



**MEDICAL AND  
PHARMACEUTICAL  
MATERIALS FOR INNOVATIVE  
HEALTHCARE PRODUCTS**

**Celanese Healthcare  
Solutions**



# TECHNOLOGY. DESIGN. PERFORMANCE.

Celanese offers one of the broadest ranges of healthcare materials in the industry. With over 40 years of technical expertise, Celanese is the trusted development partner and first-choice chemistry solution provider to enhance your ability to meet the demands of next generation healthcare technologies. Our innovation platforms and customized solutions provide high-quality, advanced and biocompatible polymers to help our clients innovate new healthcare technologies, mitigate risk through regulatory compliance and create eco-responsible materials.

## ART OF MATERIAL SELECTION & ENGAGEMENT.

Our experts work with manufacturers and engineers to help understand, articulate and develop material needs in diverse application bases. The Celanese integrated engagement model makes it easy to innovate together with our broad portfolio, process support, part design, global footprint and continued investment into healthcare technology.

<b>Broad Portfolio</b>	<ul style="list-style-type: none"> <li>• Covers a wide range of chemical resistance, mechanical performance and usage temperatures</li> <li>• Ability to customize materials to meet varying application CTQs</li> </ul>
<b>Process Support</b>	<ul style="list-style-type: none"> <li>• Individualized Field Technical support across our customers ecosystem (molding, extrusion, troubleshooting, testing)</li> <li>• End-to-end (pellet to part) support</li> </ul>
<b>Material Design</b>	<ul style="list-style-type: none"> <li>• Advanced computer aided engineering and design</li> <li>• Application and subject matter expertise (aesthetics, tribology, etc.) to support part design challenges</li> </ul>
<b>Global Footprint</b>	<ul style="list-style-type: none"> <li>• Ten technical and customer centers across the globe</li> <li>• Technical support in every time zone</li> </ul>



# REDUCE BARRIERS. ACHIEVE A NEW LEVEL OF PROVEN MATERIAL QUALITY.

## THE CELANESE HEALTHCARE SERVICE PACKAGE – OUR COMMITMENT:

- Risk reduction and stability increase for customers
- Service that delivers support through the total product cycle
- Leadership in Material Quality
- Long-term supply assurance without change of formulation
- Extensive research and development capabilities
- Processing guidance and support
- Design and regulatory support
- Global regulatory approvals
- Material compliance to FDA and EU requirements
- Animal- and latex-free formulations
- Certified biocompatibility - (USP Class VI / ISO 10993, etc.)
- FDA Drug Master File
- FDA Device Master File
- Expanded Certificate of Inspection
- Application of GMP-principles

## MATERIAL TECHNOLOGIES FOR NEXT GENERATION DEVICES.



### VITALDOSE® CONTROLLED RELEASE EXCIPIENT EVA

Regulator-approved, easy-processing, controlled-release drug delivery



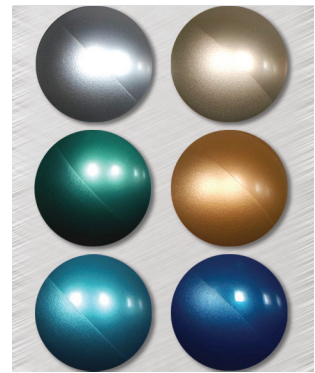
### HOSTAFORM® MT® SLIDEX® POM

Exceptional low friction and noise in drug delivery devices



### VECTRA® LCP FOR LASER DIRECT STRUCTURING

Integration of structure and electronics in a single component for smart medical devices



