

Your supplier for medical plastics and specialities



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

Medical Portfolio

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Our principals for medical specialities



Silicone Coatings and Lubricants

Dow Silicones Corporation

Non-Curing Siliconisation Fluid

Product	Description	Grade
360 Medical Fluid 20 cSt 100 cSt 350 cSt 1000 cSt 12500 cSt	Polydimethylsiloxane Dimeticones in various viscosities Bacterial endotoxins controlled	Dimethicone NF Dimethicone/Silicone Oil EP Certificate of Suitability (CEP) US-DMF
365,35 % Dimethicone NF Emulsion 366,35 % Dimethicone NF Emulsion	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™ 365 and Dow Corning™ 366, 35 % Dimethicone NF Emulsion
- Siliconisation of syringes, vials, ampoules, stoppers, filaments and medical device components

Curing Siliconisation Fluid

Product	Description	Grade
MDX4-4159 50 % Medical Grade Dispersion	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
Q7-9180 Silicone Fluid 0.65 cSt 1.0 cSt	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

Dow Silicones Corporation

Pressure Sensitive Adhesives (PSA)

Product	Description	Grade
MG-2401 Silicone PSA	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
MG-2501 Silicone PSA	Solvent: Ethyl Acetate Medium tack 64 % solid content	
MG-2502 Silicone PSA	Solvent: Ethyl Acetate High tack 59 % solid Content	
MG-2410 Silicone PSA	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)

New Product	Description	Application
MG 7-1010	Two-part, platinum-catalyzed, soft, fillerless silicone elastomeric adhesive, transparent, low viscosity, solventless High adhesion Fast cure	Wearable monitoring, medical tapes, diagnostics

- Highest adhesion performance in SSA offering
- Provides design flexibility regarding coat weight and adhesion level
- High substrate anchorage on most substrates without priming
- Direct and transfer processing
- Fluorinated release liners

Product	Description	Application
7-9700 Soft Skin Adhesive MG 7-9800 Soft Skin Adhesive MG 7-9850 Soft Skin Adhesive MG 7-9900 Soft Skin Adhesive	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
IT CF-0604 Adhesion promoter	Titanium Tetrabutanolate Primer dispersed in volatile silicone solvent	Precedence of use in medical device applications
7-4107 Silicone Elastomer Membrane	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

