


Extrulen® 1050 E Registered trademark of MediTECH Ram Extruded Rod Form Data Sheet					MED-403-A8			
Raw Material:Ticona GUR 1050 ISO Cell Designation: Thermoplast ISO 11542-PE-UHMW QD, 2-2-2 ASTM Cell Designation: S-UHMW-PE0111A111					Extrulen 1050		Revision 0	
					29-Sep-09			
*Medical Grade PE-UHMW for surgical implants according to ISO 5834-1-e2007, Type 2; ISO 5834-2-2006, Type 2; and ASTM F 648-10a, Type 2								
Characteristics of Base Resin: (Source, Ticona®)		Unit	ISO Standard	Required	Avg Typ Values	ASTM Standard	Required	Avg Typ Values
Titanium, trace element; maximum		[mg/kg]	5834-1	40	13	F 648	40	13
Aluminum, trace element; maximum		[mg/kg]	5834-1	20	6	F 648	20	6
Calcium, trace element; maximum		[mg/kg]	5834-1	5	1	F 648	5	1
Chlorine, trace element; maximum		[mg/kg]	5834-1	30	11	F 648	30	11
Extraneous Particles; maximum		[-]	5834-1	3	1 - 2	F 648	3	1 - 2
Glass Transition Temperature Tg		[°C]	3146	na	-110	ISO 3146	na	-110
Crystallization Temperature Range Tc (20-160°C)		[°C]	3146	na	134.5 - 142.5	ISO 3146	na	134.5 - 142.5
Oxidation Induction Time To, conducted @ 200°C		seconds	ASTM D 3895	na	58.82	D 3895	na	58.82
Ash particles, Maximum		[mg/kg]	ISO 3451-1	125	31 - 44	ISO 3451-1	125	31 - 44
Average Particle Size (Typical)		[mm]	D50	≤16 Sieve	145 - 160	D50	≤16 Sieve	145 - 160
Average molecular wt [molar mass] according to:		[g/mol*10 ⁶]	11534-1	na	9.749 to 10.266	D 4020	na	5.490 to 5.748
Data supplied by Ticona, converted from [IV]		[g/mol*10 ⁶]	Margolies'	na	8.234 to 8.656			
Elongational stress Flow Value; F(150/10) minimum		[MPa]	5834-1	≥.42	.48 to .50	D-4020	≥.42	.48 to .50
Viscosity Number [RSV]		[mL/g]	5834-1	≥3200	3532 to 3677	D-4020	≥3200	3532 to 3677
Porosity; (Bulk Density)		g/cm ³	DIN 53 479	na	.43 to .44	D 1895	na	.43 to .44
Crystallinity; DSC, (1st heat, 20C - 160C)		[%]	3146	na	49 - 58	D 3417	na	49 - 58
Conformances: Resin & Fabricated Forms; (Ticona Data)			Optional Processing Available:			*Sterilization (Industry Standard)		
USP Class VI Biocompatibility		Yes	-Ram Extruded Shapes			Ethylene Oxide		Yes
ISO 10933 Cytotoxicity		Yes	-Additive Blended / Compounded			Gas Plasma		Yes
Drug Master File -DMF, EU		10916	-Gamma Cross-Linking			Gamma [inert		Yes
Drug Master File -DMF, USA		10904	-Inert Atmosphere Processing			Superheated steam 121		No
Device Master File - MAF		588	-Pre-forming and Cut Blocks			Superheated steam 134		No
ISO 5834-1-2005 and 5843-2-2006		Type 2	-High Temperature Thermal Cross-Linking					
ASTM F 648-07e1		Type 2				*Not conducted by MediTECH		
Characteristics of This Annealed, Fabricated Form		Unit	ISO Standard	Required	Avg Typ Values	ASTM Standard	Required	Avg Typ Values
Density, (Annealed Material)		[kg/m ³]	1183	927 - 944	932-934	D792/D1505	927-944	932-934
Tensile stress at yield [tensile strength]		[MPa]	527	≥19	>22	D 638	≥19	>22
Tensile stress at break [ultimate tensile strength]		[MPa]	527	≥40	>49	D 638	≥40	>49
Elongation Percent at break		[%]	527	≥340	>400	D 638	≥340	>400
Tensile (Young's) modulus; 2mm thick specimens:		[MPa]	527	na	>550	D 638	na	>550
ASTM Type IV @ 2 mm and ISO Type 5 @ 2 mm								
Notched Impact Strength at 23°C (Charpy, Izod)		[kJ/m ²]	11542-2	90	>100	F 648	73	>100
Shore hardness D-scale, 15 s value		[-]	868	≥60	67	D 2240	≥60	67
Poisson's Ratio (*Data supplied by Ticona)		[-]	5834-2	*0.45	*0.45	F 648	*0.45	*0.45
Crystallinity; DSC, (1st heat, 20C - 160C)		[%]	3146	na	>58	D 3417	na	>58
Water absorption at 23 °C until saturation		[%]	62	<0.01	<0.05	D 570	<0.01	<0.05
Thermal Properties (Fabricated Form)								
Melting Point DSC, 10K/min		[°C]	3146	na	135.68	D 3417	na	135.68
Vicat softening point, 10N, 50 C°/Hr		[°C]	306	na	135	D 1525 B	na	135
Coef. of Linear thermal expansion; 23 °C to 80 °C		K ⁻¹	11359	na	1.8*10 ⁻⁴	D 696	na	1.8*10 ⁻⁴
Heat Deflection T: HDT/A [1.8 MPa] 66psi/264psi		[°C]	75 pt 1/2	na	[45]	D 648	na	82 / 48
Thermal Conductivity		[W/(m*K)]	DIN 52612	na	approx. 0.4	DIN 52612	na	approx 0.4
Glass Transition Temperature Tg		[°C]	DSC	na	-110	DSC	na	-110
Crystallization Temperature Range Tc (20-160°C)		[°C]	DSC	na	128.72 - 144.10	DSC	na	128.72 - 144.10
Oxidation Induction Time To, conducted @ 200°C		seconds	ASTM D 3895	na	15.618	D 3895	na	15.618
Ash particles, maximum		[mg/kg]	ISO 3451 -1	150	72 - 121	ISO 3451-1	125	72 - 121
Ageing Performance Test Results: (ASTM F2101-01); Shelf aged 1 Year in Air Results: Surface Oxidation Index 0.00 ; Bulk Oxidation Index 0.00								
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