

1. PRODUCT DESCRIPTION

A.V. fistula needles set has Ultra-wall and siliconized needle with or without back eye. It is available for fixed and rotating wing. Clear and kink-resistant tube fitted with female luer lock and pinch clamp. It has PVC Tube and SS Needle. Duration of Use: Short term.

2. DEVICE CLASSIFICATION AND RULE

The device is classified as Class IIa/Rule 7, medical device (classification as per ANNEX–VIII of EU MDR 2017/745).

3. INTENDED USE

AV Fistula needle set use in conjunction with connector of Hemodialysis blood tubing set. Used to connect blood lines to the blood vessel through needle when dialysis is carried out.

4. MATERIAL OF CONSTRUCTION

S. No.	Component	Material Used
1.	Needle	Stainless Steel
2.	PVC Tube	PVC
3.	Female luer lock	Polycarbonate
4.	Wing Body	PVC
5.	Needle Cover	PP
6.	Threaded Stopper	HDPE
7.	C-Clamp	POM

5. PRODUCT SPECIFICATION

S.No.	Product	Type	Gauge/Size	GMDN Code	Classification
1.	**AV Fistula Needle**	-	14 G, 15G, 16G, & 17G	43363	Rule-7 IIa

6. REFERENCE COMPLIANCE STANDARD

S. No.	Name Of Standard	ISO Standard No.
Standard for AV Fistula Needle		
1.	6% Luer -Small-bore connectors for liquids and gases in health care applications	ISO 80369-7:2017
2.	Transfusion equipment for medical use: for single use, gravity feed	ISO 1135-4:2010
3.	Sampling Procedure For Inspection By attributes	ISO 2859-1 : 1999 IS 2500-1:2000
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, labeling and information to be supplied -- Part 1: General requirements	EN ISO 15223-1:2016
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 11607-1:2017
11	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	EN ISO 11607-2:2017
12.	Sterilization of health care products- Biological indicators for ethylene oxide sterilization processes	EN ISO 11138-2:2017
13.	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	EN ISO 10993-1:2009
14.	Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	EN ISO 10993-3:2014
15.	Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood	EN ISO 10993-4:2017
16.	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	EN ISO 10993-5:2009
17.	Biological evaluation of medical devices -Part 6: Tests for local effects after implantation	EN ISO10993-6:2016
18.	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals	EN ISO 10993-7:2008
19.	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	EN ISO 10993-10:2013
20.	Biological evaluation of medical devices - Part 11 : Tests for systemic toxicity	EN ISO 10993-11:2018
21.	Biological evaluation of medical devices - Part 12 : Sample preparation and reference materials	EN ISO 10933-12:2012
22.	Biological evaluation of medical devices- Part 17 : Establishment of allowable limits for leachable substances	EN ISO 10993-17 :2009
23.	Medical devices -- Quality management systems -- Requirements for regulatory purposes	EN ISO 13485:2016
24.	Medical devices – application of risk management to medical devices	EN ISO 14971:2012
25.	European council directive concerning medical devices	MDD 93/42/EEC , 2007/47/EC
26.	Clean rooms and associated controlled environments- bio-contamination control- general principles and methods	EN ISO 14698-1:2003
27.	Clean rooms and associated controlled environments- bio-contamination control- evaluation and interpretation of bio-contamination	EN ISO 14698-2:2003

7. PACKAGING DETAILS and SPECIFICATIONS

7. OTHER DETAILS

Intended Use: Refer the instruction for use before the application.

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.

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.

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.

8. COMPLIANCE INFORMATION

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

9. ABBREVIATIONS

QMS – Quality Management System

GMDN – Global Medical Device Nomenclature

A.V. Fistula Needle – Arteriovenous Fistula Needle

MKP – Medical Kraft Paper

DISPOSAFE HEALTH AND LIFE CARE LTD.

(Authorized Signatory)