

Fig.: I.V. Set with Y-Site with Needleless Connector

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, Isoprene, SS.

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.)

3. PRODUCT CHARACTERISTICS & INTENDED USE

An intravenous (I.V.) administration set is a medical device used to easily deliver nutrients and medications in a fluid form directly into a patient's bloodstream. These commonly used devices are used across a wide range of clinical settings, including hospitals, nursing homes and private domiciles, to deliver a required nutrient and/or medication, such as insulin, hormones, antibiotics, chemotherapy drugs, and pain relievers. I.V. administration sets allow the user to control the rate, duration and quantity of fluid.

- Sharp piercing spike for easy insertion in the fluid tube.
- Infusion set with drop rate -15 to 20/ml complies ISO 8536-4.
- Kink resistant tube & transparent collapsible drip chamber with fluid filter.
- Needleless Y-connector injection site for safe and convenient administration of additional medication.
- Sterile, individually packed
- Effective roller controller for consistent flow rate.

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.

- **PRODUCT SHELF LIFE & STORAGE**

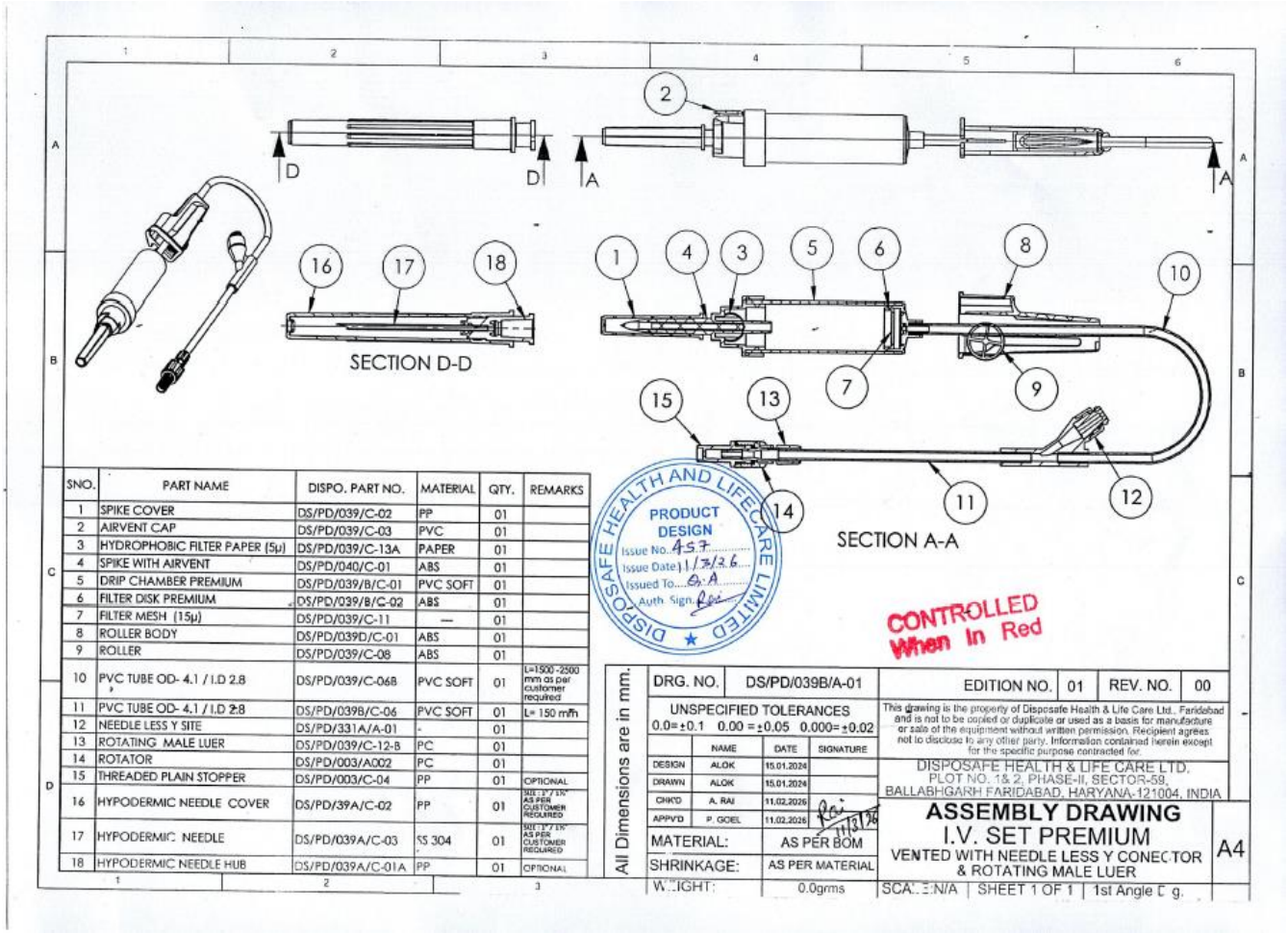
I.V. Infusion Set is supplied as "STERILE".
This device has the shelf life of 5 years from the date of sterilization if the package is intact.
Storage condition: Temperature: 10℃ to 45℃ & Humidity: 65% + 5%.