Dymax MD® Adhesives Light Cure Technology

Multipurpose Adhesives

	Unique Product Features	Properties							
		Recommended Substrates	Nominal Viscosity cP	Rheology	Durmeter Hardness	Tensile Break MPa; psi	Elongation @Break %	Elastic Modulus	Fluorescing
1072-M	Flexible, moisture resistant Plastic bonder	COC, COP, SS, PS, PU, PVC	1.000	Newtonian	A58	4,8 700	700	3,4 500	no
1120-M	LED-Curable Plastic bonder	ABS, PA, PC, PS, PU, PVC	300	Newtonian	D70	19; 2.800	30	158 23.000	Ultra-red®
1121-M	LED Curable Plastic bonder	ABS, PC, PU, PVC	450	Newtonian	D65	15,8 2.300	225	175,8 25.500	Blue
1128A-M	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
1162-M	Low Viscosity Plastic-to-metal Bonder	PC, SS, GL, PVC, ABS	200	Newtonian	D75	15 2.100	140	390 57.000	Blue
1165-M	Clear, flexible plastics Adhesive	PC, PVC, PU, ABS, EVA	11.500	Newtonian	A55	2,6 380	200	1,6 230	Blue
1180-M	Universal metal & Plastic bonder	PC, PVC, PU, ABS, SS	150	Newtonian	D70	17 2.400	90	310 45.000	Blue
1180-M-UR	Universal metal & Plastic bonder	PC, PVC, PU, ABS, SS	150	Newtonian	D70	17 2.500	66	330 48.000	Ultra-Red®
1187-M	Moisture-resistant, flexible Plastic Bonder	PC, PVC, ABS, PET	450	Newtonian	D60	19,9 2.900	200	158 23.000	Blue
1201-M-SC	Flexible Adhesive with See-Cure	PC, PVC, PU, ABS, PET, PEBA	600	Newtonian	D60	14 2.000	170	120 17.000	No
1202-M-SC	Flexible See-Cure	PC, PVC, PU, ABS, PET, PEBA	600	Newtonian	D60	14 2.000	170	120 17.000	No
1204-M-SC	Flexible, low shrinkage, See-Cure	PVC, PU, ABS, PC, EVA	12.000	Newtonian	A60	6,9 1.000	380	5,1 740	No
1208-T-UR-SC	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®
1209-M-UR-SC	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	Durmeter Hardness	Tensile Break MPa; psi	Elongation @Break %	Elastic Modulus	Fluorescing
201-CTH Range	Low Durometer, plastics & metals	ABS, NiTi, PC, PS, PU	450 & 6.500	Newtonian & Thixotropic	D30	9 1.300	270	17 2.400	no
203A-CTH Range	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
204-CTH Range	Nylon, PEBA and other Plastics	PA, PC, PEBA, PET, PU, PVC	Various 150 – 24.000	Newtonian & Thixotropic	D50 – D60 D70	12 – 19 1.800 – 2.700	150 - 240	34 – 350; 5.000 – 51.000	Blue
206-CTH	General Purpose	ABS, PC, PET, PETG, PS	150 & 6000	Newtonian & Thixotropic	D55	17,2 2.500	90	308 44.800	Blue
208-CTH	Nylon & PEBA	ABS, PA, PC, PEBA, PET, PS, PU, PVC	225	Newtonian	D70	9 1.300	250	69 10.000	Blue
209-CTH	Multipurpose Adhesive	ABS, PC, PET, PS	300	Newtonian	D65	17 2.500	120	300 44.000	Blue
210-CTH	LED Curable	ABS, PA, PC, PVC, PU	150	Newtonian	D70	17 2.400	90	310 45.000	Blue
211-CTH-SC	LED Cure, See-Cure	ABS, PA, PC, PVC, PU	450	Newtonian	D62	16 2.300	140	320 46.000	No
212-CTH-UR	LED Cure, Encompass®	PC, PL, PS, PVC	10.000	Thixotropic	D53	18 2.600	185	116 17.000	Ultra-Red®
215-CTH-UR	LED Cure, Plastic Bonder, Encompass™	ABS, Nylon 12, PC, PEBA, PET, PVC	20.000	Thixotropic		15.1 2.200	360	165 24.000	Ultra-Red®

Needle Bonding

	Unique Product Features	Properties							
		Recommended Substrates	Nominal Viscosity cP	Rheology	Durmeter Hardness	Tensile Break MPa; psi	Elongation @Break %	Elastic Modulus	Fluorescing
1160-M	Low viscosity Adhesive for tight tolerances	ABS, PC, SS	90	Newtonian	D75	21 3.000	50	510 74.000	Blue
1161-M	Multipurpose	ABS, PC, SS	300	Newtonian	D75	21 3.000	120	300 44.000	Blue
1162-M	Multipurpose	ABS, PC, PP, SS	200	Newtonian	D75	14 21.000	160	393 57.000	Blue
1163-M	Multipurpose	ABS, PC	5.000	Newtonian	D55	13 1.900	160	90 136.000	Blue
1180-M Range	Variety of Viscosity and Rheological characteristics	ABS, GL, PP, SS	150 – 6.000	Newtonian	D70	17 2.500	66 & 150	330 48.000	Blue & Ultra-Red®
1193-M Range	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®
1400 Range	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®

Dow Silicones Corporation

RTV – Low Consistency Rubber

Product	Description	Grade
SILASTIC™ MDX4-4210 Medical Grade Elastomer	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
Silastic™ Medical Adhesive Silicone, Type A	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
7-9600 Soft Filling Elastomer	Two-part, platinum-catalyzed unfilled silicone elastomer	DMF