### CELANESE APPEARANCE POLYMERS

Improved haptics and appearance for medical devices



# GLOBAL REACH AND CAPABILITIES

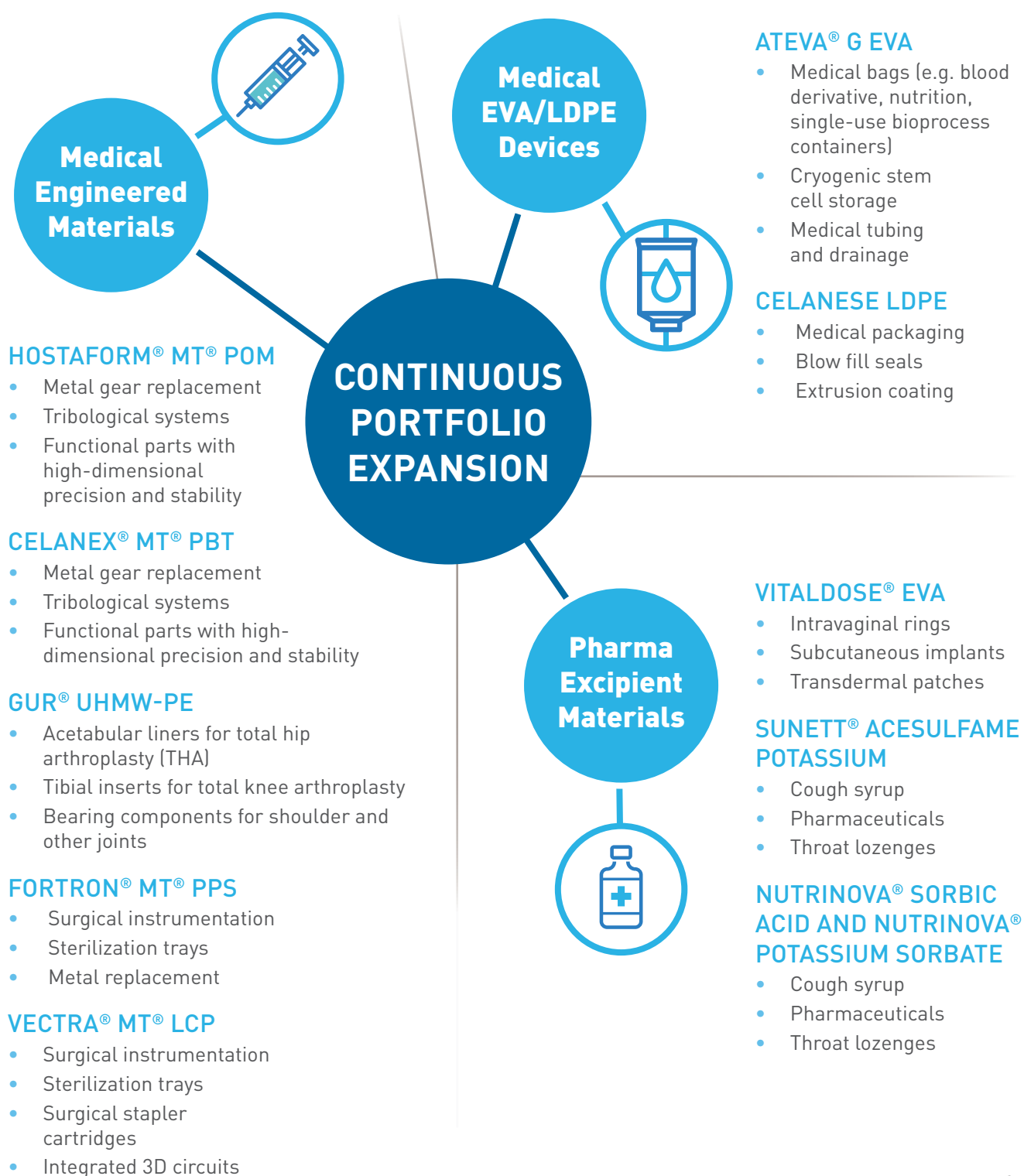


- Product and Processing Technology Development
- CAE/Design
- Color Development
- Environmental Testing
- Advanced Analytics and Research
- Physical and Mechanical Testing
- Specialty Applications
- Customized Pharmaceutical Development Support



# INNOVATE WITH CELANESE, YOUR TRUSTED PARTNER FOR MEDICAL AND PHARMACEUTICAL POLYMERS.

Celanese strives to maintain one of the broadest material portfolios in the industry through constant innovation and expansion. Our existing, enhanced and select material solutions offer a wide range of mechanical, chemical and temperature properties and characteristics.



