

## Your supplier for medical plastics and specialities



Device Adhesives and Encapsulants  
 Engineering Polymers  
 High Performance Polymers  
 Polyolefins  
 Silicone Coatings and Lubricants  
 Silicone Elastomers  
 Silicone Tubings  
 Skin Adhesives  
 Styrenic Copolymers  
 Thermoplastic Elastomers  
 Transparent Polymers

## Medical Portfolio

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## Our principals for medical specialties



# Silicone Coatings and Lubricants

## Non-Curing Siliconisation Fluid

Product	Description	Grade
<b>360 Medical Fluid</b> <b>20 cSt</b> <b>100 cSt</b> <b>350 cSt</b> <b>1000 cSt</b> <b>12500 cSt</b>	Polydimethylsiloxane Dimeticones in various viscosities Bacterial endotoxins controlled	Dimethicone NF Dimethicone/Silicone Oil EP Certificate of Suitability (CEP) US-DMF
<b>366,35 % Dimethicone NF Emulsion</b>	Emulsion containing 35 % of Dow Corning™ 360 Medical Fluid 350 cSt	TF

- Lubricants for medical device components, glass, metals, plastics and rubbers
  - Hydrophobic: Dow Corning™ 360 Medical Fluid
  - Water-dilutable: Dow Corning™ 366, 35 % Dimethicone NF Emulsion
- Siliconisation of syringes, vials, ampoules, stoppers, filaments and medical device components

## Curing Siliconisation Fluid

Product	Description	Grade
<b>MDX4-4159 50 % Medical Grade Dispersion</b>	50 % dispersion of an amino functional dimethylsiloxane copolymer	US-DMF

- Cures at room temperature to form a dry coating
- Lubricant for cutting edges, hypodermic needles and cannulas

## Solvent for Siliconisation

Product	Description	Grade
<b>Q7-9180 Silicone Fluid</b> <b>0.65 cSt</b> <b>1.0 cSt</b>	Hexamethyldisiloxane Octamethyltrisiloxane High purity, volatile silicone fluids	US-DMF, TF

- Solvent for Dow Corning™ 360 Medical Fluid and MDX4-4159 50 % Medical Grade Dispersion

# Silicone Skin Adhesives

## Pressure Sensitive Adhesives (PSA)

Product	Description	Grade
<b>MG-2401 Silicone PSA</b>	Solvent: Hexamethyldisiloxane Medium tack 32 % solid content	Medical device Grade  Cytotoxicity, Skin Irritation & Skin Sensitization in compliance with ISO 10993  One-Part, polycondensed Polydimethylsiloxane/ silicate resin adhesive
<b>MG-2402 Silicone PSA</b>	Solvent: Ethyl Acetate Medium tack 64 % solid content	
<b>MG-2502 Silicone PSA</b>	Solvent: Ethyl Acetate High tack 59 % solid Content	
<b>MG-2410 Silicone PSA</b>	Hot-Melt Very High tack Melt viscosity: 30.300 cP	

- High adhesion and conformity to skin
- Extended wear times
- High gas and moisture permeability
- Non-sensitizing, non-irritating
- Adhesion of dressings, prosthetics, sensors and other devices to the body

## Soft Skin Adhesives (SSA)

Product	Description	Application
<b>7-9700 Soft Skin Adhesive</b> <b>MG 7-9800 Soft Skin Adhesive</b> <b>MG 7-9850 Soft Skin Adhesive</b> <b>MG 7-9900 Soft Skin Adhesive</b>	Two-part, platinum-catalyzed, soft, fillerless silicone elastomeric adhesive Transparent Low viscosity Solvent free	Medical device with gentle removal

- For scar therapy, wound dressing and other medical device applications providing
- Gentle skin adhesion, atraumatic removal
- Low peel release force
- Adhesion properties are maintained after several applications
- Polyolefinic release liners

## Complementary products

Product	Description	Grade
<b>IT CF-0604 Adhesion promoter</b>	Titanium Tetrabutanolat Primer dispersed in volatile silicone solvent	Precedence of use in medical device applications
<b>7-4107 Silicone Elastomer Membrane</b>	Soft flexible silicone backing substrate Layer thickness ~ 75 µm Supplied on polycarbonate carrier	Made from 50 Shore Medical Grade Liquid Silicone Rubber

