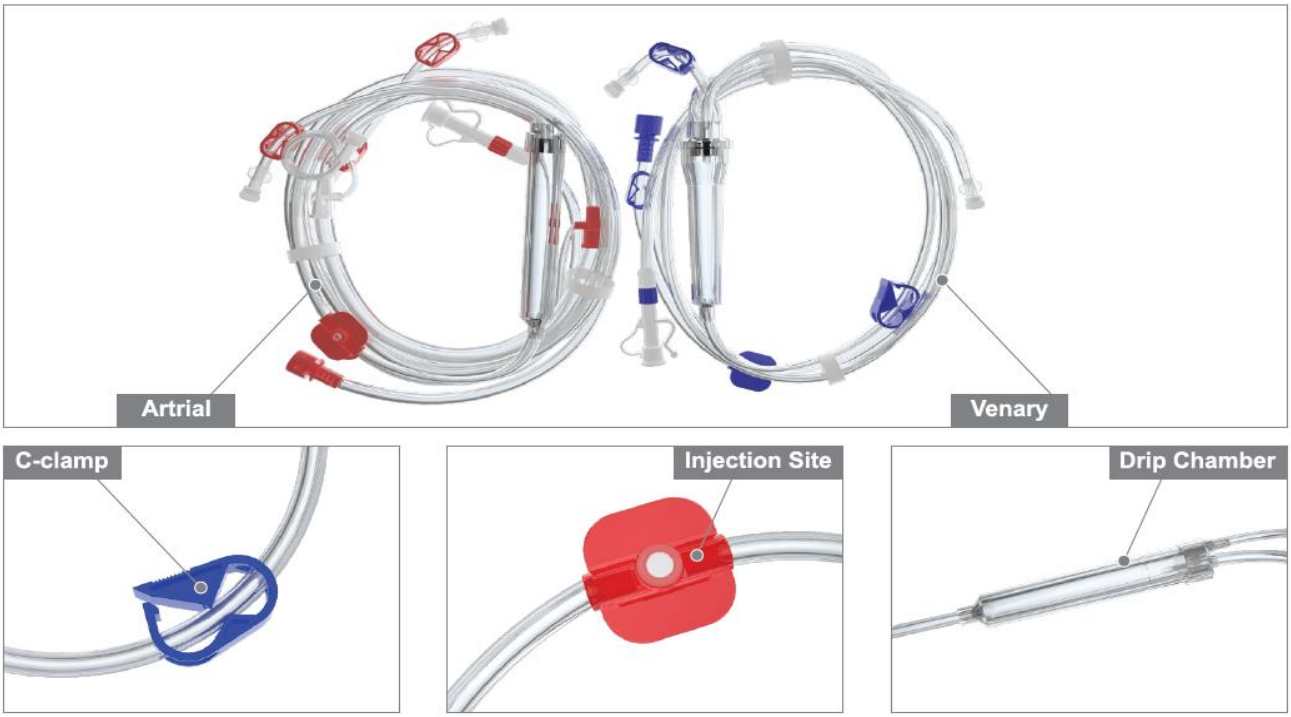


1. PRODUCT DESCRIPTION:

Bloodline tube set is made of plastic with a peristaltic pump connector tube which pumps the blood from patient vascular system to dialyzer machine, dialyzer filter and back to patient. It is a single use device. Duration of Use: Short term.

2. DEVICE CLASSIFICATION AND RULE:

The device is classified as Class IIa/Rule 2, medical device as per EU MDR 2017/745 Annexure VIII.

3. INTENDED USE:

Blood lines set are intended to transfer blood from patients vascular access system to the hemodialyzer through an arterial tubing and from the hemodialyzer to the patient vascular system via venous tubing. Material of Composition: PVC, ABS, PP, Isoprene, HDPE, POM.

4. PRODUCT FEATURES

Basic Product Features: High & reliable Disposafe's High quality, ensuring patients safety:

- Certified quality systems for development and production.
- Perfect compatibility to machine interfaces.
- Assuring highest safety and performance with most machines.
- Pump tube with high elasticity P.V.C material for long term use.
- Exclusive use of plasticizers with high Hemocompatibility and negligible cytotoxic reactions.
- Highly colour coded components. No additional clamp required.

- ETO sterilized with unique pre-conditioning and degassing process resulting in minimal residual ETO content.

➢ **Soft, Kink resistant, P.V.C Tubing:**
- Pump segment 9.8mm*6.6mm
- DEHP Free Plasticizer
- Priming Volume 150ml
- Well documented safety characteristics.

