



Pharmed Medical Industries



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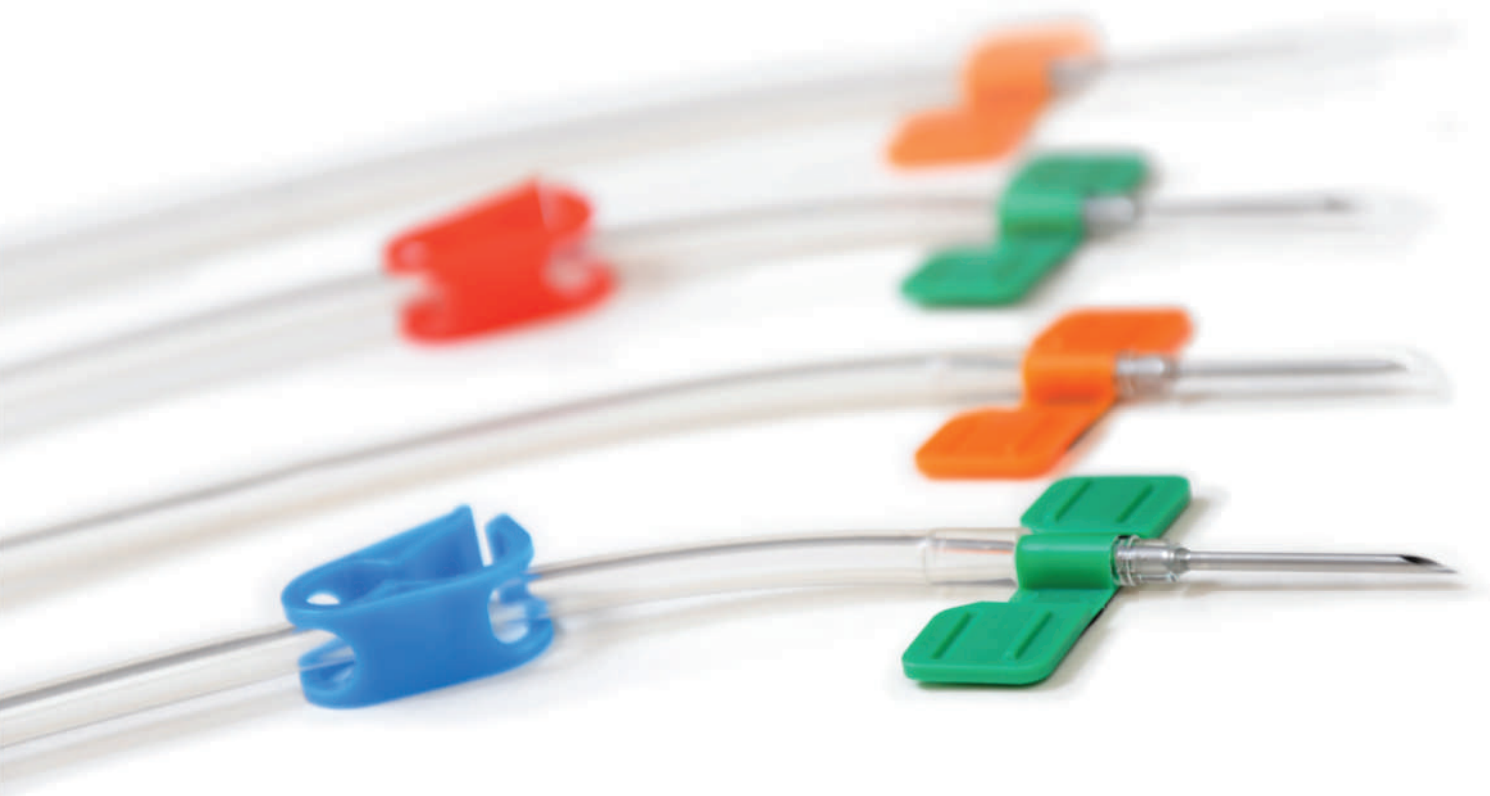
Pharmed Medical Industries have been established in 2012, as a member of ICD group, concerned with the production of dialysis disposables as well as the supply of dialysis related medications. Using both knowledge and know-how from the pioneering companies and applying the latest technologies, the company's activities are directed towards improving the quality of its products which are manufactured using high-grade raw material. Pharmed medical industries produces disposable dialysis products, including Sodium Bicarbonate powder (Bags and cartridges), different model blood line sets for adult and pediatric, Fistula Needle Set, Concentrated Hemodialysis Acidic Solution and strategic products such as Blood Bag and Phlebotomy Bag, Hemoconcentration Set for Adult and pediatric. The company has managed to obviate the requirements of quality management system according to EN ISO 13485. In addition, Most of Pharmed products have been certified by CE mark.