# Device Adhesives and Encapsulants

## Multipurpose Adhesives

	Unique Product Features	Properties							
		Recommended Substrates	Nominal Viscosity cP	Rheology	Durometer Hardness	Tensile Break MPa; psi	Elongation @Break %	Elastic Modulus	Fluorescing
<b>1072-M</b>	Flexible, moisture resistant Plastic bonder	COC, COP, SS, PS, PU, PVC	1.000	Newtonian	A58	4,8 700	700	3,4 500	no
<b>1120-M</b>	LED-Curable Plastic bonder	ABS, PA, PC, PS, PU, PVC	300	Newtonian	D70	19; 2.800	30	158 23.000	Ultra-red®
<b>1121-M</b>	LED Curable Plastic bonder	ABS, PC, PU, PVC	450	Newtonian	D65	15,8 2.300	225	175,8 25.500	Blue
<b>1128A-M</b>	Impact resistant Adhesive with secondary heat cure	SS, AL, NiTi, PA, PU, ABS, GL	600	Newtonian	D80	30 4.300	13	640 93.000	Blue
<b>1162-M</b>	Low Viscosity Plastic-to-metal Bonder	PC, SS, GL, PVC, ABS	200	Newtonian	D75	15 2.100	140	390 57.000	Blue
<b>1165-M</b>	Clear, flexible plastics Adhesive	PC, PVC, PU, ABS, EVA	11.500	Newtonian	A55	2,6 380	200	1,6 230	Blue
<b>1180-M</b>	Universal metal & Plastic bonder	PC, PVC, PU, ABS, SS	150	Newtonian	D70	17 2.400	90	310 45.000	Blue
<b>1180-M-UR</b>	Universal metal & Plastic bonder	PC, PVC, PU, ABS, SS	150	Newtonian	D70	17 2.500	66	330 48.000	Ultra-Red®
<b>1187-M</b>	Moisture-resistant, flexible Plastic Bonder	PC, PVC, ABS, PET	450	Newtonian	D60	19,9 2.900	200	158 23.000	Blue
<b>1201-M-SC</b>	Flexible Adhesive with See-Cure	PC, PVC, PU, ABS, PET, PEBA	600	Newtonian	D60	14 2.000	170	120 17.000	No
<b>1202-M-SC</b>	Flexible See-Cure	PC, PVC, PU, ABS, PET, PEBA	600	Newtonian	D60	14 2.000	170	120 17.000	No
<b>1204-M-SC</b>	Flexible, low shrinkage, See-Cure	PVC, PU, ABS, PC, EVA	12.000	Newtonian	A60	6,9 1.000	380	5,1 740	No
<b>1208-T-UR-SC</b>	LED curable, Plastic and Metal bonder, Encompass™	ABS, PC, PMMA, PS, SS	6.000	Thixotropic	D70	19 2.800	170	277 40.300	Ultra-Red®
<b>1209-M-UR-SC</b>	Self-leveling, Encompass™	ABS, PC, PS, PVC, SEBS	Tbd	Newtonian	Tbd	15,6 2.275	770	641 93.000	Ultra-Red®



## Catheter Assembly Adhesives

	Unique Product Features	Properties							
		Recommended Substrates	Nominal Viscosity cP	Rheology	Durometer Hardness	Tensile Break MPa; psi	Elongation @Break %	Elastic Modulus	Fluorescing
<b>201-CTH Range</b>	Low Durometer, plastics & metals	ABS, NiTi, PC, PS, PU	450 & 6.500	Newtonian & Thixotropic	D30	9 1.300	270	17 2.400	no
<b>203A-CTH Range</b>	Catheter and Guidewires, secondary heat cure	ABS, NiTi, PS, PSU	Various 55 – 11.000	Newtonian & Thixotropic	D80 -D85	28 - 32 3.800 – 4.600	7 - 13	550 – 640; 80.000 – 93.000	Blue
<b>204-CTH Range</b>	Nylon, PEBA and other Plastics	PA, PC, PEBA, PET, PU, PVC	Various 150 – 24.000	Newtonian & Thixotropic	D50 – D60	12 – 19 1.800 – 2.700	150 - 240	34 – 350; 5.000 – 51.000	Blue
<b>206-CTH</b>	General Purpose	ABS, PC, PET, PETG, PS	150 & 6000	Newtonian & Thixotropic	D70	17,2 2.500	90	308 44.800	Blue
<b>208-CTH</b>	Nylon & PEBA	ABS, PA, PC, PEBA, PET, PS, PU, PVC	225	Newtonian	D55	9 1.300	250	69 10.000	Blue
<b>209-CTH</b>	Multipurpose Adhesive	ABS, PC, PET, PS	300	Newtonian	D70	17 2.500	120	300 44.000	Blue
<b>210-CTH</b>	LED Curable	ABS, PA, PC, PVC, PU	150	Newtonian	D65	17 2.400	90	310 45.000	Blue
<b>211-CTH-SC</b>	LED Cure, See-Cure	ABS, PA, PC, PVC, PU	450	Newtonian	D70	16 2.300	140	320 46.000	No
<b>212-CTH-UR</b>	LED Cure, Encompass®	PC, PL, PS, PVC	10.000	Thixotropic	D62	18 2.600	185	116 17.000	Ultra-Red®
<b>215-CTH-UR-SC</b>	LED Cure, Plastic Bonder, Encompass™	ABS, Nylon 12, PC, PEBA, PET, PVC	20.000	Thixotropic	D53	15.1 2.200	360	165 24.000	Ultra-Red®

