

Fig.1: HEMODIALYSIS CATHETER

1. PRODUCT DESCRIPTION:

Hemodialysis catheter kit also referred to as a dialysis catheter kit is manufactured and used in attaining long-term vascular access for hemodialysis and apheresis. The dialysis kit may be inserted through the skin and is primarily positioned in the internal jugular vein region of an adult patient. An alternate insertion site includes the subclavian vein.

Hemodialysis catheter is a single, double and triple lumen radiopaque catheter with a polyester cuff. The catheter comes in multiple sizes, ranging from 8 French to 14 French, featuring an innovative radiused distal configuration. Our unique shaped design is intended to leverage the outside of the arc of both the arterial and venous lumens to eliminate the vein wall as an obstruction

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:

A dialysis catheter is a catheter used for exchanging blood to and from the hemodialysis machine from the patient. The dialysis catheter contains two lumens: Venous. Arterial Hemodialysis catheter kit also referred to as a dialysis catheter kit is manufactured and used in attaining long-term vascular access for hemodialysis and

apheresis. The dialysis kit may be inserted through the skin and is primarily positioned in the internal jugular vein region of an adult patient. An alternate insertion site includes the subclavian vein.

- Colour coded luer for easy identification of artery & venous infusion lines.
- Available with single, double & triple lumen extensions for neonates & adults.
- Made of Polyurethane material which provides strength during insertion.
- Radio-opaque catheter with clear, definite marking to ensure correct placement of catheter under X-ray.
- Soft tip designed to resist positional occlusion and reduces trauma.
- Curved extensions for jugular vein approaches to make the catheter more comfortable for the patient.

4. PRODUCT VARIANTS:

Following variants are available for the products:

S.NO	Product	Type	GMDN Code	Classification / Rule
1.	Hemodialysis Catheter	Single Lumen, Double Lumen & Triple Lumen	34161	Class-III, Rule-7

Type	Size
Double Lumen	11.5Fr x 13cm (Curved) 11.5Fr x 15cm (Straight)
Triple Lumen	12Fr x 13cm (Curved) 12Fr x 15cm (Straight)

5. MATERIAL OF CONSTRUCTION:

S.No	Component Description	Material used
1.	Catheter Double Lumen	Poly Urethane
2.	Introducer needle/ Y-Shape needle	PC+ SS
3.	Guidewire ST/ J-tip	SS
4.	Dilator	PP
5.	Scalpel	SS
6.	Blade No. 11	SS
7.	Latex Plug	Isoprene
8.	Thumb Scalpel Handle	ABS
9.	Injection Stopper	ABS
10.	Scalpel Cap	LLDPE
11.	Surgical Dripe	Cloth
12.	Hypodermic Needle Cover	PP
13.	Hypodermic Needle	SS
14.	Needle Hub	PP
15.	Hollow Syringe 5 ml	PP, SS

6. PRODUCT SPECIFICATION:

- Indwelling catheter
- Y-Introducer needle with valve

- J-tip nitinol guide wire
- Dilators 2 no's
- Luer lock syringe
- Scalpel

7. REFERENCE COMPLIANCE STANDARD:

S No.	Name of Standard	Number
	Central Venous Catheter	
1.	Intravascular catheters — Sterile and single-use catheters Part 8: Catheters for extracorporeal blood treatment	ISO 10555-8:2024
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 and skin sensitization	EN ISO 10993-10:2021

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	01 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: 16615

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