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Top quality raw materials, the highest standards of quality management systems based on EN ISO 13485 and PIC/S, CE requirements according to Directive 93/42/EEC and professional human resources are the backbone of our manufacturing policy. A robust R&D system is our golden bridge to the new horizons and constant developments ahead of us.





Fistula Needle Set

The fistula needle set plays a major role in alleviating patients' pain since it is in direct contact with patient body surface. Pharmed Medical Industries is a producer of fistula needle in the three different sizes: 16 ,15, and 17 G. Among the assets of fistula needle set are:

- Precise diagonal cutting and entirely smooth penetrating tip provides the best possible skin puncture and ensures a pain free needle injection with minimal skin traction
- Steady angle-free slant at the needle's tip
- A big oval back on the arterial needle which:
 - Maximizes the blood flow
 - Minimizes skin tissue damage
- An ultra-thin wall which:
 - Increases the blood flow
 - Minimizes skin tissue damage and pain at penetration
- Silicon coating for
 - Straight and smooth movement in the vessel
 - Enhanced and pain-free needle penetration
- Standard hardness level and color codes for arterial and venous clamps
- DEHP Free.
- Sterilized with ETO and Non-pyrogenic
- Certified with CE2195 Mark.



Product	Gauge	Product Code	Pieces/Packing	Wing Type	Wing Color	Safety Guard	Tube Length (mm)	Needle Length (mm)
Venous Fistula Needle (MC)	15 G	4218364	180	Rotating	Blue	No	150	25
Arterial Fistula Needle (MC)	15 G	4218366	180	Rotating	Blue	No	150	25
Venous Fistula Needle (MC)	16 G	4218342	180	Rotating	Green	No	150	25
Arterial Fistula Needle (MC)	16 G	4218340	180	Rotating	Green	No	150	25
Venous Fistula Needle (MC)	17 G	4218356	180	Rotating	Orange	No	150	25
Arterial Fistula Needle (MC)	17 G	4218354	180	Rotating	Orange	No	150	25
Fistula Needle Set (Venous & Arterial) MC	15 G	4218384	180	Rotating	Blue	No	150	25
Fistula Needle Set (Venous & Arterial) MC	16 G	4218302	180	Rotating	Green	No	150	25
Fistula Needle Set (Venous & Arterial) MC	17 G	4218359	180	Rotating	Orange	No	150	25





Blood Line Set

- In compliance with BS EN ISO 8637-2 standard requirements
- Made of medical grade raw material
- Made of transparent plastic material without cytotoxic reactions
- Follow ergonomic design principles and have simple but safe connections
- Segmental color coding
- Special geometric venous chamber design
- Sufficient color coded clamps
- Including clamp at heparin infusion site
- Having transducer protector
- Ability to measure fistula efficiency in standrad blood line Sets and pediatric AV- sets
- Arterial Blood pressure sensor, before the pump in standard Blood Line Set models SB, SG, SF.
- Having prime solution collection bag in the standard Blood Line Set models SB, SG, SF.
- Arterial Blood pressure sensor after and before the pump in standrad blood line set SB
- Sterilized with ETO and Non-pyrogenic
- CE2195 mark for Blood line Sets models SB, SU,SG, SF
- HDF Online AV-Set model with safe line, treatment Hemodiafiltration, suitable for the BBraun dialog⁺ HDF Online dialysis machine.
- Pediatric AV-Set does not contain DEHP phthalates.
- Pharmed Medical Industries Company is the first and the only manufacturer of Pediatric AV-Sets and HDF Online AV-Sets in Iran.