## Needle Bonding

	Unique Product Features	Properties							
		Recommended Substrates	Nominal Viscosity cP	Rheology	Durometer Hardness	Tensile Break MPa; psi	Elongation @Break %	Elastic Modulus	Fluorescing
<b>1160-M</b>	Low viscosity Adhesive for tight tolerances	ABS, PC, SS	90	Newtonian	D75	21 3.000	50	510 74.000	
<b>1161-M</b>	Multipurpose	ABS, PC, SS	300	Newtonian	D75	21 3.000	120	300 44.000	Blue
<b>1162-M</b>	Multipurpose	ABS, PC, PP, SS	200	Newtonian	D75	14 21.000	160	393 57.000	Blue
<b>1163-M</b>	Multipurpose	ABS, PC	5.000	Newtonian	D55	13 1.900	160	90 136.000	Blue
<b>1180-M Range</b>	Variety of Viscosity and Rheological characteristics	ABS, GL, PP, SS	150 – 6.000	Newtonian	D70	17 2.500	66 & 150	330 48.000	Blue
<b>1193-M Range</b>	High speed manufacturing	PC, PP, SS	2.800	Thixotropic	D70	18 & 21; 2.600 & 3.100	180 & 200	190 & 250 28.000 & 36.000	Blue & Ultra-Red®
<b>1400-M Range</b>	LED Cureable adhesives for metals and plastics, high speed needle bonding	PC, PS, SS, PMMA, ABS, PP, PETG	150 – 7.000	Newtonian & Thixotropic	D57 – D70	15 – 23; 2.200 – 3.400	80 – 180	359 – 447; 55.000 – 65.000	Blue & Ultra-Red® Blue & Ultra-Red®
<b>NEW 1406-M</b>	LED optimized 385/405 nm, resists yellowing, low viscosity for improved wetting, fast cure, superior water resistance	ABS, PC, PEI, PETG, PMMA, PS, SS, PE & PP may require surface treatment	150	Thixotropic	D70	15 & 2.200	120	419 / 60.800	Blue

## RTV – Low Consistency Rubber

Product	Description	Grade
<b>SILASTIC™ MDX4-4210 Medical Grade Elastomer</b>	Two-part, platinum-catalyzed, room-temperature-curing and pourable silicone elastomer	EP 3.1.9. „Silicone elastomer for closures and tubing“  Meets USP Class VI, 90-day implant

- Biomedical Grade
- Medical device encapsulation, mold making and prototyping

## RTV Adhesive

Product	Description	Grade
<b>Silastic™ Medical Adhesive Silicone, Type A</b>	One-part, low-slump, translucent silicone material, solventless Cures at room temperature between 50-60 % relative humidity	USP Class VI, 90-day implant

- Assembling and sealing of medical device components
- Encapsulating of electrical components for medical devices
- Can be diluted with Q7-9180 Fluids to desired concentration and viscosity

## Soft Filling Elastomer

Product	Description	Grade
<b>7-9600 Soft Filling Elastomer</b>	Two-part, platinum-catalyzed unfilled silicone elastomer	DMF

