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

- fluteck™ P 2000

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