Blood Line Set specification						
Blood Line Set Model	Idnt.code	Dimension of Pump Segment			Volume of line blood pathway ($\pm\%10$) ml	
		Outer Diameter (mm)	Inner Diameter (mm)	Length (mm)	Venous line	Arterial line
Blood line Set, SU	4212200	9.8	6.5	380	62	82
	4212204					
Blood line Set, SF	4212222	9.8	6.5	380	65	82
Blood line Set, SF With drain bag	4212220				76	
Blood line Set, SB	4212212	9.8	6.5	340	74	82
Blood line Set, SB With drain bag	4212214					
Blood line Set, SG	4212216	12.0	8.0	380	62	90
Blood line Set, SG With drain bag	4212219					
Arterial line, SF	4212238	9.8	6.5	380	-	82
Venous line, SF	4212239	-	-		65	-
HDF Online AV-Set	4212234	12.0	8.0	340	70	90
Pediatric AV-Set	4212250	9.8	6.5	340	42	52

SF(For Fresenius machines and suitable for all machines)
 SG(for Gambro machines)
 SB(for BBraun machines)

SU and Pediatric AV-set suitable for all machines
 HDF(for BBraun dialog+ HDF online machines)



Sodium Bicarbonate Powder Bag and Cartridge

(RenaBag, RenaBag S, RenaCart, RenaCart B)

(NaHCO₃ , Eur.Ph, USP, BP)

Pharmed Medical Industries Company produce cartridges (RenaCart, RenaCart B) and bags (RenaBag, RenaBag S) containing Sodium Bicarbonate powder.

- Fully automatic manufacturing procedure to meet the latest world technologies
- Bicarbonate sodium powder in compliance with USP,BP and Eur. Ph standards and regulations
- RenaBag and RenaBag S containers are made of (PE/PA) raw material which secure the products' transparency, lightness, flexibility, and stock space friendliness.
- Biocompatible
- Effective filters and mesh in inlet and outlet to prevent damages to the machine caused by unsolved powder
- Preventing environmental pollution using a cap for Renacart's input and output port and using plastic packaging bag for Renacart B
- Suitable for up to 5 hours dialysis at 500 ml/min speed.
- CE2195 mark for RenaCart , RenaBag ,RenaBag S
- RenaCart B suitable for JMS dialysis machine



RenaBag

RenaBag S

RenaCart

RenaCart B

Product	Product Code	Bag / Cartridge material	Pieces/Packing	Dialysate Flow Rate
RenaBag 550g	4315205	PA/PE	16	500 ml/min
RenaBag 650g	4315210			
RenaBag 750g	4315230			
RenaBag S 550g	4315215			
RenaBag S 650g	4315220			
RenaBag S 750g	4315240			
RenaCart 550g	4315305	PP	10	
RenaCart 650g	4315310			
RenaCart 750g	4315315			
RenaCart B 550g	4315316	PE	10	
RenaCart B 650g	4315314			
RenaCart B 750g	4315318			



Concentrated Hemodialysis Acidic Solution

All hemodialysis concentrates are produced in compliance with BP, Eur. Ph, USP, and FDA regulations. The production of various types of hemodialysis concentrates allows for the most proper choice consistent with the patients' clinical conditions.

Concentrates are Non-sterile and Non-pyrogenic.

Acidic formula concentrates

- Acidic formula type I for hyperkalemia state
- Acidic formula type II for all dialysis patients
- Acidic formula type III for hypokalemia and CHF patients and those receiving digoxin medication





Product	Product Code	Packaging	Pieces/Packing	Volume (liter)
Acidic Solution I	4316205	Gallon	2	5
Acidic Solution II	4316210	Gallon	2	5
Acidic Solution III	4316215	Gallon	2	5





Blood Bags

The production of various types of blood bags was initiated in Pharmed Medical Industries since 2014 following broad expert and technical feasibility studies. Building upon the attempts made by the research and development complex and the technical knowledge transmission of leading manufacturers in the world, the company has fulfilled its desired objective to design Blood Bags capable of collecting, retaining, transfusing, separating, and injecting blood and its components. Being a critical medical product, Pharmed Company's Blood Bags are produced in conformity with BS EN ISO 3826-1 and BS EN ISO 3826-3 standards in absolutely hygienic and safe conditions. Regarding applicability, they are closely compatible with the blood transfer set; moreover, they are sterile, non-toxic, free from pyrogenic material, made of flexible PVC, and contain anticoagulant. Also there are small side bags attached to them which allow for the hygienic separation of platelets from the blood.

Depending on the usage and needs, Blood Bags are produced in single, double, triple, quadruple in 350 and 450 collection volumes. All various types of blood bags produced in this company come with sampling bag and needle safety guard.