- Filling material for external form prostheses and pressure cushions

# Silicone Elastomers

## High Consistency Rubber (HCR)

Product	Description	Grade
<b>QP1-xx Silicone Elastomer</b>	Uncatalysed silicone rubber base Processable by peroxide or addition cure For addition cure cross linkers, catalysts and cure inhibitors are offered separately xx: available in various durometers (30, 50, 60, 70)	Appropriate quality principles Biocompatibility tests (see table page 14)
<b>C6-1xx Silicone Elastomer</b>	Two-part, platinum catalyzed HCR xx: available in various durometers (35, 50, 65, 80)	EP 3.1.9. "Silicone elastomer for closures and tubing" - Volatile matter - Subst. soluble in hexane FDA Regulation 21 CFR 177.2600 Biocompatibility tests (see table page 14)
<b>C6-2xx Silicone Elastomer</b>	One-part, enhanced tear resistant HCR HCR for peroxide cure Peroxide initiator selected by customer xx: available in various durometers (35, 50, 65)	EP 3.1.9. "Silicone elastomer for closures and tubing" - Volatile matter - Subst. soluble in hexane FDA Regulation 21 CFR 177.2600 Biocompatibility tests (see table page 14)
<b>C6-350 LH</b>	Two-part, platinum catalyzed HCR 50 Shore Low Hysteresis for demanding applications like peristaltic pump tubing	EP 3.1.9. "Silicone elastomer for closures and tubing" - Volatile matter - Subst. soluble in hexane FDA Regulation 21 CFR 177.2600 Biocompatibility tests (see table page 14)
<b>Silastic™ Q7-47xx BioMedical Grade HCR</b>	Two-part, platinum-catalyzed, enhanced tear-resistant silicone elastomers xx: available in various durometers (20, 35, 50, 65, 80)	EP 3.1.9. "Silicone elastomer for closures and tubing" - Volatile matter - Subst. soluble in hexane TF FDA Regulation 21 CFR 177.2600 Biocompatibility tests (see table page 14)
<b>Silastic™ Q7-45xx BioMedical Grade HCR</b>	One-component, peroxide-cured, enhanced tear-resistant silicone elastomers xx: available in various durometers (35, 50, 65)	EP 3.1.9. "Silicone elastomer for closures and tubing" - Volatile matter - Subst. soluble in hexane TF FDA Regulation 21 CFR 177.2600 Biocompatibility tests (see table page 14)

- Fabrication of medical/surgical/diagnostic devices and components
- Fabrication of extruded parts

## Liquid Silicone Rubber (LSR)

Product	Description	Grade
<b>QP1-xx Liquid Silicone Rubber</b>	Two-part, platinum catalyzed liquid silicone rubbers xx: available in various durometers (20, 30, 40, 45, 50, 60, 70, 75) Excellent mechanical properties: - High tear strength - Low compression set - Reduced mold fouling	Appropriate quality principles Biocompatibility tests (see table page 14)
<b>QP1-2xx Liquid Silicone Rubber</b>	Two-part, platinum catalyzed liquid silicone rubbers 2xx: available in various durometers (30, 40, 50, 60, 70) Optimized formulation for: - Reduced processing cycles - Improved pot life (72 hours at 25°C after mixing) - Improved rheological profile for intricate parts	Appropriate quality principles Biocompatibility tests (see table page 14)
<b>C6-5xx Elastomer</b>	Two-part, platinum catalyzed liquid silicone rubbers xx: available in various durometers (30, 40, 50, 60, 70)	EP 3.1.9. "Silicone elastomer for closures and tubing" - Volatile Matter - Subst. soluble in hexane FDA Regulation 21 CFR 177.2600 Biocompatibility tests (see table page 14)
<b>Silastic™ Q7-48xx BioMedical Grade LSR</b>	Two-part, platinum-catalyzed liquid silicone rubbers xx: available in various durometers (40, 50, 60, 70)	EP 3.1.9. "Silicone elastomer for closures and tubing" - Volatile matter - Subst. soluble in hexane TF FDA Regulation 21 CFR 177.2600 Biocompatibility tests (see table page 14)

- Injection molding of precision and intricate parts of medical devices (O-rings, stoppers and closures)
- Designed for fully automatic molding systems
- Fabric coating

# Biocompatibility Tests – Dow Corning™ Silicone Elastomers

	Dow Corning™ QP1-xx Series	Dow Corning™ QP1-2xx Series	Dow Corning™ Class VI Series	Dow Corning™ BioMedical Grade Series
<b>Cytotoxicity<sup>(1)</sup></b>	•	•	•	•
<b>Mutagenicity</b>				•
<b>Hemolysis</b>				•
<b>Skin Sensitization</b>		• <sup>(3)</sup>	•	•
<b>Pyrogenicity (USP)</b>				•
<b>90-day Implant (exceeds USP Class VI)</b>				•
<b>&lt;29-day Implant (exceeds USP Class VI)</b>	•	•	•	•
<b>USP Class V and VI<sup>(2)</sup></b>	•	•	•	•
<b>Selected EP Tests<sup>(4)</sup></b>			•	•

(1) ISO 10993-5: Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity (2009)

