

1. PRODUCT DESCRIPTION

I.V. Cannula / Catheter are 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 FEP/PUR/PTFE tube (the Catheter) etc., which is inserted into a vein over a hollow introducer needle, after which the needle is withdrawn and discarded.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.

2. DEVICE CLASSIFICATION AND RULE

The device is classified as Class IIa/Rule 7, medical device Rule 2017.

3. PRODUCT CHARACTERISTICS & 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 It is inserted into a vein over a hollow introducer needle after which the needle is withdrawn and discarded.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 VARIANTS

Variants		Gauges
I.V. Cannula	With wings & with Injection Port	14G,16G,17G,18G,20G, 22G, 24G, 26G
	With Wings & Without Injection Port	14G,16G,17G,18G,20G, 22G, 24G, 26G
	Without wings & Without Injection Port	14G,16G,17G,18G,20G, 22G, 24G, 26G
	Small wings & without Injection Port	14G,16G,17G,18G,20G, 22G, 24G, 26G

5. MATERIAL OF CONSTRUCTION

S. No.	Components	Material Used
1.	Body (Plain) Body (with wings) Body (with thumb control)	P.P. (Polypropylene)
2.	Catheter Holder	Polyacetal +Master Batch
3.	Catheter	F.E.P (Fluorinated ethylene propylene) PUR (Polyurethane)

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		PTFE (Polytetrafluoroethylene)
4.	Silicon Tube	Silicon
5.	Port Cap	High density polyethylene (HDPE) (50%) + Low density polyethylene (LDPE) (50%) + Master Batch
6.	Needle	SS 304 Stainless Steel
7.	Needle Hub	P.P. (Polypropylene)
8.	Hub Cover	P.P. (Polypropylene)
9.	Threaded Stopper/Luer Cap	High-density polyethylene (HDPE) + Master Batch White
10.	Needle Cover	P.P. (Polypropylene)
11.	Flashback Chamber	P.P.

6. PRODUCT SPECIFICATION:

Technical Specification (I.V. Cannula)							
S.no.	**Gauge (G)**	**Length (mm)**	**Tolerance (mm)**	**Outer dia (±0.04mm)**	**Colour (Port cap)**	**Flow rate(ml/min)**	**Tolerance of Flow rate**
1.	14	45	± 1.0	2.1	Orange	270	-10%-+15%
2.	16	45	± 1.0	1.8	Grey	200	-10%-+15%
3.	17	45	± 1.0	1.5	White	125	-10%-+15%
4.	18	45	± 1.0	1.3	Green	90	-10%-+15%
5.	20	32	± 1.0	1.1	Pink	60	-10%-+15%
6.	22	25	± 1.0	0.9	Blue	36	-20%-+25%
7.	24	19	± 1.0	0.7	Yellow	23	-20%-+25%
8.	26	19	± 1.0	0.6	Violet	15	-20%-+25%

7. REFERENCE COMPLIANCE STANDARD

S.No.	**Name Of Standard**	**Standards**	
1.	Intravascular Catheters- Sterile and single use catheters- Part 1- General requirements	ISO 10555-1:2023	Harmonized
2.	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General	EN ISO 15223-1:2021	Harmonized

	requirements.		
3.	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices Amendment 1: Revision of Annex E, Single batch release	ISO 11135:2014/Amd 1:2018	Harmonized
4.	Sterilization of health care products - Biological indicators - Part 1: General requirements.	EN ISO 11138-1:2017	Harmonized
5.	Sterilization of health care products-Microbiological methods - Part 1: Determination of a population of microorganism on products.	EN ISO 11737-1:2018, EN ISO 11737-1:2018/A1:2021	Harmonized
6.	Biological evaluation of medical devices - part 1, Evaluation and testing within a risk management process.	EN ISO 10993-1: 2020	Harmonized
7.	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.	EN ISO 10993-3:2014	Harmonized
8.	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood.	EN ISO 10993-4:2017	Harmonized
9.	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.	EN ISO 10993-5:2009	Harmonized
10.	Biological evaluation of medical devices -Part 6: Tests for local effects after implantation.	EN ISO 10993-6:2016	Harmonized
11.	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals.	EN ISO 10993-7:2008 And 1:2019	Harmonized
12.	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.	EN ISO 10993-11:2018	Harmonized
13.	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials.	EN ISO 10993-12:2021	Harmonized
14.	Biological evaluation of medical devices Part 17: Toxicological risk assessment of medical device constituents	ISO 10993-17:2023	Harmonized
15.	Medical devices-Quality management systems-Requirements for regulatory purposes.	ISO 13485:2016	Harmonized
16.	Medical devices-application of risk management to medical devices.	EN ISO 14971:2019	Harmonized
17.	Intravascular Catheters- Sterile and single use catheters-Part 2- Over -needle peripheral catheters.	EN ISO 10555-5:2013	Harmonized
18.	6% Luer- Small-bore connectors for liquids and gases in health care application.	EN ISO 80369-7:2021	Harmonized

8. PACKAGING DETAILS AND SPECIFICATIONS

S. NO.	Type of Packaging	No. of Pieces
1.	Blister Pack (Tyvek / PVC film) Blister Pack (MG paper / PVC film)	01
2.	Inner (Duplex) Box	100
3.	Outer/Master Carton (Corrugated box)	1000

9. OTHER DETAILS

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

Method of Sterilization: sterilized using Ethylene Oxide

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

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.

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

10. 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

CE Marking: TUV SUD Product Service GmbH, EC Notified body No. 0123

GMDN Code: 64574

ABBREVIATIONS

QMS – Quality Management System

GMDN – Global Medical Device Nomenclature