Description

Blood Bags are disposable and presented in two anticoagulant types:

1. Sterile Blood Bag with CPDA – 1 anticoagulant
2. Sterile Blood Bag with CPD

Sterilization Method

- Steam Sterilization

In Compliance with

- BS EN ISO 3826
- BP, Eur. Ph, and USP

CE 2195
SZUTEST





General Specifications

Components and Raw Material

Anticoagulant Solution

CPD and CPDA -1 anticoagulants make blood storage possible for up to 21 and 35 days, respectively.

Plastic and Polymeric Material

Collection and transfer bags are made of PVC with DEHP and platelet bags have TOTM plasticizers. Platelet bags with adequate gas permeability which provides platelet storage up to 5 days. Bags are embossed to avoid sticking to each other during the autoclave process; rounded edges reduce loss of blood components in the course of transferring. All these material are made of transparent medical grade and particle-free raw materials to facilitate monitoring during the course of transferring.

Needle and Safety Guard

- Ultra-thin walled silicon-coated needle
- Minimal stress and pain to the donor
- Safety guard that improves safety of the operator and the treatment process by eliminating needle sticks



Sampling Bag with Accessories

The sampling bag is used to collect blood flow from the donor and prevents from contamination caused by indigenous bacteria on the skin. maximum 35 ml blood volume could be transfused by this sampling bag. Moreover, the blood collection tube facilitates the sampling process by using vacuum tubes.



Labeling and Packaging

Pharmed Medical Industries is the registered member of the International Council for Commonality in Blood Banking Automation (ICCBBA) to use the International Society of Blood Transfusion's (ISBT) barcode for systematic identification and tracing.

Label Specifications

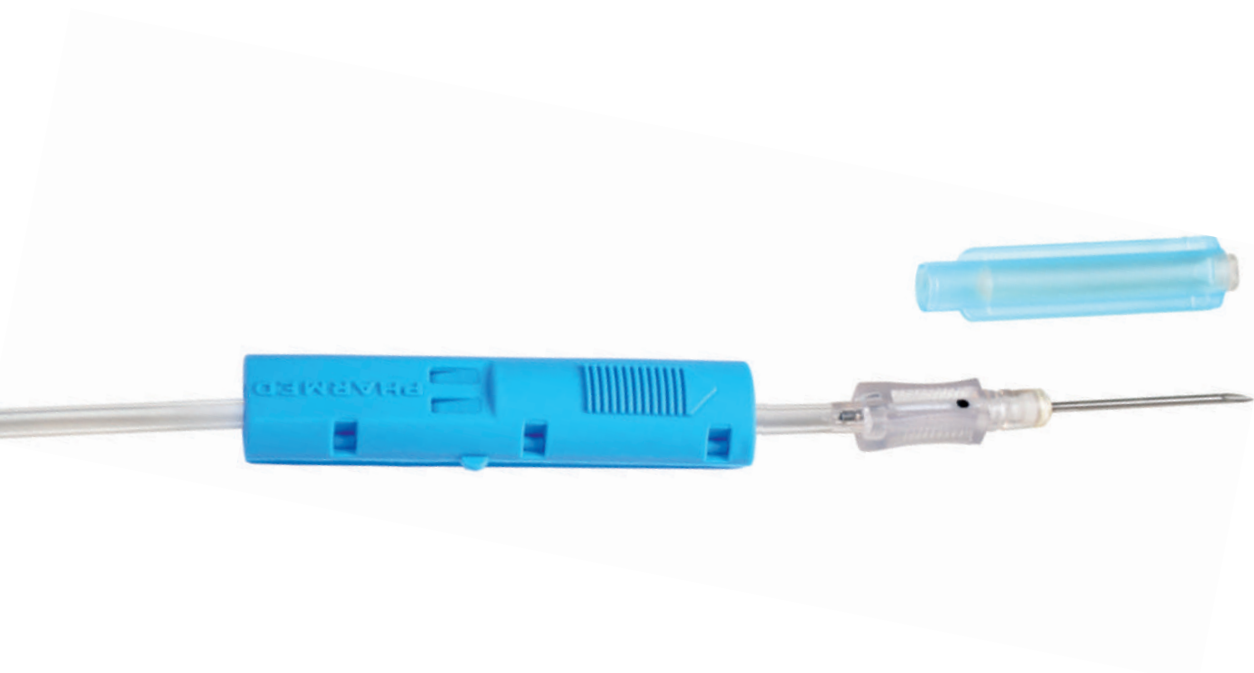
- Easy to write on
- Tamper evident
- Resistance against tear, water, and centrifugation
- Legible, Clear, and easy to understand
- Barcoded in compliance with ISBT 128