(2) USP Plastic Class VI: United States Pharmacopeia (USP) Biologic Reactivity Tests, In Vivo

(3) Representative testing performed for highest and lowest durometer

(4) Monograph 3.1.9: Silicone Elastomer for Closures and Tubing: Substances soluble in hexane & volatile matter

# Silicone Tubing

## Medical Tubing

Product	Description	Grade
<b>Silastic™ Medical Grade Tubing</b> <b>Rx-50</b> <b>Rx-65</b> <b>Rx-80</b> <b>Rx Pump</b>	Platinum-cured silicone tubing Extruded from Silastic™ brand Bio Medical Grade Elastomer	EP 3.1.9. "Silicone elastomer for closures and tubing" USP Class VI FDA and ISO criteria cGMP

- Ensures maximum biocompatibility
- Suitable for human contact up to 29 days
- RX Pump: Bacterial Endotoxin (LAL) and batch pyrogen testing performed
- Infusion therapy (drug delivery, nutritional therapy/feeding tubes)
- Medical catheters (urology catheters, respiration catheters)

## Pharma Tubing

Product	Description	Grade
<b>Pharma Tubing</b> <b>50 Shore A</b> <b>65 Shore A</b> <b>80 Shore A</b>	Platinum-cured silicone tubing For high purity pharmaceutical fluid transfer and filling applications	EP 3.1.9. "Silicone elastomer for closures and tubing" USP Class VI, FDA and ISO criteria cGMP
<b>Pharma Reinforced Tubing</b> <b>65 Shore A</b>	Platinum-cured silicone tubing Fiber-reinforced tubing for high-pressure and vacuum applications	EP 3.1.9. "Silicone elastomer for closures and tubing" USP Class VI, FDA and ISO criteria
<b>Pharma Advanced Pump Tubing</b>	Specifically formulated platinum-cured silicone tubing for peristaltic pump applications Providing up to six times the pump life of standard platinum-cured silicone tubing	EP 3.1.9. "Silicone elastomer for closures and tubing" USP Class VI, FDA and ISO criteria cGMP

- Pharmaceutical grade silicone tubing
- For high purity pharmaceutical & biotechnological fluid transfer and filling application
- Increased kink and pressure resistance with higher durometers
- Extruded from Silastic™ brand BioMedical Grade Elastomer

## Our Principals for medical plastics





## INEOS Olefins & Polymers – Polypropylene (PP)

**Characteristics** Eltex® MED – excellent optical properties, high transparency, low odour, high purity

**Medical Applications** inhaler components, syringe cylinders & pistons, thin-walled containers for pharmaceutical applications, BFS – Blow Fill Seal (bottles and ampoules) – \* PP terpolymer for film applications, medical IV bags

Grade	MFR (230°C/2,16 kg) (g/10min)	Flexural Modulus (MPa)	Approvals					Sterilization		
			FDA	USP	EP	DMF	EFSA	Steam	EtO	Gamma

### Eltex® MED HPP

100-MG03	3	1450	x	x	3.1.3; 3.1.6	x	x	x	(x)	–
100-MG12	12	1400	x	x	3.1.3; 3.1.6	x	x	x	(x)	–
100-MG25	25	1200	x	x	3.1.3; 3.1.6	x	x	x	(x)	–

### Eltex® MED RCP

200-MG02	1,8	900	x	x	3.1.3; 3.1.6	x	x	x	(x)	–
240-MS23	23	980	x	x	–	–	x	x	x	–
KS357*	5	620	x	x	3.1.3	–	x	x	(x)	–

(x) upon request

## INEOS Olefins & Polymers – High Density Polyethylene (HDPE)

**Characteristics** Eltex® MED – high flow, good dimensional stability, high purity  
Eltex® – good chemical resistance, best organoleptic properties

**Medical Applications** syringes (syringe piston), thin-walled containers for pharmaceutical applications, caps & closures

Grade	MFR (190°C/2,16 kg) (g/10min)	Density (MPa)	Approvals					Sterilization		
			FDA	USP	EP	DMF	EFSA	Steam	EtO	Gamma

### Eltex® MED

HD5226EA-M	26	953	x	x	3.1.3; 3.1.5	x	x	x	x	–
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### Eltex®

HD5130EA-B	2,4	952	x	–	(x)	x	x	(x)	(x)	–
HD5211EA-B	11	951	x	–	(x)	–	x	(x)	(x)	–
HD6070EA-B	7,6	960	x	–	(x)	–	x	(x)	(x)	–

