SZUTEST

Certificate Number: 2195-MED-2010101

Product specifications:

Product Name	Model Name
Non-Sterile Sodium Bicarbonate Powder Bag and Cartridge	RenaBag 550g
	RenaBag 650g
	RenaBag 750g
	RenaBag S 550g
	RenaBag S 650g
	RenaBag S 750g
	RenaCart 550g
	RenaCart 650g
	RenaCart 750g
Sterile Blood Line Set	Blood Line Set, SU
	Blood Line Set, SF
	Blood Line Set, SG
	Blood Line Set, SB
Sterile Blood Bag	Single Blood Bag CPD
	Double Blood Bag CPD
	Triple Blood Bag CPD
	Quadruple Blood Bag CPD
	Single Blood Bag CPDA-1
	Double Blood Bag CPDA-1
	Triple Blood Bag CPDA-1
	Quadruple Blood Bag CPDA-1
	Phlebotomy Bag 450
	Phlebotomy Bag 350
Sterile Fistula Needle Set	Fistula Needle set (Venous & Arterial) (MC) 15G
	Venous Fistula Needle (MC) 15G
	Arterial Fistula Needle (MC) 15G
	Fistula Needle set (Venous & Arterial) (MC) 16G
	Venous Fistula Needle (MC) 16G
	Arterial Fistula Needle (MC) 16G
	Fistula Needle set (Venous & Arterial) (MC) 17G
	Venous Fistula Needle (MC) 17G
	Arterial Fistula Needle (MC) 17G

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.
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SZUTEST

EC CERTIFICATE

According to Annex II of the Directive 93/42/EEC on Medical Devices

Full Quality Assurance System

Certificate Number: 2195-MED-2010101

Manufacturer: **Pharmed Medical Industries**

Head Office: No. 44, 5th Floor, Saadat Abad Street, Tehran, P.O Box.: 1998898638, IRAN

Factory: 2nd Bustan, West Hafez Blvd., Eshtehard Industrial Zone, P.O Box.: 31881-14366, IRAN

Product(s):

1. **Non-Sterile Sodium Bicarbonate Powder Bag and Cartridge**
2. **Sterile Blood Line Set**
3. **Sterile Blood Bag**
4. **Sterile Fistula Needle Set**

Model(s): Product specifications are stated on the following page(s).

Reference Report No: MM0802-P001-R01, MM0802-P001-R02, MM0802-P001-R03, MM0802-P001-R04, MM0802-P001-R05

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s). For class I devices with sterile conditions the quality management system evaluation is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with measuring function the quality management system evaluation is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements.

This EC certificate is valid till 2024-05-26.

Issue Date: 2020-04-10
Revision No.: 01 Rev.
Revision Date: 2021-04-26

Rukiye BALKAN
Deputy General Manager

This version of certificate has come into force on 23.03.2017. 1/2. 2195-MED-2010101 Rev.01

FR.MED.34 R:05