## Celanese Engineered Materials for Medical Applications

Material Description	Typical Medical Applications	Grade	Description	Thin-Wall Sections or Long Flow Lengths	Thick-Wall Section Parts	Excellent Impact Resistance	High Strength with Flexibility	High Strength with Rigidity
<b>Hostaform® MT® and Hostaform® acetal copolymer (POM)</b>								
<ul style="list-style-type: none"> <li>Thermally stable</li> <li>High chemical resistance</li> <li>Excellent impact resistance</li> <li>Suitable for repeat steam sterilization cycles</li> <li>Sliding properties</li> <li>High hardness and rigidity</li> <li>Spring properties</li> </ul>	<ul style="list-style-type: none"> <li>Drug delivery systems</li> <li>Metal gear replacement</li> <li>Snap fittings</li> <li>Tribological systems</li> <li>Sliding mechanisms</li> <li>Clips and clamps</li> <li>Functional parts with high-dimensional precision and stability</li> <li>Housings</li> <li>Dental instrumentation</li> <li>Surgical instrumentation components</li> <li>Orthopedic trial sizers</li> </ul>	MT 2U01	Stiff flowing for extrusion and thick-walled parts	▲	+	●	+	▲
		MT 8U01	Standard flow, unfilled	●	▲	●	+	▲
		MT 12U01	Easy flow, unfilled	+	▲	●	+	▲
		MT 12U03	Easy flow, unfilled, increased stiffness	+	▲	●	+	▲
		MT 24U01	Very easy flow, unfilled	+	▲	●	+	▲
		MT 8R02	Standard flow, slip modified	●	▲	▲	+	▲
		MT 12R01	Easy flow, slip modified	+	▲	▲	+	▲
		MT 8F01	Standard flow, PTFE modified	●	▲	▲	+	▲
		MT 8F02	Standard flow, PTFE modified	●	▲	▲	+	▲
		MT 24F01	Very easy flow, PTFE modified	+	▲	▲	+	▲
		MT 8U05	Standard flow, fluoresces under UV light	●	▲	●	+	▲
MT SlideX 1203	Standard flow with tribological modification	●	▲	●	+	▲		
MT SlideX 2404	Easy flow with tribological modification	+	▲	●	+	▲		
<b>Celanex® MT® and Celanex® thermoplastic polyester (PBT)</b>								
<ul style="list-style-type: none"> <li>Ideal sliding and wear behavior</li> <li>High-dimensional stability</li> <li>Good chemical resistance to polar and non-polar solvents</li> <li>Gamma-resistance up to 50kGy</li> </ul>	<ul style="list-style-type: none"> <li>Drug delivery systems</li> <li>Metal gear replacement</li> <li>Functional parts with high-dimensional precision and stability</li> <li>Tribological systems</li> <li>Sliding mechanisms</li> <li>Snap fittings</li> <li>Clips and clamps</li> </ul>	2401MT	Standard flow, unfilled	●	▲	●	+	▲
		2402MT	Easy flow, unfilled, nucleated	+	▲	●	+	▲
		2404MT	Standard flow, PTFE modified	●	▲	▲	+	▲
