

Zeniva® ZA-500

聚醚醚酮

Solvay Specialty Polymers

Technical Data

产品说明

Zeniva® ZA-500 is a grade of polyetheretherketone (PEEK) offered for use in implantable devices.

The manufacturing facility for Zeniva® PEEK in Alpharetta, GA is ISO 13485 registered and the relevant aspects of current Good Manufacturing Practices are also applied. Our biomaterial manufacturing processes are carefully validated, and enhanced controls provide product traceability. In addition, all materials are tested in a lab that is ISO 17025 accredited. This product meets the requirements of the current version of ASTM F 2026.

Zeniva® ZA-500 is offered as resin pellets and fabricated forms such as rods and plates. The chemical, physical, and mechanical properties of finished parts are related to the processes utilized in producing the finished part (for example, molding, machining, annealing, sterilization, etc).

An FDA MAF is available and a PMDA MF is available in Japan.

总览

用途	• 人体植入物	• 医疗/护理用品	
机构评级	• ASTM F2026	• ISO 10993	• ISO 13485
形式	• Plate	• 棒材	• 粒子

物理性能	额定值	单位制	测试方法
密度 / 比重	1.29	g/cm ³	ASTM D792
机械性能	额定值	单位制	测试方法
拉伸模量	3600	MPa	ASTM D638
抗张强度 (屈服)	95.0	MPa	ASTM D638
伸长率			ASTM D638
屈服	5.2	%	
断裂	35	%	
弯曲模量	4000	MPa	ASTM D790
弯曲强度 (屈服)	150	MPa	ASTM D790
冲击性能	额定值	单位制	测试方法
悬臂梁缺口冲击强度	90	J/m	ASTM D256
热性能	额定值	单位制	测试方法
玻璃转化温度	150	°C	ASTM D3418
熔融峰值温度	340	°C	ASTM D3418
结晶峰温度 (DSC)	290	°C	ASTM D3418
充模分析	额定值	单位制	测试方法
熔体粘度 (400°C, 1000 sec ⁻¹)	430	Pa·s	ASTM D3835
补充信息	额定值	单位制	测试方法
Cytotoxicity	Pass		ISO 10993:5
Physicochemical Testing	Pass		ISO 10993:18