Pen Type I.V Cannula/Catheter Without Wings and Without Injection Port	Pencath



1. PRODUCT DESCRIPTION

I.V. Cannula / Catheter is a device for access to the human circulatory system for introduction of fluids or medicament and/or withdrawal of blood samples. It comprises of a short flexible plastic tube (the Catheter) etc., which is inserted into a vein over a hollow introducer needle, after which the needle is withdrawn and discarded.
Duration of Use: Short Term.
Material of Construction: PVC, FEP/PUR/PTFE, PP, HDPE/LDPE, SS.

2. DEVICE CLASSIFICATION AND RULE

The device is classified as Class IIa/Rule 7, medical device as per EU MDR 2017/745 Annexure VIII.

3. INTENDED USE

I.V. Cannula is a device used for introduction of fluids or medicament and/or withdrawal of blood samples through peripheral vein. It is inserted into a vein over a hollow introducer needle after which the needle is withdrawn and discarded. The I.V. Cannula is used by following aseptic technique. The use of the product is restricted to a qualified doctor or a paramedic.

4. PRODUCT FEATURES

Easy identification of the gauge size through color, as per ISO 10555-5.

- The Physical, Functional and Safety characteristics are conforming to the International Standard ISO 10555- 1 & 5.
- Sterile, Pyrogen-free until the package is intact.
- **Needle:** The device comprises a siliconized and ground Stainless Steel with ultra-thin, ultra- sharp needle with triple facet bevel to ensure smooth and painless venipuncture during cannulation thus reducing pain and discomfort experienced during the insertion.
- **Catheter:** The catheter is an integral part of the device and is made of best-in-class kink resistant and biocompatible, with extremely smooth inner and outer surfaces to ensure easy venipuncture with minimum trauma; gently tapered catheter tip aligns with the needle bevel to provide smooth transition from needle to catheter.

- **Flashback Chamber:** detachable Flashback chamber with hydrophobic filter to facilitate quick visualization of blood flashback and confirmation to successful catheter placement in vein and prevent any spillage.
- **Universal female 6% taper:** for ease of connection with other standard devices/ components having male 6% taper. The connection conforms to ISO 80369-7.
- **Needle Cover:** Transparent needle cover to prevent damage to the catheter.

5. PRODUCT VARIANTS

Following options are available with the product Pen Type Intravenous Cannula:

- Hub cover or Hub cover with filter
- Catheter material options are available, with FEP / PUR / PTFE
- Color coded part cap options is available in Normal or Flip Design
- With PP tube or Molded needle cover
- Bulk-pack of the products are also available

6. MATERIAL OF CONSTRUCTION

S. No	Component Description	Material used
1.	Flow Control Hub	PP
2.	Needle Hub	K. RESIN
3.	Body	PP
4.	Catheter Holder	POM
5.	Catheter	FEP/PUR/PTFE
6.	Needle	SS 304
7.	Needle Cover	PP
8.	Back Cover	PP
9.	Filter Paper	PAPER

7. PRODUCT SPECIFICATION

Gauge	Colour	Catheter O.D. (mm)	Catheter Length (mm)	Flow Rate (Water) (ml/min)	Packing Inner/ Outer Unit
14G	**Orange**	2.10	45	270	50/500
16G	**Grey**	1.80	45	200	50/500
17G	**White**	1.50	45	125	50/500
18G	**Deep Green**	1.30	45	90	50/500
20G	**Pink**	1.10	32	60	50/500
22G	**Blue**	0.90	25	36	50/500
24G	**Yellow**	0.73	19	23	50/500
26G	**Violet**	0.63	19	15	50/500

8. PACKAGING DETAILS AND SPECIFICATIONS

ITEM	MATERIAL
Individual Sterile	-
Inner Carton	Duplex Paper
Master Carton	5 Ply corrugation

9. REFERENCE COMPLIANCE STANDARD

Sr. No.	Title	Standard Ref. No.
1.	Intravascular Catheters- Sterile and single use catheters-Part 1- General requirements	EN ISO 10555-1:2023
2.	Intravascular Catheters- Sterile and single use catheters-Part 2- Over - needle peripheral catheters	ISO 10555-5:2013
3.	6% Luer- Small-bore connectors for liquids and gases in healthcare applications	EN ISO 80369-7:2017
4.	Medical devices - Symbols to be used with medical devicelabels, labeling and information to be supplied - Part 1: General requirements	EN ISO 15223-1:2021
5.	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/ A1:2019
6.	Sterilization of health care products - Biological indicators -Part 1: General requirements	EN ISO 11138-1:2017
7.	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms onproducts	EN ISO 11737-1:2018/ A1:2021
8.	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	EN ISO 11607-1:2020/ A1:2023
9.	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	EN ISO 11607-2:2020/ A11:2022
10.	Biological evaluation of medical devices –part 1, Evaluation and testing within a risk management process	EN ISO 10993-1: 2025
11.	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals	EN ISO 10993- 7:2008/ A11:2025
12.	Medical devices – application of risk management to medicaldevices	EN ISO 14971:2019
13.	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	ASTM-F1980
14.	Medical devices – Quality management systems – Requirements for regulatory purposes	EN ISO 13485:2016
15.	Medical devices - Information to be supplied by themanufacturer	EN ISO 20417:2021

10. OTHER DETAILS

10.1. **Intended Use:** refer the instruction for use before the application.

10.2. **Storage:** store in a cool and dry place and keep away from direct sunlight and extreme heat.

10.3. **Method of Sterilization:** sterilized using ethylene oxide.

10.4. **Shelf life:** 05 years from the month / date of sterilization.

Prepared by:	Reviewed by:	Approved by:	Issued by:	
Name: Nitin Saini Desig.: Executive, QA	Name: Hardik Bhan Desig.: Manager, QA	Name: Krishanu Bose Desig.: General Manager	Name: Hardik Bhan Desig.: MR	

10.5. **Testing and Analysis:** Testing for sterility, pyrogen content and physical characteristics (leakage testing, flow rate of lumen, penetration force, packaging integrity, etc.) is performed on each batch before release.

10.6. **Biocompatibility:** The product is tested as per the international standard ISO 10993-1 and parts applicable, and evaluation results are found conform to the standard requirements. The report from the actual study is available with Quality Assurance and will be available for review on request.

10.7. **Disposal:** Dispose of the used product in to biohazard container / clinical wastage bag or according to hospital and country specific protocol.

11. COMPLIANCE INFORMATION

Manufacturer 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**,** TUV SUD Product Service GmbH
CEMarking: TUV SUD Product Service GmbH, EC Notified body No. 0123
GMDN Code: 64574

12. ABBREVIATIONS

QMS – Quality Management System
MD – Medical Device
GMDN – Global Medical Device Nomenclature