USP Class VI

Industry

For medical and packaging equipment for the pharmaceutical industry we produce reliable, safe and biocompatible products.
The non-toxic properties of PTFE – even at high operating temperatures – combined with its self-lubrication capacity and chemical inertia, make it suitable for this specific sector.

Certification Details

The U.S. Pharmacopeial Convention (USP) aims to create standards for medications, food ingredients, dietary supplements and healthcare technologies. The USP publishes bio compatibility protocols for plastics and polymers used in medical devices or surgical equipment, that may come in contact with human tissue.
The tests to obtain the USP Class VI consist of an:

- in vitro Cytotoxicity-elution test
- in vivo Intracutaneous test
- in vivo Systemic injection test
- in vivo Implantation test

Tests

TEST	EXTRACTS	USP CLASS					
		I	II	III	IV	V	VI
Systemic injection test - injection in test model 1	Sodium chloride (intravenous)	x	x	x	x	x	x
Intracutaneous test - injection in test model 2	Alcohol saline (intravenous)		x	x	x	x	x
Implantation test - strips implanted in test model 2	Polyethylene glycol (intraperitoneal)			x		x	x
	Vegetable oil (intraperitoneal)			x	x	x	x
	Sodium chloride (intravenous)	x	x	x	x	x	x
	Alcohol saline (intravenous)		x	x	x	x	x
	Polyethilene glycol (intraperitoneal)					x	x
	Vegetable oil (intraperitoneal)				x	x	x
	None				x		x

Certified Materials

- fluteck™ P 2000
- fluteck™ P 3000

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