



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

\*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	10.6	F 648	40	10.6
Aluminum, trace element; maximum	[mg/kg]	5834-1	20	3.3	F 648	20	3.3
Calcium, trace element; maximum	[mg/kg]	5834-1	5	2	F 648	5	2
Chlorine, trace element; maximum	[mg/kg]	5834-1	30	10	F 648	30	10
Extraneous Particles; maximum	[-]	5834-1	3	0-1	F 648	3	0-1
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	55.32	D 3895	na	55.32
Ash particles, Maximum	[mg/kg]	ISO 3451-1	125	38	ISO 3451-1	125	38
Average Particle Size (Typical)	[mm]	D50	≤16 Sieve	152	D50	≤16 Sieve	152
Average molecular wt [molar mass] according to: Data supplied by Ticona, converted from [IV]	[g/mol*10 <sup>6</sup> ] [g/mol*10 <sup>6</sup> ]	11534-1 Margolies'	na	9.749 to 10.266 8.234 to 8.656	D 4020	na	5.490 to 5.748
Elongational stress Flow Value; F(150/10) minimum	[MPa]	5834-1	≥.42	0.49	D-4020	≥.42	0.49
Viscosity Number [RSV]	[mL/g]	5834-1	≥3200	3532 to 3677	D-4020	≥3200	3532 to 3677
Porosity; (Bulk Density)	g/cm <sup>3</sup>	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	Ethylene Oxide
ISO 10993 Cytotoxicity	Yes	Gas Plasma
Drug Master File -DMF, EU	10916	Gamma [inert]
Drug Master File -DMF, USA	10904	Superheated steam 121
Device Master File - MAF	588	Superheated steam 134
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 <sup>3</sup> ]	1183	927 - 944	931 / 1.2	D792/D1505	927-944	931 / 1.2
Tensile stress at yield [tensile strength]	[MPa]	527	≥19	22.4 / 0.2	D 638	≥19	21.7 / 0.3
Tensile stress at break [ultimate tensile strength]	[MPa]	527	≥40	48.2 / 2.9	D 638	≥40	50.8 / 4.4
Elongation Percent at break	[%]	527	≥340	361 / 21	D 638	≥340	426 / 27
Tensile (Young's) modulus; 2mm thick specimens: ASTM Type IV @ 2 mm and ISO Type 5 @ 2 mm	[MPa]	527	na	664 / 61	D 638	na	473 / 34
Notched Impact Strength at 23°C (Charpy, Izod)	[kJ/m <sup>2</sup> ]	11542-2	90	97 / 9	F 648	73	100.4 / 5.9
Shore hardness D-scale, 15 s value	[-]	868	≥60	66 / 1	D 2240	≥60	66 / 1
Poisson's Ratio (*Data supplied by Ticona)	[-]	5834-2	*0.46	*0.46	F 648	*0.46	*0.46
Crystallinity; DSC, (1st heat, 20C - 160C)	[%]	3146	na	>54	D 3417	na	>54
Water absorption at 23 °C until saturation	[%]	62	<0.1	<0.05	D 570	<0.1	<0.05
<b>Thermal Properties (Fabricated Form)</b>							
Melting Point DSC, 10K/min	[°C]	3146	na	136.0 / 0.2	D 3417	na	136.0 / 0.2
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 <sup>-1</sup>	11359	na	1.8*10 <sup>-4</sup>	D 696	na	1.8*10 <sup>-4</sup>
Heat Deflection T: HDT/A [1.8 MPa] 66psi/264psi	[°C]	75 pt 1/2	na	[ 45 ]	D 648	na	[ 45 ]
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	30 - 70	ISO 3451-1	150	30 - 70

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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