



Raw Material: Ticona GUR 1050
 ISO Cell Designation: Thermoplast ISO 11542-PE-UHMW QD, 2-2-2
 ASTM Cell Designation: S-UHMW-PE0111A111

Chirulen 1050 E
 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 - 10.266	D 4020	na	5.490 - 5.748
Data supplied by Ticona, converted from [IV]	[q/mol*10 ⁶]	Margolies'	na	8.234 - 8.656			
Elongational stress Flow Value; F(150/10) minimum	[MPa]	5834-1	≥.42	.48 - .50	D-4020	≥.42	.48 - .50
Viscosity Number [RSV]	[mL/g]	5834-1	≥3200	3532 - 3677	D-4020	≥3200	3532 - 3677
Porosity; (Bulk Density)	g/cm ³	DIN 53 479	na	.43 - .44	D 1895	na	.43 - .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	Ethylene Oxide
ISO 10933 Cytotoxicity	Yes	Gas Plasma
Drug Master File -DMF, EU	10916	Gamma [inert]
Drug Master File -DMF, USA	10904	Superheated steam 121 °C
Device Master File - MAF	588	Superheated steam 134 °C
ISO 5834-1-2005 and 5843-2-2006	Type 2	
ASTM F 648-07e1	Type 2	
	-Ram Extruded Shapes	Yes
	-Additive Blended / Compounded	Yes
	-Gamma Cross-Linking	Yes
	-Inert Atmosphere Processing	No
	-Pre-forming and Cut Blocks	No
	-High Temperature Thermal Cross-Linking	
		*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	933-935	D792/D1505	927-944	933-935
Tensile stress at yield [tensile strength]	[MPa]	527	≥19	>22	D 638	≥19	>22
Tensile stress at break [ultimate tensile strength]	[MPa]	527	≥40	>51	D 638	≥40	>51
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	68	D 2240	≥60	68
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	>60	D 3417	na	>60
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	136.86	D 3417	na	136.86
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	126.72 - 143.65	DSC	na	126.72 - 143.65
Oxidation Induction Time To, conducted @ 200°C	minutes	ASTM D 3895	na	17.19	D 3895	na	17.19
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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