DATA SHEET

Blood Bag

Digitally signed by Moraru Grigore
Date: 2023.11.15 10:59:31 EET
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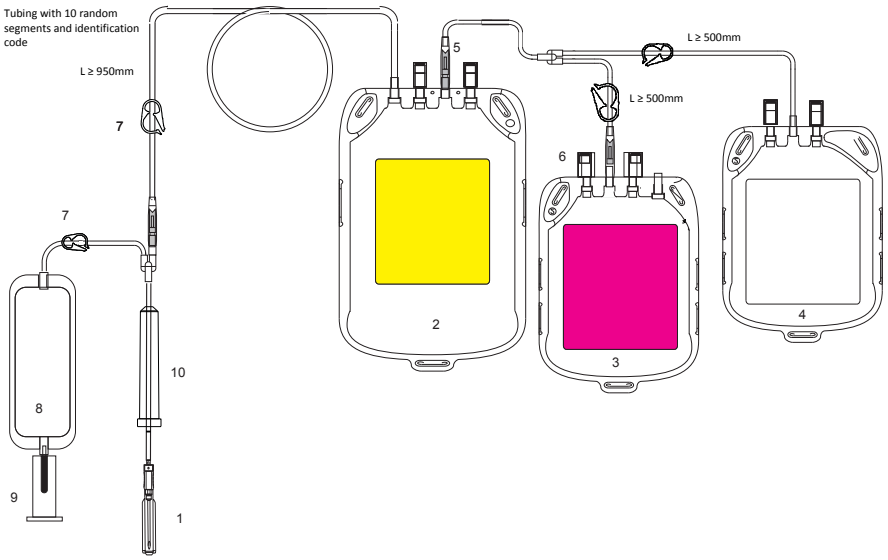
Location: Moldova

PRODUCT DESCRIPTION

Triple Blood Bag 450mL with CPDA-1 and SAG-M solution, with sampling device,For single use only.



ANTICOAGULANT SOLUTION

Prescription: Each 100ml CPDA-1 contains:

Citric Acid (anhydrous) 0.299g, Sodium Citrate (dihydrate) 2.63g, Monobasic Sodium Phosphate (monohydrate) 0.222g, Dextrose (monohydrate) 3. 19g, Adenine 0. 0275g, Water for injection to 100ml.

Prescription: Each 100ml SAG-M contains:

Sodium Chloride 0.877g, Adenine 0.0169g, Dextrose (monohydrate) 0.900g, Mannitol 0.525g, Water for injection to 100ml.

I. REGISTRATION REGULATIONS

1. **EC Registration Number**

CE 0197

Registration No.: HD 60139767 0001

EC Representative: Llins Service & Consulting GmbH (Obere Seegasse 34/2 69124 Heidelberg ,Germany)

2. **CE Scope:** Blood Bags
3. **Classification:** Class IIb
4. **Barcode Type**: ISBT128 or customized as request
5. **Language on labels:** English,Labels resistant up to -80°C and bar code

II. BAG CHARACTERISTICS

No.	Solution Type	Solution Volume	Final Solution Limit	Nominal Volume	Material
N·(2)	CPDA-1	63mL	63-68mL	450mL	PVC
N·(3)	-	-	-	400mL	PVC
N·(4)	SAG-M	100ml	100-108ml	400ml	PVC

III. COMPONENTS

No.	Specification
N·(5)	Breakaway cannula
N·(6)	Outlet ports and peel-off ports covers
N·(7)	Clamp
N·(8)	Sampling pouch
N·(9)	Vacuum tube holder
N·(10)	Needle stick protection device

IV. NEEDLE

N·(1) 16G blood collection needle with needle cap

V. STERILIZATION

Steam

VI. PACKAGING

1. **Individual Package:** PET/CPP compounded bag

2. **Over Package:** Aluminum pouch
   Qty per aluminum pouch: 3 blood bags

3. **Shipping Package:** Carton
   Qty per carton: 45 blood bags (15 aluminum pouches)

4. **Expiry Date:**
   Closed aluminum foil bag: 2 years
   Opened aluminum foil bag: 10 days

5. **Recommended storage conditions:**
   Preserve in carton box protected from light and store in a cool place, store between 1℃ to 30℃.

6. **Note:** Statements contained in this document are for reference only. For contractual information please refer to products labels.

VII. TEST PERFORMED ON PRODUCT

Tests are performed in accordance with internal standards and requirements of ISO 10993-1:2018, ISO 3826-1:2019, ISO 3826-2:2008, ISO 3826-3:2006, EP, USP etc., and are listed as below:

1. Needle: bevel, diameter, length, needle point, silicon coating, blue dot/line on bevel side, pull test, air leak test, re-capping test
2. Bag: integrity test, product configuration, dimension test, air content, pressure emptying test, filling speed, transparency, vapor Permeability, resistance to deformation and leakage, resistance to temperature variations, particulate contamination, solution volume, residue on ignition of PVC film.
3. Labelling: In accordance to ISO 3826-1:2019, labeling adherence, temper proof, printing quality, text conformity.
4. Bacterial endotoxins
5. Sterility
6. Solutions: Sodium diacid phosphate monohydrate, Sodium, Glucose Monohydrate, adenine, Total citrate (expressed as anhydrous citric acid), Mannitol, Sodium Chloride, pH, Subvisible particles, 5-hydroxymethylfurfural, Absorbance, Volume of solution.

VII. GENERAL MANUFACTURING PROCEDURE IN COMPLIANCE WITH

GMP, ISO 13485:2016, EC Directive 93/42/EEC Annex Ⅱ Article 3

IX. PRODUCT IN COMPLIANCE WITH

1. ISO 3826-1:2019 Plastics collapsible containers for human blood and blood components Part 1: Conventional containers
2. ISO 3826-2:2008 Plastics collapsible containers for human blood and blood components Part 2: Graphical symbols for use on labels and instruction leaflets
3. ISO 3826-3:2006 Plastics collapsible containers for human blood and blood components Part 3: Blood bag systems with integrated features
4. USP