

1. PRODUCT DESCRIPTION

A scalp vein set is a specialized device used for drawing blood from a vein and giving medication or intravenous (I.V.) therapy into a vein. It consists of a very fine hypodermic needle, two flexible wings, flexible transparent tubing, and a connector. The connector is attached to another device i.e. to a vacuum tube or collection bag to draw blood, or to extension tubing from an infusion pump or I.V. bag to deliver medication and fluids. It is a single use device. Duration of Use: Short term. Material of Composition: PVC, SS, PP, HDPE, LDPE.

2. DEVICE CLASSIFICATION AND RULE

The device is classified as Class IIa/Rule 7, device as per EU MDR 2017/745 Annexure VIII.

3. INTENDED USE

Scalp vein set is used for Venipuncture to give medication or the collection of blood from a vein to obtain blood samples for tests. Scalp vein sets are commonly used to perform difficult venipuncture procedures.

4. PRODUCT VARIANTS

Following variants are available for the products

S.No.	Product		GMDN Code	Classification
1.	Scalp Vein Set	With Safety Feature & Without Safety Feature	34592	Rule-7, Class-IIa

5. MATERIAL OF CONSTRUCTION

S. No.	Component description	Material Used
1.	Wing Body	PVC Soft
2.	Needle Cover	PP
3.	Tube	PVC

4.	Vein Connector	PVC
5.	Needle	S.S

6. PRODUCT SPECIFICATION

Gauge	Needle Diameter (mm)	O.D	I.D	Length	Wing Colour
18G	1.2	2.6mm	1.5mm	30cm	Pink
19G	1.1				Cream
20G	0.9				Yellow
21G	0.8				Green
22G	0.7				Black
23G	0.66				Blue
24G	0.55				Purple
25G	0.50				Orange
26G	0.45				Brown
27G	0.40				Gray

7. REFERENCE COMPLIANCE STANDARD

S No.	Harmonized standards	Standard Number
1	Infusion equipment for medical use - Part -4: Infusions sets for single use, gravity feed	ISO 8536-4:2019
2	Sterile hypodermic Needle for Single use - Requirements & test methods	ISO 7864:2016
3	6% Luer- Small-bore connectors for liquids and gases in health care applications	EN ISO 80369-7:2021
4	Sampling Procedure For Inspection By attributes	ISO 2859-1 : 1999
5	Clean Rooms And Associated Controlled Environments: Classification of air cleanliness by particle concentration	EN ISO 14644-1:2015
6	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
7	Medical devices -- Symbols to be used with medical device labels, labeling and information to be supplied -- Part 1: General requirements	EN ISO 15223-1:2021
8	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/ and 1:2018
9	Sterilization of health care products-Biological indicators- Part 1: General requirements	EN ISO 11138-1:2017
10	Sterilization of health care products- Microbiological methods- Part 1: Determination of a population of	EN ISO 11737-1:2018

	microorganisms on products	
11	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	EN ISO 11607-1:2019
12	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	EN ISO 11607-2:2019
13	Sterilization of health care products- Biological indicators for ethylene oxide sterilization processes	EN ISO 11138-2:2017
14	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	EN ISO 10993-1:2020
15	Biological evaluation of medical devices — Part 3: Tests for Genotoxicity, carcinogenicity and reproductive toxicity	EN ISO 10993-3:2014
16	Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood	EN ISO 10993-4:2017
17	Biological evaluation of medical devices — Part 5: Tests for in vitro Cytotoxicity	EN ISO 10993-5:2009
18	Biological evaluation of medical devices -Part 6: Tests for local effects after implantation	EN ISO10993-6:2016
19	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals	EN ISO 10993-7:2008
20	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	EN ISO 10993-10:2021
21	Biological evaluation of medical devices - Part 11 : Tests for systemic toxicity	EN ISO 10993-11:2018
22	Biological evaluation of medical devices - Part 12 : Sample preparation and reference materials	EN ISO 10933-12:2021
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 14971:2019
25	The European Union Medical Device Regulations	MDR 2017/745
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
28	Intravascular catheters — Sterile and single-use catheters Part 1: General requirements	ISO 10555-1:2023
29	Intravascular catheters — Sterile and single-use catheters Part 5: Over-needle peripheral catheters	ISO 10555-5:2013

8. PACKAGING DETAILS AND SPECIFICATIONS

ITEM	MATERIAL
Individual Sterile Packing (Blister)	HM Pouch
Master Carton	3 Ply corrugation

9. OTHER DETAILS

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.

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

Manufacturer 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**,** TUV SUD Product Service GmbH

CE Marking: TUV SUD Product Service GmbH, EC Notified body No. 0123

GMDN Code: 34592

ABBREVIATIONS

QMS – Quality Management System

GMDN – Global Medical Device Nomenclature