- Filling material for external form prostheses and pressure cushions

Silicone Elastomers

Dow Silicones Corporation

High Consistency Rubber (HCR)

Product	Description	Grade
QP1-xx Silicone Elastomer	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)
C6-1xx Silicone Elastomer	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)
C6-2xx Silicone Elastomer	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)
C6-350 LH	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)
Silastic™ Q7-47xx BioMedical Grade HCR	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)
Silastic™ Q7-45xx BioMedical Grade HCR	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
QP1-xx Liquid Silicone Rubber	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)
QP1-2xx Liquid Silicone Rubber	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)
C6-5xx Elastomer	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)
Silastic™ Q7-48xx BioMedical Grade LSR	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
Cytotoxicity⁽¹⁾	●	●	●	●
Mutagenicity				●
Hemolysis				●
Skin Sensitization		● ⁽³⁾	●	●
Pyrogenicity (USP)				●
90-day Implant (exceeds USP Class VI)				●
<29-day Implant (exceeds USP Class VI)	●	●	●	●
USP Class V and VI⁽²⁾	●	●	●	●
Selected EP Tests⁽⁴⁾			●	●

(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

Dow Silicones Corporation

Medical Tubing

Product	Description	Grade
Silastic™ Medical Grade Tubing Rx-50 Rx-65 Rx-80 Rx Pump	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
Pharma Tubing 50 Shore A 65 Shore A 80 Shore A	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
Pharma Reinforced Tubing 65 Shore A	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
Pharma Advanced Pump Tubing	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
- Vertically integrated supply chain

Our Principals for medical plastics

INEOS
Olefins & Polymers Europe



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 (MPa)	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

BASF – Polystyrene (PS)

Characteristics BASF – high heat resistance, good chemical resistance, good transparency (GPPS)

Medical Applications petri dishes, cuvettes, pipettes, disposable syringes

Grade	MVR (200°C/5kg) (cm ³ /10min)	Density (kg/m ³)	Approvals					Sterilization		
			FDA	USP	EP	DMF	EFSA	Steam	EtO	Gamma
158K	3	1050	x	x	3.2.2	-	x	-	x	x

(x) upon request

DowDuPont – Ethylene-Vinylacetate (EVA)

Characteristics Elvax® – good flexibility, high impact resistance, low processing temperatures

Medical Applications infusion bags, tubes, caps & closures

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

Elvax®

420A	150	18	x	-	(x)	-	x	(x)	(x)	(x)
450A	8	18	x	-	(x)	-	x	(x)	(x)	(x)
460A	2,5	18	x	-	(x)	-	x	(x)	(x)	(x)
470A	0,7	18	x	-	(x)	-	x	(x)	(x)	(x)
550A	8	15	x	-	(x)	-	x	(x)	(x)	(x)
560A	2,5	15	x	-	(x)	-	x	(x)	(x)	(x)
660A	2,5	12	x	-	(x)	-	x	(x)	(x)	(x)
670A	0,35	12	x	-	(x)	-	x	(x)	(x)	(x)
760A	2	9	x	-	(x)	-	x	(x)	(x)	(x)

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

SK CHEMICALS – PET and 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/m ³)	Approvals					Sterilization		
			FDA	USP	EP	DMF	EFSA	Steam	EtO	Gamma

SKYPET® PET

BR	0,8	1370	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 Tray, Orthopedic Trials, Medical and Dental Instruments

Grade	MFR (g/10min)	Density (kg/m ³)	Agency					Sterilization		
			FDA*	ISO 10993*	EP	DMF	EFSA	Steam	EtO	Gamma (40kGy)

