

Extrulen® 1020 E Registered trademark of MediTECH **Ram Extruded Rod Form Data Sheet**

MED-403-A6

Extrulen 1020 E

Revision 1

29-Sep-11



Raw Material:Ticona GUR 1020

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 1; ISO 5834-2-2006, Type 1; and ASTM F 648-10a, Type 1

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	11	F 648	40	11
Aluminum, trace element; maximum	[mg/kg]	5834-1	20	3.5	F 648	20	3.5
Calcium, trace element; maximum	[mg/kg]	5834-1	5	3	F 648	5	3
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	45	ISO 3451-1	125	45
Average Particle Size (Typical)	[mm]	D50	≤16 Sieve	150	D50	≤16 Sieve	150
Average molecular wt [molar mass] according to:	[g/mol*10 ⁶]	11534-1	na	5.166- 5.415	D 4020	na	3.121- 3.254
Data supplied by Ticona, converted from [IV]	[g/mol*10 ⁶]	Marqolies'	na	4.454 - 4.661			
Elongational stress Flow Value; F(150/10) minimum	[MPa]	5834-1	≥0.2	0.23	D-4020	≥0.2	0.23
Viscosity Number [RSV]	[mL/g]	5834-1	2000-3200	2197 - 2276	D-4020	2000-3200	2197 - 2276
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	66.89 - 70.23	D 3417	na	66.89 - 70.23

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 1	
ASTM F 648-07e1	Type 1	

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	≥21	>23	D 638	≥21	>23
Tensile stress at break [ultimate tensile strength]	[MPa]	527	≥35	>50	D 638	≥40	>50
Elongation Percent at break	[%]	527	≥300	>460	D 638	≥300	>460
Tensile (Young's) modulus; 2mm thick specimens: ASTM Type IV @ 2 mm and ISO Type 5 @ 2 mm	[MPa]	527	na	>575	D 638	na	>575
Notched Impact Strength at 23°C (Charpy, Izod)	[kJ/m ²]	11542-2	180	>150	F 648	126	>150
Shore hardness D-scale, 15 s value	[-]	868	≥60	68	D 2240	≥60	68
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	>58	D 3417	na	>58
Water absorption at 23 °C until saturation	[%]	62	<0.1	<0.05	D 570	<0.1	<0.05

Thermal Properties (Fabricated Form)	Unit	ISO Standard	Required	Avg Typ Values	ASTM Standard	Required	Avg Typ Values
Melting Point DSC, 10K/min	[°C]	3146	na	137.5	D 3417	na	137.5
Vicat softening point, 10N, 50 C°/Hr	[°C]	306	na	134	D 1525 B	na	134
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	[42]	D 648	na	80 / 46
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	126.21 - 143.54	DSC	na	126.21 - 143.54
Oxidation Induction Time To, conducted @ 200°C	seconds	ASTM D 3895	na	18.72	D 3895	na	18.72
Ash particles, maximum	[mg/kg]	ISO 3451 -1	150	72 - 121	ISO 3451-1	150	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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