		2405MT	Standard flow, slip modified	●	▲	●	+	▲
		Laser marking	Black with white marking	●	▲	●	+	▲
			White with black marking	●	▲	●	+	▲
<b>GUR® ultra-high molecular weight polyethylene (UHMW-PE)</b>								
<ul style="list-style-type: none"> <li>Extremely high-impact strength</li> <li>Low coefficient of friction</li> <li>Extremely high abrasion resistance</li> <li>High strength</li> <li>Gamma stable for crosslinking and sterilization</li> </ul>	<ul style="list-style-type: none"> <li>Acetabular liners for THA</li> <li>Tibial inserts for TKA</li> <li>Bearing components for shoulder and other joints</li> <li>Endoprosthetics</li> <li>Cervical disks for spine</li> </ul>	1020	Implant grade	—	—	+	▲	▲
		1050	Implant grade	—	—	+	▲	▲
		1020-E	Implant grade + vitamin E	—	—	+	▲	▲
		1050-E	Implant grade + vitamin E	—	—	+	▲	▲
<b>GUR® high molecular weight polyethylene (HMW-PE)</b>								
<ul style="list-style-type: none"> <li>Injection moldable</li> <li>Low coefficient of friction</li> </ul>		1001	Implant grade	▲	▲	●	▲	▲
<b>Fortron® MT® polyphenylene sulfide (PPS)</b>								
<ul style="list-style-type: none"> <li>High-dimensional stability</li> <li>Excellent chemical resistance</li> <li>Heat resistance up to 240°C</li> <li>Gamma, EtO and Steam Sterilizable</li> <li>Suitable for repeat steam sterilization cycles</li> </ul>	<ul style="list-style-type: none"> <li>Surgical instrumentation</li> <li>Sterilization trays</li> <li>Metal replacement</li> <li>Nonwovens used for filtration</li> </ul>	MT 9140L4	Standard flow, 40% glass fiber filled	●	▲	+	▲	+
		MT 9140L6	Easy flow, 40% glass fiber filled	●	▲	+	▲	+
<b>Vectra® MT® liquid crystal polymer (LCP)</b>								
<ul style="list-style-type: none"> <li>Extremely high rigidity in thin walled designs</li> <li>High-impact strength</li> <li>Very high heat resistance</li> <li>Suitable for repeat steam sterilization cycles</li> <li>High-dimensional stability</li> <li>Replication of very fine parts with extremely high precision</li> </ul>	<ul style="list-style-type: none"> <li>Surgical instrumentation</li> <li>Surgical stapler cartridges</li> <li>Dental devices</li> <li>Sterilization trays</li> <li>Pharmaceutical packaging</li> <li>Complete air and moisture barriers</li> <li>Integrated 3D circuits</li> </ul>	MT 1300	Unfilled	+	▲	▲	▲	+
		MT 1310	Glass fiber filled	+	▲	▲	▲	+
		MT 4310	Easy flow + glass fiber	+	▲	▲	▲	+
		MT 4350	Easy flow with mineral filler	+	▲	▲	▲	+
		MT 1335	Glass fiber + PTFE	+	▲	▲	▲	+