### Rigidex®

HD5502S	0,2	954	x	–	(x)	–	x	x	(x)	–
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(x) upon request

## INEOS Olefins & Polymers – Low Density Polyethylene (LDPE)

**Characteristics** Eltex® MED – good flow properties, good dimensional stability, high degree of cleanliness

**Medical Applications** BFS – Blow Fill Seal (bottles and ampoules), medical tubes, film applications

Grade	MFR (190°C/2,16 kg) (g/10min)	Density (kg/m³)	Approvals					Sterilization		
			FDA	USP	EP	DMF	EFSA	Steam	EtO	Gamma

### Eltex® MED

PH19N630	7,5	920	x	x	3.1.3; 3.1.4	–	x	–	x	x
PH22D630	0,3	922	x	x	3.1.3; 3.1.4	x	x	–	(x)	–
PH23H630	2	923	x	x	3.1.3; 3.1.4	x	x	–	(x)	–
PH23T630	22	923	x	x	3.1.3; 3.1.4	x	x	–	x	x
PH27D630	0,3	927	x	x	3.1.3; 3.1.4	x	x	x	(x)	–

### INEOS LDPE

19N430	7,5	920	x	–	3.1.4	–	x	–	(x)	–
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(x) upon request

## SK CHEMICALS – Polyethylenterephthalat (PET) and in glycolmodified (PETG)

**Characteristics** SKYPET® PET BR – high clarity, excellent chemical resistance, easily recyclable  
SKYGREEN® PETG S2008 – high clarity, good impact strength, easy thermoforming, good printability

**Medical Applications** blister packaging, disposable syringes, medical dishes and containers, clamshell

Grade	IV Intrinsic Viscosity	Density (kg/m³)	Approvals					Sterilization		
			FDA	USP	EP	DMF	EFSA	Steam	EtO	Gamma

### SKYPET® PET

BR	0,8	1330	x	x	x	x	x	–	x	x
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### SKYGREEN® PETG

S2008	0,78	1270	x	x	–	x	x	–	x	x
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## Solvay Specialty Polymers – Polyphenylsulfone (PPSU)

### Characteristics

Radel® – Incredibly tough, transparent plastic with a heat deflection temperature (HDT) of 207°C, excellent chemical resistance, and the ability to withstand more than 1,000 cycles of steam sterilization without any significant loss of properties. Opaque and transparent colors available.

### Medical

### Applications

Sterilization cases and trays, orthopedic devices, medical and dental instruments

Grade	MFR (g/10min)	Density (kg/m³)	Agency					Sterilization		
			FDA*	ISO 10993*	USP	DMF	EFSA	Steam	EtO	Gamma (40kGy)

### Radel®

<b>R-5000</b>	14 - 20	1290	x	x	x	-	-	x	x	x
<b>R-5100</b>	14 - 20	1290	x	x	x	-	-	x	x	x
<b>R-5800</b>	20 - 28	1290	x	x	x	-	-	x	x	x

\* Base resin is compliant. Please check with your Sales Representative to confirm that the color you purchase has the approval.

## Solvay Specialty Polymers – Polyethersulfone (PESU)

### Characteristics

Veradel® HC - rigid, high-temperature, transparent polymer offered for use in high-performance healthcare applications. The material is inherently flame retardant and highly resistant to a wide range of healthcare cleaning and disinfecting agents. It retains its transparency, mechanical properties and dimensional stability in humid, high-heat environments. It is compatible with sterilization via ethylene oxide, vaporized hydrogen peroxide, gamma radiation and steam.

### Medical

### Applications

Medical device housings

Grade	MFR (g/10min)	Density (kg/m³)	Agency					Sterilization		
			FDA*	ISO 10993*	USP	DMF	EFSA	Steam	EtO	Gamma (40kGy)

### Veradel® HC

<b>HC A-301 NT</b>	30	1370	x	x	x	-	-	x	x	x
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## Solvay Speciality Polymers – Polysulfone (PSU)

### Characteristics

Udel® – Near water-white transparent plastic with an HDT of 174°C, high strength, good chemical resistance and excellent dimensional stability when exposed to steam and oxidizing agents. Opaque, transparent and glass-filled grades available.