Packaging

- Primary packaging: PP/PET
- Secondary packaging: Al/PET:
Reduce moisture loss , Protection against sunlight.
- Final packaging : carton

Configuration	Product Code	Collection vol.	CPD vol.
Single Blood Bag	4512240	450 ml	63 ml
Double Blood Bag	4512265	450 ml	63 ml
Triple Blood Bag	4512230	450 ml	63 ml

Configuration	Product Code	Collection vol.	CPDA-1 vol.
Single Blood Bag	4512250	450 ml	63 ml
Double Blood Bag	4512260	450 ml	63 ml
Triple Blood Bag	4512220	450 ml	63 ml
Quardruple Blood Bag	4512280	450 ml	63 ml



Phlebotomy Bag

The Phlebotomy Bag is used in treatment of certain diseases in which the hemoglobin rises abnormally or red blood cells number exceeds the upper normal level, such as hemochromatosis and polycythemia.

- Collection of inoperable blood
- Non-toxic and Non-pyrogenic
- Without need to vacuum
- Use of medical grade polymers in all parts
- Medical grade PVC in all segments
- Clamp for blocking blood flow in the tube
- Sharp and smooth Silicon- coated needle for pain relief
- Safety guard for cutting prevention prior after and before blood transfusion
- Apposite Packaging in compliance according to EN ISO 3826 standard
- Include 35 cc pure water in autoclave sterilized phlebotomy bag (with CE2195 mark)
- Gauge 16 Needles, are used in all Phlebotomy Bags.



Product	Product Code	Sterile method	Packing
Phlebotomy bag 350 ml	4512320	Steam (Autoclave)	Film/Film
Phlebotomy bag 450 ml	4512310	Steam (Autoclave)	Film/Film
Phlebotomy bag WL - 350 ml	4512330	ETO	Film/Paper
Phlebotomy bag WL - 450 ml	4512340	ETO	Film/Paper

Hemoconcentration Set

Concentrating Diluted Blood in Open Cardiac Surgical Procedures

Hemoconcentrator is a medical disposable which is used in open cardiac surgical procedures. Using oxygenators and artificial hearts during the surgical procedure lets a great amount of liquid into the patients' body. These extra liquids are extruded by the use of Ultrafiltration and Convection methods and hemoconcentrators instantly after the surgery. The main part of this product is the hemofilter that is a hollow-fiber semipermeable membrane including tiny pores on its surface through which globules, proteins, and globulins cannot pass; however, it is permeable to water, keratin, urine, chloride, and glucose. This product is disposable, non-pyrogenic and sterilized with ethylene oxide gas.



Type of Hemoconcentration	UF-coefficient (ml/mmHg.h)	Blood priming Volume (ml)	Surface area (m ²)	
Hemoconcentration Set, 160 HF		Idnt.Code : 4222350		Use for Adult
Hemoconcentrator, PES 160 HF	62	89	1.6	
Hemoconcentrator, PS 160 HF	55	86	1.6	
Hemoconcentration Set, 100 HF		Idnt.Code : 4222355		Use for Pediatric
Hemoconcentrator, PS 100 HF	32	59	1.0	

Line	Volume of blood Line pathway (ml)
Arterial	25± 10%
Venous	

Medical Device Sterilization Services

Pharmed Medical Industries, using scientific knowledge and appropriate equipment is able to provide Medical Device Sterilization Services to its customers using sterile method with ethylene oxide gas and steam.

According to the customer's request and type of product, sterilization services can be performed with ethylene oxide gas with validated method based on the latest edition of the BS EN ISO 11135 standard or steam sterile based on the latest edition of the BS EN ISO 17665-1 standard.

Pharmed company has EN ISO 13485 certificate to provide sterilization services to customers and committed to implement sterilization services standards and provides all necessary quality documents to customers.





Sales and Customer Care Services

Sales, distribution, and customer care services are exclusively carried out by Medway Teb Pouyan Company.

Customer care service department is available 24 hours 7 days a week.

Customer satisfaction is our number one priority.

All complaints and suggestions shall be taken care of in the earliest time span.

Recommendations would be of great benefit for improving the products' quality.



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