	High Elongation at Yield		Very Low Friction or Noise	High-Dimensional Stability	High Temperature Operation		Cryogenic Operation	Sterilization			Food Contact		Drug/Device Masterfile	Biocompatibility		Barrier Properties	Coloration	Injection Molding	Compression Molding	Extrusion	Film Production	Machining	Special Applications
	>6%	25%			HDT >100°C	HDT >200°C		ETO	Gamma	Steam	EU	US		USP Class 6	ISO 10993								
<b>Hostaform® MT® and Hostaform® acetal copolymer (POM)</b>																							
+	-	●	●	+	-	▲	+	-	●	+	+	-	+	+	●	+	+	▲	+	-	+		
+	-	●	●	+	-	▲	+	-	●	+	+	+	+	+	●	+	+	▲	●	-	+		
+	-	●	●	+	-	▲	+	-	●	+	+	+	+	+	●	+	+	▲	-	-	+		
+	-	●	●	+	-	▲	+	-	●	+	+	+	+	+	●	+	+	▲	-	-	+		
+	-	+	●	+	-	▲	+	-	●	+	+	+	+	+	●	+	+	▲	●	-	+	Tribological	
+	-	+	●	+	-	▲	+	-	●	+	+	+	+	+	●	+	+	▲	-	-	+	Tribological	
+	-	+	●	+	-	▲	+	-	●	+	+	+	+	+	●	+	+	▲	●	-	+	Tribological	
+	-	+	●	+	-	▲	+	-	●	+	+	+	+	+	●	+	+	▲	-	-	+	Tribological	
+	-	●	●	+	-	▲	+	-	●	+	+	+	+	+	●	+	+	▲	●	-	+	UV Visibility	
+	-	+	●	-	-	▲	+	-	●	+	+	+	+	+	●	+	+	▲	-	-	+	Tribological	
+	-	+	●	-	-	▲	+	-	●	+	+	+	+	+	●	+	+	▲	-	-	+	Tribological	
<b>Celanex® MT® and Celanex® thermoplastic polyester (PBT)</b>																							
+	-	●	●	+	-	▲	+	+	●	+	+	+	+	+	●	+	+	▲	▲	▲	+	Gamma Resistant	
+	-	●	●	+	-	▲	+	+	●	+	+	+	+	+	●	+	+	▲	▲	▲	+	Gamma Resistant	
+	-	+	●	+	-	▲	+	-	●	+	+	+	+	+	●	+	+	▲	▲	▲	+	Tribological	
+	-	+	●	+	-	▲	+	+	●	+	+	+	+	+	●	+	+	▲	▲	▲	+	Gamma Resistant and Tribological	
▲	-	●	●	+	-	▲	+	▲*	●	+	+	-	-	-	●	+	+	▲	▲	▲	+	Laser Markable	
▲	-	●	●	+	-	▲	+	▲*	●	●*	●*	-	-	-	●	+	+	▲	▲	▲	+	Laser Markable	
<b>GUR® ultra-high molecular weight polyethylene (UHMW-PE)</b>																							
+	-	+	▲	-	-	+	+	+	-	+	+	+	+	+	-	▲	-	+	-	▲	+	Tribological	
+	-	+	▲	-	-	+	+	+	-	+	+	+	+	+	-	▲	-	+	-	▲	+	Tribological	
+	-	+	▲	-	-	+	+	+	-	+	+	+	+	+	-	▲	-	+	-	▲	+	Tribological	
+	-	+	▲	-	-	+	+	+	-	+	+	+	+	+	-	▲	-	+	-	▲	+	Tribological	
<b>GUR® high molecular weight polyethylene (HMW-PE)</b>																							
+	-	+	▲	-	-	+	+	+	-	+	+	+	+	+	-	▲	+	▲	▲	▲	+	Tribological	
<b>Fortron® MT® polyphenylene sulfide (PPS)</b>																							
-	-	▲	+	+	+	▲	+	+	+	+	+	+	+	+	+	▲	+	▲	▲	▲	●		
-	-	▲	+	+	+	▲	+	+	+	+	+	+	+	+	+	▲	+	▲	▲	▲	●		
-	-	▲	+	+	+	▲	+	+	+	+	+	+	+	+	+	▲	+	▲	▲	▲	●		
-	-	▲	+	+	+	▲	+	+	+	+	+	+	+	+	+	▲	+	▲	▲	▲	●		
-	-	●	+	+	+	▲	+	-	●	+	+	+	+	+	●	+	▲	▲	▲	▲	▲		

