

# TECHNICAL DATA SHEET

## fluteck™ P 2000

### PTFE Premium Grade Medical Grade

#### Product Description.

fluteck™ P 2000 PTFE Premium Grade-USP Class VI is a high tech Virgin PTFE for Ram Extrusion, Compression and Isostatic moulding, classified as medical grade according to the standard USP VI (50° C -122° F and 121° C – 250° F) and ISO 10993-1:2009.

#### Product Properties:

- Very good mechanical properties
- Exceptional temperature resistance
- High limiting oxygen index
- UV resistance
- Extremely non-adhesive
- Excellent chemical resistance.
- Excellent electrical insulating properties
- Reduced friction & wear; Low friction behaviour
- Suitable for food contact
- High degree of hydrophobicity

	Property	Method	Units	Specification
Physical	Color	-	-	White
	Specific gravity	ASTM D792	g/cm <sup>3</sup>	2,130 – 2,190
	Water absorption	ASTM D570	%	0,01
	Flamability	UL 94		V-0
Mechanical	Tensile strength	ASTM D4894	MPa	≥ 25
	Elongation	ASTM D4894	%	≥ 280
	Hardness	ASTM D2240	Shore D	≥ 54
	Ball Hardness	ASTM D785	MPa	≥ 23
	Compression strength at 1% deformation	ASTM D695	MPa	≥ 4
	Deformation under load (140 Kg/cm <sup>2</sup> for 24 hrs. At 23°C)	ASTM D621	%	10 – 13
	Permanent deformation (after 24 hrs. Relaxation at 23°C)	ASTM D621	%	6 – 7,5
	Coefficient of static friction	ASTM D1894		0,08 – 0,10
	Coefficient of dynamic friction	ASTM D1894		0,06 – 0,08
	Wearfactor K	ASTM D3702		2.900
	Wear coefficient		cm <sup>3</sup> min 10 <sup>-8</sup> Kg m h	20000 - 25000
Thermal	Thermal conductivity	ASTM C177	W/m·K	0,34
	Coefficient of linear thermal expansion From 25 to 100 °C	ASTM D696	10 <sup>-5</sup> / °C	12 - 15
Electrical	Dielectric strength	ASTM D149	kV/mm	≥ 30
	Volume resistivity	ASTM D257	Ohm·cm	10 <sup>18</sup>
	Surfaceresistivity	ASTM D257	Ohm	10 <sup>17</sup>

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#### Typical properties.

fluteck™ P 2000 is a PTFE Premium Grade preferred for parts and components requiring very good mechanical properties.

fluteck™ P 2000 offers an excellent combination of properties typical of the fluoropolymer resins:

- Service Temperature: fluteck™ P 2000 offers excellent resistance to continuous service temperatures – working conditions from -100° C (-148° F) up to 250° C (482° F) and, for limited periods, even to higher temperatures; Product's low temperature resistance allows satisfactory performance down to -200° C (-328° F).
- Chemical resistance: fluteck™ P 2000 offers high inertness towards nearly all known chemicals. Only attacked elemental alkali metals, chlorine trifluoride and elemental fluorine at high temperature and pressures might affect properties.
- Solvents resistance: fluteck™ P 2000 offers insoluble properties in all solvents up to temperatures as high as 300° C (572° F). Certain highly fluorinated oils only swell and dissolve PTFE at temperatures close to the crystalline melting point.
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#### Typical Application.

fluteck™ P 2000 PTFE Premium Grade offers useful properties in various applications such as chemical resistance, thermal stability, cryogenic properties, low coefficient of friction, low surface energy, low dielectric constant, high volume and surface resistivity, and flame resistance.

These properties allow the application of fluteck™ P 2000 PTFE Premium Grade in several fields such as Chemical, Electrical and Electronic, Petrochemical, Automotive, Mechanical, Medical, Aeronautics, Semiconductor and Food industry.

#### Statement on suitability for contact with foodstuff.

FDA Approved US Regulation

- Code of Federal regulation 21 CFR Ch.1; section 177.1550 Perfluorocarbon Resins of the Food and Drug Administration/US.

EU Regulation

- EU 1935/2004 - 10/2011 on plastic materials and articles to come in contact with food.

#### US Pharmacopeia (USP) Class VI

The United States Pharmacopeia (USP) is the non-government organization that promotes the public health by establishing state-of-the-art standards to ensure the quality of medicines and other health care technologies.

Whilst this organization is concerned with the pharmaceutical and bio-technology industries, many manufacturers of hygienic equipment will be designing multipurpose designs that may be used in a range of different industry sectors.