### Medical Applications

Medical and dental instruments, suction bottles, tubing connections, device housings, hemodialysis membranes

Grade	MFR (g/10min)	Density (kg/m³)	Agency					Sterilization		
			FDA*	ISO 10993*	USP	DMF	EFSA	Steam (40kGy)	EtO	Gamma (40kGy)

### Udel®

<b>GF-110</b>	5 - 9	1330	x	x	-	-	-	x	x	x
<b>GF-120</b>	5 - 9	1400	x	x	-	-	-	x	x	x
<b>P-1700</b>	5 - 9	1240	x	x	x	-	-	x	x	x
<b>P-3500 LCD</b>	5 - 9	1240	x	x	x	-	-	x	x	x
<b>P-3703</b>	14 - 20	1240	x	x	x	-	-	x	x	x

\* Base resin is compliant. Please check with your Sales Representative to confirm that the color you purchase has the approval.

## DuPont - Polyoxymethylene-Homopolymer (POM)

### Characteristics

Delrin® – high abrasion resistance, good creep resistance, dimensional stability

### Medical Applications

injector pens, inhaler, dosing units

Grade	Description	Approvals							Sterilization		
		FDA	USP	EP	ISO*	DMF	EFSA	GMP	Steam	EtO	Gamma

### Delrin®

<b>SC631</b>	low / medium flow	x	x	-	x	-	x	x	x	x	-
<b>SC655</b>	medium flow	x	x	-	x	-	x	x	x	x	-
<b>SC690</b>	high flow	x	x	-	x	-	x	x	x	x	-
<b>SC698</b>	high flow; silicone oil filled	x	x	-	x	-	x	x	x	x	-

\* Part 5 + 11

All DuPont products are manufactured according to Good Manufacturing Practice (GMP) principles.

## DuPont – Thermoplastic Polyester Elastomer (TPC-ET)

**Characteristics** Hytel® – good flexibility, sterilization resistance, chemical resistance, low material fatigue, high load resistance

**Medical Applications** high load resistance tubing, wrist guard, foot prosthesis

Grade	Hardness	Approvals							Sterilization		
		FDA	USP	EP	ISO*	DMF	EFSA	GMP	Steam	EtO	Gamma

### Hytel®

<b>SC956</b>	55D durometer	x	x	-	x	-	-	x	x	x	x
<b>SC969</b>	63D durometer	x	x	-	x	-	x	x	x	x	x
<b>SC976</b>	72D durometer	x	x	-	x	-	-	x	x	x	x
<b>SC988</b>	82D durometer	x	x	-	x	-	-	x	x	x	x

\* Part 5 + 11

## DuPont – Polybutylene Terephthalate (PBT)

**Characteristics** Crastin® – excellent surface finishes, good colourability, chemical resistance

**Medical Applications** components for insulin syringes

Grade	Description	Approvals							Sterilization		
		FDA	USP	EP	ISO*	DMF	EFSA	GMP	Steam	EtO	Gamma

### Crastin®

<b>SC164</b>	unreinforced, low viscosity	x	x	-	x	-	x	x	x	x	x
<b>SC193</b>	30 % glass fiber reinforced	x	x	-	x	-	x	x	x	x	x

\* Part 5 + 11

## DuPont – Polyamide (PA)

**Characteristics** Zytel® – high mechanical strength, simultaneous rigidity and impact resistance

**Medical Applications** forceps and dental compules, medical valves, filters, syringe bodies

Grade	Description	Approvals							Sterilization		
		FDA	USP	EP	ISO*	DMF	EFSA	GMP	Steam	EtO	Gamma

### Zytel®

<b>SC310</b>	high flow; PA 6.6	x	x	-	x	-	x	x	x	x	x
<b>SC315</b>	high flow; PA 6.12	x	x	-	x	-	x	x	x	x	-

\* Part 5 + 11

## LG – Methylmetacrylat-Acrylnitril-Butadien-Styrol (M-ABS)

### Characteristics

excellent transparency close to Acrylic or PC resin, impact strength, stiffness and processability, wellbalanced properties, izod impact strength and falling dart impact of LG TR ABS is relatively similar to general ABS, it is not easily cracked in the condition of low impact energy.

Grade	MFI 220°C/10kg (cm³/10min)	Density (kg/m³)	Agency					Sterilization		
			FDA	USP	EP	DMF	EFSA	Steam	EtO	Gamma

### LG TR-ABS

TR-556	5	1090	x	x	-	-	x	-	x	-
TR-557	21	1090	x	x	-	-	x	-	x	-
TR-558A	25	1011	x	x	-	-	x	-	x	-

## Idemitsu – Polycarbonate (PC)

### Characteristics

In addition to impact strength expressed in its name, the various superior properties of Tarflon®, such as transparency, heat resistance and dimensional precision are out to use widely in a variety of applications.