KEY: + Excellent Match ● Good Match ▲ Possible Match — Not Appropriate \*Contact us for recommendations

## Celanese Medical Products Data Sheet

	Unit	Testing Method	HOSTAFORM® POM						
			MT 2U01	MT 8U01	MT 12U01	MT 12U03	MT 24U01	MT 8R02	MT 12R01
<b>Property</b>									
Density	g/cm <sup>3</sup>	ISO 1183	1.41	1.41	1.41	1.41	1.41	1.4	1.41
Volume melt flow index MVR T/2.16 (°C/Kg)	cm <sup>3</sup> / 10 min	ISO 1133	2.2 (190°C)	8 (190°C)	12 (190°C)	12 (190°C)	24 (190°C)	8.5 (190°C)	12 (190°C)
Moisture absorption at 23°C until saturation	%	ISO 62	0.65	0.65	0.65	0.65	0.65	—	0.65
<b>Mechanical Properties</b>									
Tensile stress at yield (50mm/min)	MPa	ISO 527- 2/1A	62	64	65	70	65	62	65
Tensile strain at yield (50mm/min)	%	ISO 527- 2/1A	9	9	9	8	7.5	9	9
Tensile modulus	MPa	ISO 527- 2/1A	2600	2850	2900	3100	2900	2700	2900
Charpy impact strength at 23°C	kJ/m <sup>2</sup>	ISO 179/1eU	220	180	150	120	120	—	140
Charpy notched impact strength at 23°C	kJ/m <sup>2</sup>	ISO 179/1eA	8.5	6.5	6	6	5.5	8	6.5
<b>Thermal Properties</b>									
Heat deflection temperature HDT/A (1.8 MPa)	°C	ISO 75- 1/2	101	104	106	107	106	82	102
Heat deflection temperature HDT/B (0.45 MPa)	°C	ISO 75- 1/2							
Vicat softening point VST/B/50	°C	ISO 306	151	150	151	158	151	—	151
<b>Conformances – Food</b>									
Consumer articles regulations and BfR recommendations*				yes	yes	yes	yes	yes	yes
FDA regulation CFR Vol. 21 § 177.../Food contact notification – FCN				2470	2470	2470	2470	2470	2470
Drug Master File (DMF)				11559	11559	11559	11559	11559	11559
Device Master File (MAF)				1079	1079	1079	1079	1079	1079
<b>Conformances – Pharmaceuticals</b>									
USP Class VI				yes	yes	yes	yes	yes	yes
Cytotoxicity				yes	yes	yes	yes	yes	yes
<b>Sterilization</b>									
Ethylene oxide				excellent	excellent	excellent	excellent	excellent	excellent
Superheated steam 121/134°C				possible	possible	possible	possible	possible	possible
Gamma radiation				not appropriate	not appropriate	not appropriate	not appropriate	not appropriate	not appropriate

\*German Federal Institute for Risk Assessment



HOSTAFORM® POM						CELANEX® PBT			
MT 8F01	MT 8F02	MT 24F01	MT 8U05	MT SlideX 1203	MT SlideX 2404	2401MT	2402MT	2404MT	2405MT
<b>Property</b>									
1.44	1.52	1.44	1.41	1.40	1.40	1.31	1.31	1.34	1.31
8.5 (190°C)	6 (190°C)	21 (190°C)	8 (190°C)	13 (190°C)	25 (190°C)	20 (250°C)	40 (250°C)	21 (250°C)	19 (250°C)
—	0.65	—	0.65	0.6	0.6	—	—	—	—
<b>Mechanical Properties</b>									
58	48	58	64	58	55	60	60	56	60
9	7	—	9	12	7	4	4	7	10
2600	2500	2600	2850	2650	2550	2600	2700	2600	2500
—	60	80	180	160	160	NB	135	—	—
5.2	4	4	6.5	6	5.5	6	5	3.3	5
<b>Thermal Properties</b>									
102	98	100	104	93	90	55	60	55	50
						150	160	—	—
—	145	146	150	151	144	190	190	190	190
<b>Conformances – Food</b>									
yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
2470	2470	2470	2470	2470	2470	1660	1660	1660	1660
11559	11559	11559	11559	11559	11559	10033	10033	10033	10033
1079	1079	1079	1079	1079	1079	1078	1078	1078	1078
<b>Conformances – Pharmaceuticals</b>									
yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
<b>Sterilization</b>									
excellent	excellent	excellent	excellent	excellent	excellent	excellent	excellent	excellent	excellent
possible	possible	possible	possible	possible	possible	possible	possible	possible	possible
not appropriate	not appropriate	not appropriate	not appropriate	not appropriate	not appropriate	excellent	excellent	not appropriate	excellent