Standards are published in the US Pharmacopeia and the National Formulary (USP NF). Compliance to USP Class VI is often requested by end users. Testing for compliance involves an assessment of the effects of the material, and extractable, on tissue.

Two types of biological reactivity test are applicable to elastomers, plastics and polymeric materials; Chapter <87> involves **in vitro** testing and Chapter <88> involves **in vivo** testing.

- fluteck™ P 2000 is USP Class VI (50° C - 122° F and 121° C – 250° F ) approved Report N° 2009/928 SAM and S-2014-03447 SAMi.

#### ISO 10993-Biocompatibility

According to the harmonized standard EN ISO 10993-1:2009, the biological evaluation of any material or medical device intended for use in human is a structured biological evaluation programme in which the choice of tests shall take into account the chemical composition of material, including the conditions of exposure as well as the nature, degree, frequency and duration of exposure of the medical device or its constituents to the body, enabling the categorization of devices to facilitate the selection of the appropriate tests. As described in ISO 10993-1:2009, a medical device shall be categorized according to the nature and duration of body contact to facilitate identifications of appropriate data sets.

fluteck™ P 2000 isn't a medical device but it's a raw material that could be used for fabrication of a medical device. The tested fluteck™ P 2000 was subjected to biological evaluation according to ISO 10993 series. The following results were obtained:

- Cytotoxicity: according ISO 10993-5:2009, the tested item fluteck™ P 2000 must be considered **NOT CYTOTOXIC** (Report S-2014-03448 SAMi)
- Skin Irritation: according ISO 10993-10:2010, the tested item fluteck™ P 2000 must be considered **NOT IRRITANT** (Report S-2014-03449 SAMi)
- Intracutaneous reactivity: according ISO 10993-10:2010, fluteck™ P 2000 **SATISFIES** the requirements of the test (Report S-2014-03450 SAMi)
- Acute Systemic Toxicity: according ISO 10993-11:2006, fluteck™ P 2000 **DON'T CAUSE** toxic symptoms and **SATISFIES** the requirements of the test (Report S-2014-03452 SAMi)
- Sensitisation: according ISO 10993-10:2010, the tested item fluteck™ P 2000 must be considered **NOT SENSITIZING** (Report S-2014-03451 SAMi)

#### Storage and Handling.

fluteck™ P 2000 PTFE Premium Grade can be stored for a long period of life and is exceptionally resistant to aging and weather conditions up to 10 years. Specific aging tests carried out on sample exposed to aging and atmospheric conditions, showed no changes in weight and volume.

In case of semi-finished products, before processing or before the machining, it is advisable to store the material for 24 hours in the production area, preferable in a clean and dry place at a temperature of less than 25°C (77°F), preferably between 21-25°C (70-77°F). This is very important when room temperature is low; in such cases the material should be conditioned up to 72 hours in the production area in the recommended temperature range.

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#### Safety instruction.

Follow the normal precautions observed with all fluoropolymer materials.

Please consult the Material Safety Data Sheet and Product Label for information regarding the safe handling of the material. By following all precautions and safety measures, processing, machining, and using these products poses no known health risks. General handling and processing precautions include: 1) Process only in well-ventilated areas. 2) Do not smoke in working areas. 3) Avoid eye contact. 4) Avoid mouth contact. 5) If skin comes into contact with these products during handling, wash with soap and water afterwards. 6) Avoid contact with hot fluoropolymers.

The user must verify that the finished parts, made out of the semi-finished product, are technically suitable for the requested application. The user must also verify that the finished item may not cause any modification to the organoleptic properties of the foodstuff and that the item's technological fitness it is assigned to may be guaranteed.

For each foreign country market, where the articles are introduced into, it is user's responsibility to verify whether both material than articles comply with the applicable laws and regulations.

#### Delivery format.

fluteck™ P 1000 PTFE Premium Grade is supplied in the following shapes and formats:

Semi-finished products: rods, tubes, sheets, tapes, strips. Shapes and sizes as per fluorseals General Size List and/as per customer request.

Machined parts: Shapes and sizes as per customer request.

**Note:** The information contained in this technical data sheet have been collected and ranked on technical data coming from reliable statistic series gathered in the field over the years. All information are intended only as general guidelines for use at user discretion. fluorseals do not guarantee any specific result and do not assume any liability in connection with the use of the products in the described application. None of the information included in this document is to be taken as a licence to operate under, or recommendations to infringe any existing patents. Before the use, the product has to be sampled and tested in the specific application and in the field of use at working condition in order to be approved by the us

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