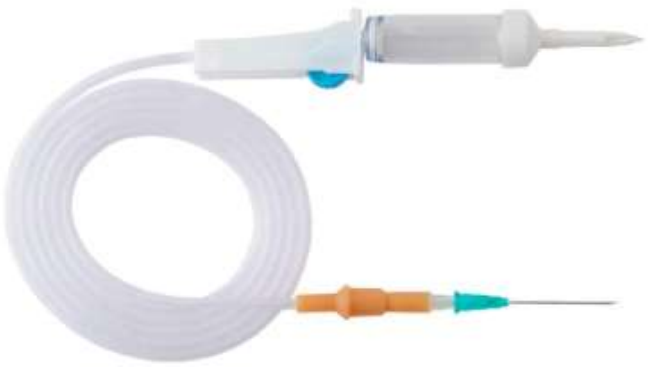
	
Fig.1:*Infusion set, vented or gravity feed*	***Fig.2:*** *Infusion set, vented with Y-site for pressure infusion*

1. PRODUCT DESCRIPTION

The I.V. Administration set is a single use sterile device. The device include a flow regulator, a drip chamber, air vent, fluid delivery tubing, connector between parts of the set, injection site & a hollow spike to penetrate and connect the tubing to an I.V. bag or other infusion fluid container. Duration of Use: Short term. Material of Composition: PVC, PP, ABS, SS.

Short term means normally intended for continuous use for between 60 minutes and 30days.

The tested period of use of our product is 96 hours.

2. DEVICE CLASSIFICATION AND RULE

The device is classified as Class IIa/Rule 7, medical device (classification as per MDR Annex II Section 1.1(f); Annex VIII.)
With needle : Class IIa/Rule 7
Without needle : Class IIa/Rule 2

3. PRODUCT CHARACTERISTICS & INTENDED USE

- **Infusion set, vented (bacteria-tight) for gravity feed:** Transfer of fluids, pharmaceuticals (excluding blood and blood components) and parenteral nutrition solutions by intravenous infusion. For use under gravity and with a pressure cuff with generated pressures up to 50 kPa (0.5 bar) only.
  Additional Feature: Closed venting cap of the drip chamber. Male Luer-Lock protection cap with hydrophobic, bacteria-tight filter available.

- **Infusion set, vented (bacteria-tight) for pressure infusion:** Transfer of fluids, pharmaceuticals (excluding blood and blood components) and parenteral nutrition solutions by intravenous infusion. For use with compatible pressure infusion pumps with generated pressures up to 200 kPa (2 bar). The product can also be used under gravity and with a pressure cuff with generated pressures up to 50 kPa (0.5 bar).
  Additional Feature: Closed venting cap of the drip chamber. Male Luer-Lock protection cap with hydrophobic, bacteria-tight filter available. With particle / air filter membrane in the drip chamber available.

- **Infusion set, vented (bacteria-tight) with Y-site for pressure infusion:** Transfer of fluids, pharmaceuticals (excluding blood and blood components) and parenteral nutrition solutions by intravenous infusion. For use with compatible pressure infusion pumps with generated pressures up to 200 kPa (2 bar). The product can also be used under gravity and with a pressure cuff with generated pressures up to 50 kPa (0.5 bar).
  Additional Feature: Closed venting cap of the drip chamber. Male Luer-Lock protection cap with hydrophobic, bacteria-tight filter available.

- Sharp piercing spike for easy insertion in the fluid tube.
- Infusion set with drop rate -20 drops/ml complies ISO 8536-4:2019 & ISO 8536-8:2015
- Kink resistant tube & transparent collapsible drip chamber with fluid filter (15 microns).
- Sterile, individually packed
- Effective roller controller for consistent flow rate.
- Latex free, DEHP free & BPA free

The product does not compromise with the clinical condition or the safety of patients. This device to be used in ambient conditions and use of the device is restricted to a qualified doctor or paramedic.

4. PRODUCT VARIANTS

Following variants are available for the products:

S.No.	Product	Size	GMDN Code	Classification / Rule
1	I.V. Infusion Set	Vented & Non-vented	35833 (for Infusion through infusion pump) 58977 (for Infusion through gravity feed)	Class-IIa, With needle : Rule 7 Without needle : Rule 2