\*German Federal Institute for Risk Assessment

## Celanese Medical Products Data Sheet

	Unit	Testing Method	GUR® UHMW-PE				
			1020	1050	1020-E	1050-E	1001
<b>Property</b>							
Density	g/cm <sup>3</sup>	ISO 1183	0.93	0.93	0.93	0.93	0.95
Volume melt flow index MVR (190°C/21.6 Kg)	cm <sup>3</sup> /10 min	ISO 1133	NA	NA	NA	NA	1.1
Moisture absorption at 23°C until saturation	%	ISO 62	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01
<b>Mechanical Properties</b>							
Tensile stress at yield (50mm/min)	MPa	ISO 527-1 and 527-2	19*	19*	19*	19*	25
Tensile modulus	MPa	ISO 527-1 and 527-2	690	660	690	660	1100
Charpy impact strength at 23°C	kJ/m <sup>2</sup>	ISO 179/1eU	no break	no break	no break	no break	
Charpy double notched impact strength at 23°C	kJ/m <sup>2</sup>	ISO 11542-2	240	180	240	180	45
<b>Thermal Properties</b>							
Heat deflection temperature HDT/A (1.8 MPa)	°C	ISO 75-1/2	42	42	42	42	42
Vicat softening point VST/B/50	°C	ISO 306	80	80	80	80	80
<b>Conformances – Food</b>							
Consumer articles regulations and BfR recommendations**			yes	yes	yes	yes	yes
FDA regulation CFR Vol. 21 § 177.../ Food contact notification – FCN			1520 (2.1; 2.2)	1520 (2.1; 2.2)	1520 (2.1; 2.2)	1520 (2.1; 2.2)	1520 (2.1; 2.2)
Drug Master File (DMF)			10904	10904	10904	10904	
Device Master File (MAF)			588	588	588	588	
<b>Conformances – Pharmaceuticals</b>							
USP Class VI			yes	yes	yes	yes	yes
Cytotoxicity			yes	yes	yes	yes	yes
<b>Sterilization</b>							
Ethylene oxide			excellent	excellent	excellent	excellent	excellent
Superheated steam 121/134°C			not appropriate	not appropriate	not appropriate	not appropriate	not appropriate
Gamma radiation			excellent	excellent	excellent	excellent	excellent
			FORTRON® PPS				
	Unit	Testing Method	MT 9140L4		MT 9140L6		
<b>Property</b>							
Density	g/cm <sup>3</sup>	ISO 1183	1.65		1.65		
Reinforcing material			glass fiber		glass fiber		
Concentration of reinforced materials	Weight %	ISO 3451, Part 1	40		40		
Volume melt flow index MVR T/2.16 (°C/Kg)	cm <sup>3</sup> /10 min	ISO 1133	NA		NA		
Moisture absorption at 23°C until saturation	%	ISO 62	0.02		0.02		
<b>Mechanical Properties</b>							
Tensile stress at break (5mm/min)	MPa	ISO 527-2/1A	190		195		
Tensile strain at break (5mm/min)	%	ISO 527-2/1A	1.8		1.9		
Tensile modulus (1mm/min)	MPa	ISO 527-2/1A	14700		14700		
Charpy impact strength at 23°C	kJ/m <sup>2</sup>	ISO 179/1eU	48		53		
Charpy notched impact strength at 23°C	kJ/m <sup>2</sup>	ISO 179/1eU	9		10		
<b>Thermal Properties</b>							
Heat deflection temperature HDT/B (0.45 MPa)	°C	ISO 75-1/2	280		280		

\*These products show no yield point. The number given is stress at 50% elongation.