Radel®

R-5000	14 - 20	1290	x	x	-	-	-	x	x	x
R-5100	14 - 20	1290	x	x	-	-	-	x	x	x
R-5800	20 - 28	1290	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 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/m ³)	Agency					Sterilization		
			FDA*	ISO 10993*	EP	DMF	EFSA	Steam (40kGy)	EtO	Gamma (40kGy)

Udel®

GF-110	5 - 9	1330	x	x	-	-	-	x	x	x
GF-120	5 - 9	1400	x	x	-	-	-	x	x	x
P-1700	5 - 9	1240	x	x	-	-	-	x	x	x
P-3500 LCD	5 - 9	1240	x	x	-	-	-	x	x	x
P-3703	14 - 20	1240	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	Steam	EtO	Gamma

Delrin®

SC631	low / medium flow	x	x	-	x	-	x	x	x	-
SC652	medium flow; advanced lubricant	x	x	-	x	-	x	x	x	-
SC655	medium flow	x	x	-	x	-	x	x	x	-
SC690	high flow	x	x	-	x	-	x	x	x	-
SC699	high flow; silicone oil filled	x	x	-	x	-	x	x	x	-

* Part 5 + 11

DuPont – Thermoplastic Polyester Elastomer (TPC-ET)

Characteristics Hytrel® – 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	Steam	EtO	Gamma

Hytrel®

SC938	30D durometer	x	x	-	x	-	x	x	x	x
SC948	40D durometer	x	x	-	x	-	x	x	x	x
SC956	55D durometer	x	x	-	x	-	-	x	x	x
SC969	63D durometer	x	x	-	x	-	x	x	x	x
SC976	72D durometer	x	x	-	x	-	-	x	x	x
SC988	82D durometer	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	Steam	EtO	Gamma

Crastin®

SC164	unreinforced, low viscosity	x	x	-	x	-	x	x	x	x
SC193	30 % glass fiber reinforced	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	Steam	EtO	Gamma

Zytel®

SC310	high flow; PA 6.6	x	x	-	x	-	x	x	x	x
SC315	high flow; PA 6.12	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
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 (cm ³ /10min)	Density (kg/m ³)	Approvals					Sterilization		
			FDA	USP	EP	DMF	EFSA	Steam 134°C (no load)	EtO	Gamma
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 PU – Thermoplastic Polyurethan (TPU) – Elastollan® Ether-TPU

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.

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.
Important parts:

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.

Your contact for medical plastics

Nils Müller
European Product Manager
Tel: +49 40 32008-309
n.mueller@biesterfeld.com

Or please contact your local sales representative.

Your contact for medical specialties

Tubing

Nina Held
Junior Product Manager
Tel: +49 40 32008-620
n.held@biesterfeld.com

Coatings, Adhesives and Elastomers

Robert Radsziwill
Product Manager
Tel: +49 40 32008-601
r.radsziwill@biesterfeld.com

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Biesterfeld Spezialchemie GmbH – Life Science, Healthcare
Ferdinandstrasse 41
20095 Hamburg
Germany
Phone: +49 40 32008-0
healthcare@biesterfeld.com

Registered Office: Hamburg, Commercial Register: AG Hamburg, HRB 66970, VAT ID DE196 930 661
Managing Directors: Peter Wilkes, Thomas Arnold

Biesterfeld Plastic GmbH
Ferdinandstrasse 41
20095 Hamburg
Germany
Phone: +49 40 32008-0
plastic@biesterfeld.com

Registered Office: Hamburg, Commercial Register: AG Hamburg, HRB 41045, VAT ID DE811 186 394
Managing Director: Carsten Harms, Martin Umbach

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Notes



Biesterfeld

Competence in Solutions

Biesterfeld Spezialchemie GmbH

Biesterfeld Plastic GmbH

Ferdinandstrasse 41

20095 Hamburg

Germany

Tel.: +49 40 32008-0

Fax: +49 40 32008-340

healthcare@biesterfeld.com

plastic@biesterfeld.com

www.biesterfeld.com