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	Class-IIa, Rule-7

5. DRAWINGS



SNO.	PART NAME	DISPO. PART NO.	MATERIAL	QTY.	REMARKS
1	SPIKE COVER	DS/PD/039/C-02	PP	01	
2	AIRVENT CAP	DS/PD/039/C-03	PVC	01	
3	HYDROPHOBIC FILTER PAPER (5µ)	DS/PD/039/C-13A	PAPER	01	
4	SPIKE WITH AIRVENT	DS/PD/040/C-01	ABS	01	
5	DRIP CHAMBER PREMIUM	DS/PD/039/B/C-01	PVC SOFT	01	
6	FILTER DISK PREMIUM	DS/PD/039/B/C-02	ABS	01	
7	FILTER MESH (15µ)	DS/PD/039/C-11	—	01	
8	ROLLER BODY	DS/PD/039D/C-01	ABS	01	
9	ROLLER	DS/PD/039/C-08	ABS	01	
10	PVC TUBE OD- 4.1 / I.D 2.8	DS/PD/039/C-068	PVC SOFT	01	L=1500 -2500 mm as per customer required
11	PVC TUBE OD- 4.1 / I.D 2.8	DS/PD/039B/C-06	PVC SOFT	01	L= 150 mm
12	NEEDLE LESS Y SITE	DS/PD/331A/A-01	-	01	
13	ROTATING MALE LUER	DS/PD/039/C-12-B	PC	01	
14	ROTATOR	DS/PD/003/A002	PC	01	
15	THREADED PLAIN STOPPER	DS/PD/003/C-04	PP	01	OPTIONAL
16	HYPODERMIC NEEDLE COVER	DS/PD/39A/C-02	PP	01	SIZE : 0" / 1½" AS PER CUSTOMER REQUIRED
17	HYPODERMIC NEEDLE	DS/PD/039A/C-03	SS 304	01	SIZE : 0" / 1½" AS PER CUSTOMER REQUIRED
18	HYPODERMIC NEEDLE HUB	DS/PD/039A/C-01A	PP	01	OPTIONAL

	NAME	DATE	SIGNATURE
DESIGN	ALOK	15.01.2024	
DRAWN	ALOK	15.01.2024	
CHKD	A. RAI	11.02.2026	
APPVD	P. GOEL	11.02.2026	
MATERIAL:	AS PER BOM		
SHRINKAGE:	AS PER MATERIAL		
WEIGHT:	0.0grms		

UNSPECIFIED TOLERANCES 0.0=±0.1 0.00 =±0.05 0.000=±0.02

All Dimensions are in mm.

Assembly Drawing I.V. Set

Prepared By:	Reviewed By:	Approved By:	Issued By:	
				DISPOSAFE HEALTH AND LIFE CARE LTD.

6. MATERIAL OF CONSTRUCTION

S.No	Component Description	Material used
1.	Spike cover	PP (Polypropylene)
2.	Air vent cap	PVC (Polyvinyl chloride)
3.	Hydrophobic filter paper (5µ)	Paper
4.	Spike with air vent	ABS (Acrylonitrile butadiene styrene)
5.	Drip Chamber Premium	PVC Soft (Polyvinyl chloride)
6.	Filter Disk Premium	ABS (Acrylonitrile butadiene styrene)
7.	Filter Mesh (15 µ)	-
8.	Roller Body	ABS (Acrylonitrile butadiene styrene)
9.	Roller	ABS (Acrylonitrile butadiene styrene)
10.	PVC Tube O.D- 4.1 / I.D- 2.8	PVC Soft (Polyvinyl chloride)
11.	PVC Tube O.D- 4.1 / I.D- 2.8	PVC Soft (Polyvinyl chloride)
12.	Needle Less Y-site	-
13.	Rotating Male Luer	PC (Polycarbonate)
14.	Rotator	PC (Polycarbonate)
15.	Threaded Plain Stopper	PP (Polypropylene)
16.	Hypodermic Needle Cover	PP (Polypropylene)
17.	Hypodermic Needle	SS 304 (Stainless Steel)
18.	Hypodermic Needle Hub	PP (Polypropylene)

7. PRODUCT SPECIFICATION

Type	Capacity	Packing Inner/ Outer Unit
Vented	15/20 drop/ml	25/500
Non-Vented	15/20 drop/ml	25/500

8. 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 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact	ISO 8536 - 14 : 2016
3.	Small-bore connectors for liquids and gases in healthcare applications	EN ISO 80369 - 7 : 2021
4.	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
5.	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
6.	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
7.	Sterilization of health care products - Biological indicators - Part 1: General requirements	EN ISO 11138-1:2017
8.	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products	EN ISO 11737-1:2018
9.	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	EN ISO 11607-1:2019
10.	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	EN ISO 11607-2:2019
11.	Biological evaluation of medical devices –part 1, Evaluation and testing within a risk management process	EN ISO 10993-1: 2020
12.	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals	EN ISO 10993-7:2008
13.	Medical devices – application of risk management to medical devices	EN ISO 14971:2019
14.	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	ASTM-F1980
15.	Medical devices - Quality management systems - Requirements for regulatory purposes	EN ISO 13485:2016
16.	Clean Rooms And Associated Controlled Environments: Classification of air cleanliness by particle concentration	EN ISO 14644-1:2015
17.	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
18.	Biological evaluation of medical devices Part 17: Toxicological risk assessment of medical device constituents	EN ISO 10993-17: 2023
19.	Biological evaluation of medical devices Part 18: Chemical characterization of medical device materials within a risk management process	EN ISO 10993-18: 2020

9. PACKAGING DETAILS AND SPECIFICATIONS

ITEM	MATERIAL	No. of Pcs.
Primary Packing	HM Pouch	01
Secondary Packing	LD Pouch	25
Tertiary Packing (Master Carton)	5 Ply	500

10. 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

European Representative: CE partner 4U BV

GMDN: 35833