\*\*German Federal Institute for Risk Assessment

## Celanese Medical Products Data Sheet

			FORTRON® PPS	
			MT 9140L4	MT 9140L6
<b>Conformances – Food</b>				
Consumer articles regulations and BfR recommendations*			yes	yes
FDA regulation CFR Vol. 21 § 177.../ Food contact notification – FCN			FCN 40	FCN 40
Drug Master File (DMF)			14844	14844
Device Master File (MAF)			1097	1097
<b>Conformances – Pharmaceuticals</b>				
USP Class VI			yes	yes
Cytotoxicity			yes	yes
<b>Sterilization</b>				
Ethylene oxide			excellent	excellent
Superheated steam 121/134°C			excellent/ excellent	excellent/ excellent
Gamma radiation			excellent	excellent

	Unit	Testing Method	VECTRA® LCP				
			MT 1300	MT 1310	MT 4310	MT 4350	MT 1335
<b>Property</b>							
Density	g/cm <sup>3</sup>	ISO 1183	1.40	1.62	1.61	1.74	1.62
Reinforcing material			without	glass fiber	glass fiber	mineral filled	glass/PTFE
Concentration of reinforced materials	Weight %	ISO 3451, Part 1	0	30	30	40	35
Volume melt flow index MVR T/2.16 (°C/Kg)	cm <sup>3</sup> / 10 min	ISO 1133	NA	NA	NA	NA	NA
Moisture absorption at 23°C until saturation	%	ISO 62-4	0.003	0.04	0.03	0.005	0.002
<b>Mechanical Properties</b>							
Tensile stress at break (5mm/min)	MPa	ISO 527-2/1A	182	190	150	105	171
Tensile strain at break (5mm/min)	%	ISO 527-2/1A	3.4	2.1	1.6	3.2	3.3
Tensile modulus	MPa	ISO 527-2/1A	10600	15000	15000	9800	11000
Charpy impact strength at 23°C	kJ/m <sup>2</sup>	ISO 179/1eU	267	33	43	58	38
Charpy notched impact strength at 23°C	kJ/m <sup>2</sup>	ISO 179/1eA	95	26	22	6	26
<b>Thermal Properties</b>							
Heat deflection temperature HDT/A (1.8 MPa)	°C	ISO 75-1/2	187	235	276	230	230
Heat deflection temperature HDT/B (0.45 MPa)	°C	ISO 75-1/2	—	250	—	—	250
Vicat softening point VST/B/50	°C	ISO 306	145	160	195	195	146
<b>Conformances – Food</b>							
Consumer articles, regulations and BfR recommendations*			yes	yes	yes	yes	yes
FDA regulation CFR Vol. 21 § 177 Food contact notification – FCN			FCN 103	FCN 103	FCN 103	FCN 103	FCN 103
Drug Master File (DMF)			8464	8464	8464	8464	8464
Device Master File (MAF)			315	315	315	315	315
<b>Conformances – Pharmaceuticals</b>							
USP Class VI			yes	yes	yes	yes	yes
Cytotoxicity			yes	yes	yes	yes	yes
<b>Sterilization</b>							
Ethylene oxide			excellent	excellent	excellent	excellent	excellent
Superheated steam 121/134°C			possible/ possible	possible/ possible	possible/ possible	possible/ possible	possible/ possible
Gamma radiation			excellent	excellent	excellent	excellent	excellent



**HEALTHCARE MATERIALS**  
healthcare.celanese.com

---

#### Contact Information

Engineered Materials and  
EVA Polymers

t: +1-800-914-9405

e: [healthcare@celanese.com](mailto:healthcare@celanese.com)

Food Ingredients

t: +1-800-786-3883

e: [foodingredients-am@celanese.com](mailto:foodingredients-am@celanese.com)

---

Copyright © 2018 Celanese or its affiliates. All rights reserved.

Celanese®, registered C-ball design and all other trademarks identified herein with the ©, TM, SM, unless otherwise noted, are trademarks of Celanese or its affiliates.

This publication was printed March 2018 based on Celanese's present state of knowledge, and Celanese undertakes no obligation to update it. Because conditions of product use are outside Celanese's control, Celanese makes no warranties, express or implied, and assumes no liability in connection with any use of this information. Nothing herein is intended as a license to operate under or a recommendation to infringe any patents. MED-016-MedicalandPharmaPolymers-Bro-EN-r1-0418