

EC CERTIFICATE

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

Full Quality Assurance System

Certificate Number: 2195-MED-2009102

Manufacturer: Meditechsys Co.
Head Office: No. 44, 5th Floor, Saadat Abad Street, Tehran, 1998836795 and 1998836794, IRAN
Factory: 3rd Tangestan, West Hafez Blvd., Estehard Industrial Zone IRAN

Product(s): Hollow Fiber Haemodialyzer

Model(s):
1. Polysulfone Hollow Fiber Haemodialyzer (High Flow and Low Flux)
2. Polyethersulfone Hollow Fiber Haemodialyzer (High Flow and Low Flux)

Reference Report No: MM0801-P001-R01, MM0801-P001-R02

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: 2020-03-31



Rukiye BALKAN
Deputy General Manager

SZUTEST

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Product specification:

1. Ethylene Oxide Sterilized Haemodialyzers

Product Name	Content	Model Name
Low Flux Hollow Fiber Haemodialyzer	Polysulfone	PS 10 LF, PS 13 LF, PS 16 LF, PS 18 LF, PS 20 LF
	Polyethersulfone	PES 10 LF, PES 13 LF, PES 16 LF, PES 18 LF, PES 20 LF
High Flux Hollow Fiber Haemodialyzer	Polysulfone	PS 100 HF, PS 130 HF, PS 160 HF, PS 180 HF, PS 200 HF
	Polyethersulfone	PES 130 HF, PES 160 HF, PES 180 HF, PES 200 HF

2. Gamma Sterilized Haemodialyzers

Product Name	Content	Model Name
Low Flux Hollow Fiber Haemodialyzer	Polysulfone	PSR 10 LF, PSR 13 LF, PSR 16 LF, PSR 18 LF, PSR 20 LF
	Polyethersulfone	PESR 10 LF, PESR 13 LF, PESR 16 LF, PESR 18 LF, PESR 20 LF
High Flux Hollow Fiber Haemodialyzer	Polysulfone	PSR 100 HF, PSR 130 HF, PSR 160 HF, PSR 180 HF, PSR 200 HF
	Polyethersulfone	PESR 130 HF, PESR 160 HF, PESR 180 HF, PESR 200 HF