➢ **Large Shield Injection Ports:**
- Latex free septum injection site allow easy injection access.
- Latex finger protection shield for safe injection access
- Colour Coded

➢ **Ergonomic Patient Connector:**
- Optimal grip on rotational part allow ease of use.
- Easy to remove protective caps.
- Easily ensure secure connection.

➢ **Sterilization**: Sterilized through E.O. gas.
- Shelf life: 5 years.
- Storage Conditions: Store in Cool and Dry place, Keep away from Direct Sunlight.

5. CLASSIFICATION:

S.N	Product	GMDN Code	Classification
1	Blood Lines Set	34999	Rule-2, Class-IIa

6. CONSTRUCTION OF MATERIAL:

BLOOD LINE SET		
S. NO	**COMPONENT**	**MATERIAL USED**
1.	Dialyzer Connector	PVC Rigid (Polyvinyl chloride)
2.	PVC Tube	PVC Soft (Polyvinyl chloride)
3.	Pump Connector	PVC Soft (Polyvinyl chloride)
4.	Pump Segment Tube	PVC Soft (Polyvinyl chloride)
5.	Drip Chamber	PVC Soft (Polyvinyl chloride)
6.	Drip Chamber Cover	PVC Soft (Polyvinyl chloride)
7.	Injection Site	PVC Rigid (Polyvinyl chloride)
8.	Rotating Male Luer	PVC Rigid (Polyvinyl chloride)
9.	Locking Ring	PVC Rigid (Polyvinyl chloride)
10.	Recirculation Connector	PVC Rigid (Polyvinyl chloride)
11.	C-Clamp Big	POM (Polyoxymethylene)
12.	C-Clamp Mini	POM (Polyoxymethylene)
13.	Female Luer	PVC Rigid (Polyvinyl chloride)
14.	Threaded Stopper	HDPE (High-Density Polyethylene)

15.	Isoprene Rubber	Isoprene

7. HARMONIZED STANDARD:-

S. No.	Name Of Standard	Standards
1.	Transfusion equipment for medical use Part 5: Transfusion sets for single use with pressure infusion apparatus	ISO 1135-5:2025
2.	Small bore connectors for liquids and gases in healthcare - Part 7: Particular requirements for connectors for intravascular or subcutaneous use.	EN ISO 80369-7:2021
3.	Medical devices - Quality management systems - Requirements for regulatory purposes	EN ISO 13485:2016
4.	Medical Devices - Application for Risk Management to Medical Devices	EN ISO 14971:2019
5.	Biological evaluation of medical devices. Part 1: Evaluation and testing as part of the risk management process	EN ISO 10993-1:2020
6.	Biological evaluation of medical devices. Part 3: Genotoxicity, carcinogenicity and reproductive toxicity tests	ISO 10993-3:2015
7.	Biological Evaluation of Medical Devices - Part 4: Selection of Tests Relevant to Blood Interactions	EN ISO 10993-4:2017
8.	Evaluation of the biological effects of medical devices - Part 5: In vitro cytotoxicity tests.	ISO 10993-5:2009
9.	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residues.	EN ISO 10993-7:2008
10.	Evaluation of the biological effects of medical devices - Part 11: Systemic toxicity tests	EN ISO 10993-11:2018
11.	Biological evaluation of medical devices - Part 12: Sample preparation and control samples	EN ISO 10993-12:2021
12.	Symbols used on medical device labels in labeling and information provided.	EN ISO 15223-1:2023
13.	Sterilization of medical devices - Microbiological methods - Part 1: Determination of the microbial population on products	EN ISO 11737-1:2021
14.	European Union Medical Devices Regulation	MDR 2017/745
15.	Medical devices - Part - 1: Application of usability engineering to medical products.	IEC 62366-1:2015/Amd 1:2020
16.	Medical Devices - Aftermarket Surveillance for Manufacturers	ISO 20416:2020
17.	Sterilization of medical devices - Chemical indicator - Part 1 General requirements	EN ISO 11140-1:2015

18.	Medical devices-Post market Surveillance for manufacturer	ISO/TR 20416:2020
19.	Sterilization of health care products-Biological indicator-Part 1 General requirement	EN ISO 11138-1:2017
20.	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.	ASTM-F1980

8. Others 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.

9. COMPLIANCE INFORMATION:

Manufacturing Site 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

CE Marking: TUV-SUD Product Services