

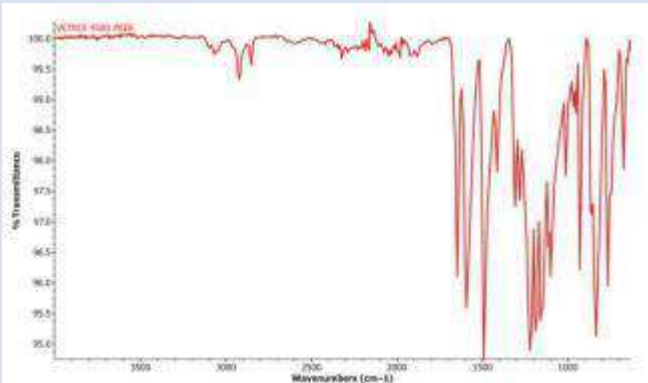
**PEEK Medical Implant Technical Data Sheet(TDS)**

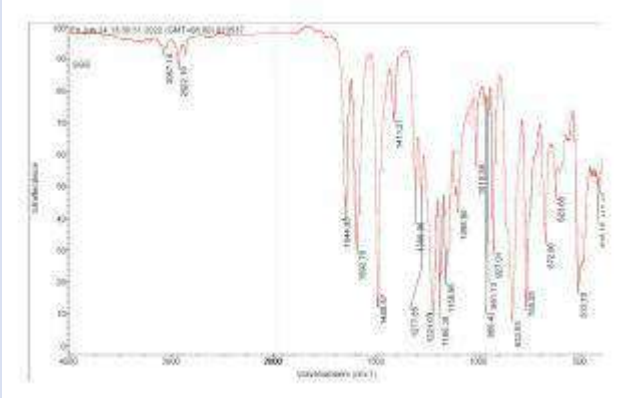
Mechanical Properties, Conditions	Reference Standard	Method	Specification	Result
Tensile Strength at Yield (zero slope), min	ASTM F2026	ISO 527, 1B-Shaped, 50mm/min ASTM D638, IV-Shaped, 5.08cm/min	90MPa	108MPa
Tensile Strength at Break, min	ASTM F2026		70MPa	75.2MPa
Elongation at Break, min	ASTM F2026		5%	12%
Flexural Strength, min	ASTM F2026	ISO 178/	110MPa	168MPa
Flexural Modulus, min	ASTM F2026	ASTM D790	3GPa	3.95GPa
Impact Strength, Notched Izod, min	ASTM F2026	ISO 180/ ASTM D256	4kJ/m <sup>2</sup>	5.9kJ/m <sup>2</sup>

Biological Properties, Conditions	Reference Standard	Method	Specification	Result
Genotoxicity	ISO 10993-3	ISO 10993-3	Negative	Negative
Animal Intracutaneous (Intradermal) Reactivity	ISO 10993-10	ISO 10993-10	≤1	0
Skin Sensitization	ISO 10993-10	ISO 10993-10	≤1	0
Acute Systemic Toxicity	ISO 10993-11	ISO 10993-11	No Acute Systemic Toxicity	No Acute Systemic Toxicity
Subchronic Systemic Toxicity	ISO 10993-11	ISO 10993-11	No Subchronic Systemic Toxicity	No Subchronic Systemic Toxicity
Local Effects after Implantation	ISO 10993-6	ISO 10993-6	No obvious difference between the test sample & the control sample	No obvious difference between the test sample & the control sample
In Vitro Cytotoxicity	ISO 10993-5	ISO 10993-5	≤1	1
Evaluation of Haemolytic Properties	ISO 10993-4	ISO 10993-4	<5%	1%
Material Mediated Pyrogens	ISO 10993-11	ISO 10993-11	No Pyrogenic Responses	No Pyrogenic Responses

Chemical Properties, Conditions	Reference Standard	Method	Specification	Result
Total Heavy Metals (Ag, As, Bi, Cd, Cu, Hg, Mo, Pb, Sb, & Sn), max	ASTM F2026	US Pharmacopeia, Test 233	<100ppm	<100ppm

Physical Properties, Conditions	Reference Standard	Method	Specification	Result
Glass Transition Temperature, $T_g$	ASTM F2026	ISO 11357-2/ ASTM D3418	125-165 °C	152.6°C
Melt Temperature, $T_m$	ASTM F2026	ISO 11357-3/ ASTM D3418	320-360 °C	338.3°C
Recrystallization Temperature, $T_c$	ASTM F2026	ASTM D3418	260-320 °C	283.7°C
Viscosity	ASTM F2026	ISO 11443	400-480 Pa.s	434Pa.s
Density	ASTM F2026	ISO 1183/ ASTM D1505	1280-1320 kg/m <sup>3</sup>	1300kg/m <sup>3</sup>
Melt Mass-Flow Rate (MFR)	Nil	ASTM D1238 (400°C, 2.16kg)	Nil	10g/10min
Mold Shrinkage in flow direction	Nil	ASTM D955	Nil	1.1%
Mold Shrinkage in transverse direction	Nil		Nil	1.4%

Other Properties, Conditions: Infrared Spectrum	Reference Standard: ASTM F2026	Method: ASTM E1252
Specification	Representative Infrared Spectra of PEEK 	

<p>Other Properties, Conditions: Infrared Spectrum</p>	<p>Reference Standard: ASTM F2026</p>	<p>Method: ASTM E1252</p>
<p>Result</p>	<p>Representative Spectra of PEEK Medical Implant</p> 	

Updated on August 29, 2025