

Fig.1: Central Venous Catheter

1. PRODUCT DESCRIPTION:

The central venous catheter is placed into a large vein leading into the heart and comes out through a small opening in the chest area. This opening is called the exit site. A CVC can be used to give you fluids, blood products, and medicine. It can also be used to take blood samples. Duration of Term: Short Term.

2. DEVICE CLASSIFICATION AND RULE:

The device is classified as Class III/Rule 7, medical device (classification as per MDR Annex II Section 1.1(f); Annex VIII.)

3. PRODUCT CHARACTERISTICS & INTENDED USE:

It is indicated for use in patients requiring administration of solutions, blood sampling, central venous pressure monitoring and injection of contrast media. CVC kit should be used, manipulated, and removed only by a qualified, licensed physician or other health care practitioner authorized by and under the direction of such physician. Medical techniques and procedures described in these instructions do not represent all medically accepted protocols, nor are they intended as a substitute for a physician's experience and judgment in treating any specific patient.

- Central Venous Catheter made of specially formulated and bio-compatible Polyurethane material provides strength during insertion and long term venous access of the Fluids.
- Medical grade Polyurethane material minimizes risk of irritation and softens at body temperature to conform to the body tissues and reduces the risk of vascular trauma.
- Specially designed soft & beveled tip for smooth & easy insertion of catheter.
- Color coded for easy identification of arterial & venous line.
- Radio-opaque catheter with clear, definite marking to ensure correct placement of catheter.
- Sterile individually packed in medical grade packing.

4. PRODUCT VARIANTS:

Following variants are available for the products:

S.NO	Product	Size	Type	GMDN Code	Classification / Rule

1.	Central Venous Catheter	• **SINGLE Lumen CVC Catheter** 3FR to 9FR / 11G, 12G, 14G, 16G, 18G & 20G / L-60mm, 80mm, 100mm, 130mm, 150mm, 160mm, 200mm, 300mm- with/without 3 way stop cock • **DOUBLE LUMEN CVC Catheter** 4FR to 8FR / 14G, 16G, 18G & 22G (P&D combination), L-60 mm, 80mm, 130mm, 160mm, 200mm & 300mm- with/without 3 way stop cock • **TRIPLE LUMEN CVC Catheter** 4.5FR, 5FR, 5.5FR, 7FR & 12FR / 12G, 16G, 18G, 20G, 22G & 23G (P,D & M combination), L-60mm, 80mm, 130mm, 150mm, 160mm, 200mm & 300mm- with/without 3 way stop cock	Single Lumen, Double Lumen & Triple Lumen	36257	Class-III, Rule-7

5. MATERIAL OF CONSTRUCTION:

S.No	Component Description	Material used
1.	Catheter Quad Lumen	Poly Urethane
2.	Y-Shape Introducer needle	PC+ SS
3.	Guidewire	SS
4.	Syringe	PP+SS
5.	Dilator	PP
6.	Thumb scalpel Handle	ABS
7.	Blade No. 11	SS
8.	Scalpel Cap	LLDPE
9.	Injection Stopper	ABS
10.	Latex Plug	Poly Isoprene
11.	Hypodermic Needle Cover	PP
12.	Hypodermic Needle	SS
13.	Needle Hub	PP
14.	Catheter Clamp	PVC
15.	3-WSC Body	PC
16.	3-WSC Tap	HDPE+LDPE
17.	Rotator	PC
18.	Threaded Stopper	HDPE
19.	Plain Stopper	PP

6. PRODUCT SPECIFICATION:

- Indwelling Catheter
- Kink resistant J-tip nitinol guide wire
- Luer lock syringe
- Scalpel
- Catheter holder clamp

- Y-introducer needle with valve
- Dilator
- Lipid resistant three way stopcock
- Catheter Holder

7. REFERENCE COMPLIANCE STANDARD:

S No.	Name of Standard	Number
	Central Venous Catheter	
1.	Intravascular catheters — Sterile and single-use catheters Part 3: Central venous catheters	ISO 10555-3:2013
2.	Small-bore connectors for liquids and gases in healthcare applications Part 7: Connectors for intravascular or hypodermic applications	ISO 80369-7:2021
	General	
3.	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
4.	Clean Rooms And Associated Controlled Environments: Classification of air cleanliness by particle concentration	EN ISO 14644-1:2015
5.	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
6.	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements	EN ISO 15223-1:2021
7.	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
8.	Sterilization of health care products - Biological indicators - Part 1: General requirements	EN ISO 11138-1:2017
9.	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products	EN ISO 11737-1:2018
10.	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems	EN ISO 11607-1:2019
11.	Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes	EN ISO 11607-2:2019
12.	Biological evaluation of medical devices –part 1, Evaluation and testing within a risk management process	EN ISO 10993-1: 2018
13.	Biological evaluation of medical devices — Part 3: Tests for Genotoxicity, carcinogenicity and reproductive toxicity	EN ISO 10993-3:2014
14.	Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood	EN ISO 10993-4:2009
15.	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	EN ISO 10993-5:2009
16.	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals	EN ISO 10993-7:2008
17.	Biological evaluation of medical devices - Part 10: Tests for irritation	EN ISO 10993-10:2021

	and skin sensitization	
18.	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	EN ISO 10993-11:2017
19.	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	EN ISO 10993-12:2021
20.	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances	EN ISO 10993-17:2023
21.	Clean rooms and associated controlled environments- bio-contamination control- general principles and methods	EN ISO 14698-1:2003
22.	Clean rooms and associated controlled environments- bio-contamination control- evaluation and interpretation of bio-contamination	EN ISO 14698-2:2003
23.	Medical devices -- Quality management systems -- Requirements for regulatory purposes	ISO 13485:2016
24.	Medical devices – application of risk management to medical devices	EN ISO 14971:2019
25.	European council directive concerning medical devices	MDR 2017/745

8. PACKAGING DETAILS:

Packaging specifications		
1.	Blister Pack (PVC film)	01 Nos.
2.	Inner (Duplex) Box	10 Nos.
3.	Outer / Master Carton (Corrugated box)	40 Nos.

9. COMPLIANCE INFORMATION:

Manufacturer Information: Disposafe Health and Life Care Ltd., Plot No. 1 & 2, Phase-II, Sec-59, Ballabgarh, 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:36257

10. ABBREVIATIONS:

QMS – Quality Management System
GMDN – Global Medical Device Nomenclature
PP – Polypropylene
PC – Polycarbonate
H.D.P.E – High-density polyethylene
L.L.D.P.E – Linear Low-density polyethylene
S.S. – Stainless Steel
A.B.S. - Acrylonitrile Butadiene Styrene
3 W.S.C. – Three way Stopcock