### Medical

### Applications

laboratory equipment, medical packaging

Grade	MVR 300°C/1,2kg (cm³/10min)	Density (kg/m³)	Approvals					Sterilization		
			FDA	USP	EP	DMF	EFSA	Steam 134°C (no load)	EtO	Gamma

### Tarflon®

IR 1700	27	1200	x	x	-	-	x	x	x	x
IR 1900	19	1200	x	x	-	-	x	x	x	x
IR 2200	12	1200	x	x	-	-	x	x	x	x
IR 2500	8	1200	x	x	-	-	x	x	x	x
IR 2600	6	1200	x	x	-	-	x	x	x	x

## BASF Polyurethanes – Thermoplastic Polyurethan (TPU) – Elastollan® Ether-TPU

### Elastollan®

### Characteristics

Shore A 70 – Shore D 74, high flexibility, superior mechanical strength, low abrasion, outstanding hydrolysis resistance, good resistance to micro-organisms and excellent transparency.

### Medical

### Applications

Use of all BASF PU materials in medical applications requires prior approval by BASF PU. Approvals depend on the specific application requirements of the respective grades and need to be checked and confirmed by BASF PU.

## USI – Cyclic Block Copolymers (CBC)

### Characteristics

The main properties of CBC include high transparency, superb purity, low extractables, excellent chemical resistance, low moisture uptake, low autofluorescence and superior UV-Vis transmittance

### Medical Applications

Bio-diagnostic devices, syringes, vials, laboratory equipment, medical packaging, dental applications, microwell plates

Grade	MVR (260°C / 2.16 kg) (g/10 min)	Density (kg/m <sup>3</sup> )	Approvals					Sterilization		
			FDA	USP	EP	DMF	EFSA	Steam	EtO	Gamma

### ViviOn™

<b>ViviOn™ 1325</b>	13	940	x	x	-	x	-	x	x	x
<b>ViviOn™ 0510</b>	4.5	940	x	x	-	x	-	x	x	x
<b>ViviOn™ 8210</b>	200	940	x	x	-	x	-	x	x	x

## Approvals

**FDA** - The Food and Drug Administration (FDA) is an agency within the US Public Health Service that provides a number of health-related services and sets standards regarding the packaging and labeling of food. All drugs and medical devices admitted in the USA have to be examined by the FDA and have to be compliant with their regulations.

**ISO 10993** - The ISO 10993, regulated by the International Organization for Standardization (ISO), is a standard series for the biological evaluation of medical devices. The aim of the standard is to evaluate the biological assessment regarding the biocompatibility of the materials with the human body.

Test	Method
Genotoxicity	ISO 10993-3
Cytotoxicity	ISO 10993-5
Bone and muscle implant tests	ISO 10993-6
Sensitization	ISO 10993-10
Intracutaneous toxicity	ISO 10993-10
Acute systemic toxicity	ISO 10993-11
Subchronic toxicity	ISO 10993-11
Complete characterization <sup>(1)</sup>	ISO 10993-18
Physico-chemical	ISO 10993-18

*(1) Including exhaustive extractions and risk assessment*

**DMF** - A Drug Master File (DMF) is a confidential, detailed document about active substances contained in the medical product. It is submitted from manufacturers to the U.S. Food and Drug Administration (FDA). A DMF contains the chemistry, manufacturing and controls of a component of a drug product. There is no legal obligation to create a DMF and to submit it to the authorities.

**USP** - The United States Pharmacopeia (USP) includes standards to guarantee the quality and purity of medicines and health technologies worldwide. It covers tests relating to the biological reactivity of elastomers, plastics and other polymer materials with direct or indirect customer contact. USP Class VI is the most stringent test and accepted in the sector.

**EP** - The European Pharmacopoeia (EP) includes the quality check of pharmaceuticals in Europe. All in the European countries produced medicines and medical devices must correspond to the set. EP Quality standards (Europe)

EP 3.1.3	Release of pharmaceuticals of some additives
EP 3.1.4	Release of pharmaceuticals of PE without additives
EP 3.1.5	Release of pharmaceuticals of PE with additives (Additives will be checked for compatibility of pharmaceuticals)
EP 3.1.6	Release of pharmaceuticals of PP with additives (Additives will be checked for compatibility of pharmaceuticals)
EP 3.1.9	Silicone Elastomer for Closures and Tubing

**EFSA** - The European Food Safety Authority (EFSA) is an European agency that provides information and scientific advice on existing and emerging risks in the food chain. It covers all topics that have a direct or indirect impact on food and feed safety, including animal health and welfare, plant protection, plant health, and nutrition.



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## Notes

## Notes



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