ISO 10993

行业

对于医药行业的医疗和包装设备，我们生产可靠、安全的生物相容产品。
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

ISO-10993 是使用全身毒性和皮内反应性测试的标准。其还包括额外的细胞毒性、遗传毒性、慢性毒性和血液相容性测试，以及更多涉及的全身毒性测试。
其根据身体接触的性质和持续时间对医疗器械进行分类。
ISO-10993 测试之所以要求较高，是因为其主要用于永久或半永久植入患者体内的医疗器械。
对于不打算植入或与患者接触时间较短的器械，ISO-10993 测试的必要性没那么强，但适用范围会更广

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试验

医疗器械分类 按生物效应

身体接触的性质			细胞毒性	致敏性	刺激性或皮内反应性	全身毒性（急性	亚慢性毒性（亚急性）	遗传毒性	植入	血液相容性
分类	接触	接触持续时间 A – 短期（≤24 小时） B – 长期（>24 小时至 30 天） C – 永久（>30 天）								
表面器械	皮肤	A	X*	X	X					
		B	X	X	X					
		C	X	X	X					
	黏膜	A	X	X	X					
		B	X	X	X					
		C	X	X	X		X	X		
	破裂或受损表面	A	X	X	X					
		B	X	X	X					
		C	X	X	X		X	X		
外部接入器械	血液间接路径	A	X	X	X	X				X
		B	X	X	X	X				X
		C	X	X		X	X	X		X
	组织/骨/牙本质	A	X	X	X					
		B	X	X	X	X	X	X	X	
		C	X	X	X	X	X	X	X	
	循环血液	A	X	X	X	X				X
		B	X	X	X	X	X	X	X	X
		C	X	X	X	X	X	X	X	X
植入器械	组织/骨	A	X	X	X					
		B	X	X	X	X	X	X	X	
		C	X	X	X	X	X	X	X	
	血液	A	X	X	X	X	X		X	X
		B	X	X	X	X	X	X	X	X
		C	X	X	X	X	X	X	X	X

* 叉号表示基于风险分析的生物安全评估所需的数据终点。如果现有数据足够，则无需进行额外测试。

获得认证的材料

- fluteck™ P 2000

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ISO 10993

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

ISO-10993 is a standard, that use systemic toxicity and intracutaneous reactivity testing. It also includes additional cytotoxicity, genotoxicity, chronic toxicity, and hemocompatibility tests, as well as more involved systemic toxicity testing.
It categorizes medical devices according to nature and duration of body contact
The additional intensity of ISO-10993 testing is due to it primarily being required for medical devices that will be permanently or semi-permanently implanted into a patient.
For devices that are not intended to be implanted or will have limited contact with patients, ISO-10993 testing may be more extensive than necessary.

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Tests

MEDICAL DEVICE CATEGORIZATION BY BIOLOGICAL EFFECT

Nature of body contact			Cytotoxicity	Sensitization	Irritation or intracutanous reactivity	Systemic toxicity (acute)	Subchronic toxicity (subacute)	Genotoxicity	Implantation	Haemocompatibility
Category	**Contact**	**Contact duration A - limited (≤24 h) B - prolonged (>24 h to 30 d) C - permanent (>30 d)**								
Surface device	Skin	A	X[a]	X	X					
		B	X	X	X					
		C	X	X	X					
	Mucosal membrane	A	X	X	X					
		B	X	X	X					
		C	X	X	X		X	X		
	Breached or compromised surface	A	X	X	X					
		B	X	X	X					
		C	X	X	X		X	X		
External communicating device	Blood pathm indirect	A	X	X	X	X				X
		B	X	X	X	X				X
		C	X	X		X	X	X		X
	Tissue/bone/dentln	A	X	X	X					
		B	X	X	X	X	X	X	X	
		C	X	X	X	X	X	X	X	
	Circulating blood	A	X	X	X	X				X
		B	X	X	X	X	X	X	X	X
		C	X	X	X	X	X	X	X	X
Implant device	Tissue/bone	A	X	X	X					
		B	X	X	X	X	X	X	X	
		C	X	X	X	X	X	X	X	
	Blood	A	X	X	X	X	X		X	X
		B	X	X	X	X	X	X	X	X
		C	X	X	X	X	X	X	X	X

* The crosses indicate data endpoints that can be necessary for a biological safety evaluation, based on a risk analysis. Where existing data are adequate, additional testing is not required.

Certified Materials

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