USP VI 级

行业

对于医药行业的医疗和包装设备，我们生产可靠、安全且具有生物相容性的产品。
PTFE 具有无毒特性（即使在高工作温度下也无毒），还具备自润滑能力和化学惰性，因而适用于这一特定领域。

认证详情

美国药典公约 (USP) 旨在为药物、食品配料、膳食补充剂和医疗保健技术制定标准。USP 公布了医疗器械或手术设备中使用的塑料和聚合物的生物相容性协议，这些塑料和聚合物可能会与人体组织接触。要获得 USP VI 级认证，需要进行的试验包括：

- 体外细胞毒性洗脱试验
- 体内皮内试验
- 体内全身注射试验
- 体内植入试验

试验

试验	提取物	USP 级别					
		I	II	III	IV	V	VI
全身注射试验-试验模型 1 中注射	氯化钠（静脉注射）	x	x	x	x	x	x
皮内试验-试验模型 2 中注射	酒精盐水（静脉注射）		x	x	x	x	x
植入试验-试验模型 2 中植入板条	聚乙二醇（腹腔注射）			x		x	x
	植物油（腹腔注射）			x	x	x	x
	氯化钠（静脉注射）	x	x	x	x	x	x
	酒精盐水（静脉注射）		x	x	x	x	x
	聚乙二醇（腹腔注射					x	x
	植物油（腹腔注射）				x	x	x
	无				x		x

获得认证的材料

- fluteck™ P 2000
- fluteck™ P 3000

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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

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