

Blood Transfusion Set

1. PRODUCT DESCRIPTION

Blood Transfusion set is used in delivering measured & regulated blood to patient. It is made up of cylindrical drip chamber with/without vent connected to a tube provided with filter to prevent passage of any clot into the patient. It is employed for intravascular, gravity-controlled transfusion of blood or blood element. Duration of Use: Short term. Material of Construction: PVC, Latex, ABS, PP, PC, SS.

2. DEVICE CLASSIFICATION AND RULE

The device is classified as Class IIa/Rule 7/2, medical device (classification as per MDR Annex II Section 1.1(f); Annex VIII)

Class-IIa, Rule-7 (With Needle) & Class-IIa, Rule-2 (Without Needle)

3. PRODUCT CHARACTERISTICS & INTENDED USE

Intended Purpose: Blood Transfusion Set is used to administer blood from a container (plastic bag or glass bottle) to a patient's vascular system.

Features:

- Sharp piercing spike for easy insertion in the Container.
- Blood Transfusion set with drop rate -20drops/ml.
- Transparent & flexible drip chamber.
- Kink resistant tube & transparent collapsible drip chamber with Blood filter.
- Sterile, individually packed
- Effective roller controller for consistent flow rate.

The product does not compromise with the clinical condition or the safety of patients.\

4. PRODUCT VARIANTS

Following variants are available for the products

S.No.	Product	Type	GMDN Code	Classification/ Rule
1	**Blood Transfusion Set**	Vented & Non-vented	35405	Class-IIa, Rule-7 (With Needle) & Class-IIa, Rule-2 (Without Needle)

5. MATERIAL OF CONSTRUCTION

S. No.	Component Description	Material used
1.	Spike	ABS (Acrylonitrile butadiene styrene)
2.	Spike cover	PP (Polypropylene)
3.	Drip chamber	PVC (Poly Vinyl Chloride)
4.	PVC Tube	PVC (Poly Vinyl Chloride)
5.	Roller	ABS (Acrylonitrile butadiene styrene)
6.	Clamp	ABS (Acrylonitrile butadiene styrene)
7.	Filter with mesh	Nylon
8.	Air vent cap	PVC (Poly Vinyl Chloride)
9.	Top Connector	ABS (Acrylonitrile butadiene styrene)
10.	Bottom connector	PP (Polypropylene)
11.	Micro Dripper	PVC (Poly Vinyl Chloride)
12.	Dripper S.S. Tube	SS 304 stainless steel
13.	Filter paper	Paper
14.	Hypodermic Needle Hub & cover	PP (Polypropylene)
15.	Hypodermic needle	SS 304 stainless steel
16.	Male luer lock	PC (Polycarbonate)
17.	Plain stopper	PP (Polypropylene)

6. PRODUCT SPECIFICATION:

Variant	Capacity	Packing Inner	Packing Outer
Vented	20 drop/ml	25	500
Non-Vented	20 drop/ml	25	500

7. REFERENCE COMPLIANCE STANDARD

S No.	Name of Standard	Number
	Blood Transfusion set	
1.	Transfusion equipment for medical use Part 4: Transfusion sets for single use, gravity feed	ISO 1135-4:2025
	General	
2.	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
3.	Clean Rooms And Associated Controlled Environments: Classification of air cleanliness by particle concentration	EN ISO 14644-1:2015
4.	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
5.	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
6.	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices	ISO 11135:2014/Amd 1:2018
7.	Sterilization of health care products - Biological indicators - Part 1: General requirements	EN ISO 11138-1:2017
8.	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products	EN ISO 11737-1:2018
9.	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems Amendment 1: Application of risk management	ISO 11607-1:2019/Amd 1:2023
10.	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes Amendment 1: Application of risk management	ISO 11607-2:2019/Amd 1:2023
11.	Biological evaluation of medical devices –part 1, Evaluation and testing within a risk management process	EN ISO 10993-1: 2020
12.	Biological evaluation of medical devices — Part 3: Tests for Genotoxicity, carcinogenicity and reproductive toxicity	EN ISO 10993-3:2014
13.	Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood	EN ISO 10993-4:2009
14.	Biological evaluation of medical devices — Part 5: Tests for in vitro	EN ISO 10993-5:2009

	cytotoxicity	
15.	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals	EN ISO 10993-7:2008
16.	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	EN ISO 10993-10:2021
17.	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	EN ISO 10993-11:2018
18.	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	EN ISO 10993-12:2021
19.	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances	EN ISO 10993-17:2023
20.	Clean rooms and associated controlled environments- bio-contamination control- general principles and methods	EN ISO 14698-1:2003
21.	Clean rooms and associated controlled environments- bio-contamination control- evaluation and interpretation of bio-contamination	EN ISO 14698-2:2003
22.	Medical devices -- Quality management systems -- Requirements for regulatory purposes	ISO 13485:2016
23.	Medical devices – application of risk management to medical devices	EN ISO 14971:2019
24.	European council directive concerning medical devices	MDR 2017/745

8. PACKAGING DETAILS and SPECIFICATIONS

ITEM	MATERIAL
Primary Packing	HM Pouch
Inner Carton	Kraft Pulp Paper
Master Carton	Kraft Pulp Paper

9. 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 (Particulate contamination, leakage, tensile strength, dimension of the closure-piercing device, determination of flow rate when using an air-inlet device, tubing, efficiency of the blood filter, drip chamber and drip tube, Flow rate of infusion fluid and injection site & sealing peel open force) 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.

10. 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 GmbH

GMDN: 35405