5. MATERIAL OF CONSTRUCTION

S. No	Component Description	Material used
1.	Drip Chamber	PVC (Polyvinyl chloride) Phthalate free plasticizer
2.	Filter Disc with hydrophobic filter (0.45µ)	ABS (Acrylonitrile butadiene styrene)
3.	Spike plain/Spike with air vent	ABS (Acrylonitrile butadiene styrene)
4.	Spike cover	PP (Polypropylene)
5.	Air vent cap	PP (Polypropylene)
6.	Roller	ABS (Acrylonitrile butadiene styrene)
7.	Clamp	ABS (Acrylonitrile butadiene styrene)
8.	Tube	PVC (Polyvinyl chloride) Phthalate free plasticizer
9.	Blunt tip needle	SS 304 stainless steel
10.	Micro Dripper	PVC (Polyvinyl chloride) Phthalate free plasticizer
11.	Top connector	ABS (Acrylonitrile butadiene styrene)

12.	Bottom connector	PP(Polypropylene)
13.	Flow regulator	ABS (Acrylonitrile butadiene styrene)

Phthalate free plasticizer *is used within the PVC material procured from the approved suppliers.*

Yes, Filter disc is the air filter in the drip chamber upper part for ventilation

Yes, Tip needle is used for dropper of drip chamber

6. PRODUCT SPECIFICATION

Type	O.D	I.D	Tube Length	Pressure Resistance	Packaging
Infusion set, vented (bacteria-tight) for gravity feed	3.0 mm	4.1 mm	175 cm	Max. 0.5 bar	100 pcs
Infusion set, vented (bacteria-tight) for pressure infusion	3.0 mm	4.1 mm	175/200 cm	Min. 2 bar	100 pcs
Infusion set, vented (bacteria-tight) with Y-site for pressure infusion	3.0 mm	4.1 mm	175/200 cm	Min. 2 bar	100 pcs

7. REFERENCE COMPLIANCE STANDARD

S.No.	Title	Standard Ref. No.
1.	Infusion equipment for medical use -- Part 4: Infusion sets for single use, gravity feed	EN ISO 8536-4:2019
2.	Infusion equipment for medical use. Part 8: Infusion sets for single use with pressure infusion apparatus	ISO 8536-8:2015
3.	Infusion equipment for medical use. Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact	ISO 8536-14:2016
4.	Infusion equipment for medical use. Part 10: Accessories for fluid lines for single use with pressure infusion equipment	ISO 8536-10:2015
5.	Small-bore connectors for liquids and gases in healthcare applications Part 1: General requirements	ISO 80369-1:2018
6.	Small-bore connectors for liquids and gases in healthcare applications	EN ISO 80369 - 7 : 2021
7.	Sampling procedures for inspection by attributes -- Part 1 Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection	ISO 2859-1:1999
8.	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements	EN ISO 15223-1:2021
9.	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices	EN ISO 11135:2014
10.	Sterilization of health care products - Biological indicators - Part 1: General requirements	EN ISO 11138-1:2017
11.	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products	EN ISO 11737-1:2018

12.	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	EN ISO 11607-1:2019
13.	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	EN ISO 11607-2:2019
14.	Biological evaluation of medical devices –part 1, Evaluation and testing within a risk management process	EN ISO 10993-1: 2020
15.	Biological evaluation of medical devices. Part 17: Toxicological risk assessment of medical device constituents	EN ISO 10993-17: 2023
16.	Biological evaluation of medical devices. Part 18: Chemical characterization of medical device materials within a risk management process	EN ISO 10993-18: 2020
17.	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals	EN ISO 10993-7:2008
18.	Medical devices – application of risk management to medical devices	ISO 14971:2019
19.	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	ASTM-F1980
20.	Medical devices - Quality management systems - Requirements for regulatory purposes	EN ISO 13485:2016
21.	Clean Rooms And Associated Controlled Environments: Classification of air cleanliness by particle concentration	EN ISO 14644-1:2015
22.	European council directive concerning medical devices	MDD 93/42/EEC , 2007/47/EC
23.	European Medical device Regulations	EU MDR 2017/745
24.	Clean Rooms And Associated Controlled Environments: Monitoring to provide evidence of clean room performance related to air cleanliness by particle concentration	EN ISO 14644-2:2015

8. PACKAGING DETAILS AND SPECIFICATIONS

S.No.	Type of Packaging	Packaging Material
1.	Primary Packing	HM Pouch (HDPE- High-Density Polyethylene)
2.	Master Carton	5 Ply Corrugated Box

9. COMPLIANCE INFORMATION

Manufacturing Site Information: Disposafe Health and Life Care Ltd., Plot No. 1 & 2, Sec-59, Phase-II, Ballabhgarh, Faridabad-121004, Haryana (INDIA)

Drug Manufacturing License No.: MFG/MD/2019/000106

QMS Certification: EN ISO 13485:2016

CE Marking: TUV-SUD Product Services GmbH
GMDN: 35833 (for Infusion through infusion pump)
58977 (for Infusion through gravity feed)