Biesterfeld
Competence in Solutions

Your supplier for medical plastics and specialties

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

Medical Portfolio

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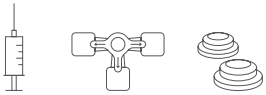
Our principals for medical specialities

Silikonisierung



Type	Description	Compliance				Sterilization		
		INCI	USP NF	Ph. Eur.	DMF	Steam	ETO	Gamma
Liveo™ 360 Medical Fluid								
20 cSt.	PDMS (Polydimethylsiloxan) Silicone fluid for lubrication and siliconization of glass, metals, plastics and rubber Soluble in non-polar solvents as Liveo™ Q7-9180 0,65 cSt./1 cSt. or aliphatic- and aromatic hydrocarbon compounds	✓	✓	✓	✓	30 min./ 120°C	✓	50 kGy
100 cSt.		✓	✓	✓	✓	30 min./ 120°C	✓	50 kGy
350 cSt.		✓	✓	✓	✓	30 min./ 120°C	✓	50 kGy
1000 cSt.		✓	✓	✓	✓	30 min./ 120°C	✓	50 kGy
12500 cSt.		✓	✓	✓	✓	30 min./ 120°C	✓	50 kGy

Material Type	Compliance				Sterilization		
	INCI	USP NF	Ph. Eur.	DMF	Steam	ETO	Gamma
Liveo™ 366 35% Dimethicone Emulsion							
H2O + 35% PDMS **Waterborne silicone fluid for lubrication and siliconization of glass** **Soluble in water (preferably WFI)**	✓*	✓*	✓*	✓*	30 min./ 120°C	✓	50 kGy

* no monograph exists for dimethicone emulsion but PDMS used in the production is compliant as shown in the table

Material Type	Compliance				Sterilization		
	INCI	USP NF	Ph. Eur.	DMF	Steam	ETO	Gamma
Liveo™ MDX4-4159 50% Medical Grade Dispersion							
50% aminofunctional dimethylsiloxane copolymer in Stoddard solvent **Fluid curing causes films to deposit and adhere to metal cutting edges** **Soluble in non-polar solvents as as LiveoTM Q7-9180 0,65 cSt./1 cSt. or aliphatic- and aromatic hydrocarbon compounds** **Ideal curing conditions: 25-70°C, 55-60% relative humidity for 24h. Lubricity properties further improve for 7-10 days at RT or 3-7 days at 70°C.**	-	Class VI (coat-ed on stain-less steel	-	-	30 min./ 120°C	✓	50 kGy

Type	Description	Compliance				Sterilization		
		INCI	USP NF	Ph. Eur.	DMF	Steam	ETO	Gamma
Liveo™ Q7-9180 Silicone Fluid								
0,65 cSt.	Hexamethyldisiloxan Solvent/carrier/excipient for pharmaceutical applications Fast evaporation, flash point -3°C Solvent for LiveoTM 360 Medical Fluids, LiveoTM MDX4-4159 50% Medical Grade Dispersion	✓	✓	✓	✓	30 min./ 120°C	✓	50 kGy
1 cSt.	Octamethyltrisiloxan Solvent/carrier/excipient for pharmaceutical applications Fast evaporation, flash point 34°C Solvent for LiveoTM 360 Medical Fluids, LiveoTM MDX4-4159 50% Medical Grade Dispersion	✓	✓	✓	✓	30 min./ 120°C	✓	50 kGy

Hautkleber

Type	Description	Characteristics				Compliance		
		Viscosity Part A & B (mPa/s) at 25°C	Penetration after Cure (mm/10)	Adhesion (N/2,5 cm)[1]	Release (N/2,5 cm)	ISO 10993-5 Cytotoxicity	ISO 10993-10 Skin-Irritation & Sensitization	FDA DMF
Liveo™ MG Series Soft Skin Adhesives (SSA)								
7-9700 SSA	Two-part (1:1 by weight), PT-catalyzed, soft fillerless elastomeric adhesive	500/ 320	90	0,6	0,11	✓	✓	-
MG 7-9800 SSA	Non-sensitizing, gentle adhesion to skin, repositionable	500/ 320	90	0,6	0,11	✓	✓	✓
MG 7-9850 SSA	Wound care and scar therapies	2900/ 2900	135	1,1	0,03	✓*	✓*	✓
MG 7-9900 SSA	Knife-over-roll coating process recommended,	5100/ 5100	140	1,9	0,05	✓*	✓*	✓
	*based on biocompatibility test data from analogous materials							

[1]: @ 250 µm, peel force from polycarbonate

Type	Description	Characteristics				Compliance		
		% solid content in solvent type	Viscosity (mPa/s) at 25°C	Adhesion (N/2,5 cm)[1]	Shear (kg)	ISO 10993-5 Cytotoxicity	ISO 10993-10 Skin-Irritation & Sensitization	FDA DMF
Liveo™ MG Series Pressure Sensitive Adhesives (PSA)								
MG-2401 PSA	One-part, polycondensed PDMS/silicate resin adhesives Non-repositionable	32% in HMDS	90	17,2	21	✓	✓	-
MG-2402 PSA	Adherence of medical wearable devices, appliances as stoma-devices, surgical dressings/pads, external prosthetic devices, patient monitoring devices	64%, Ethyl-acetate	2500	17,2	21	✓	✓	-
MG-2502 PSA	Transfer coating, brushing process or hotmelt-coating equipment recommended,	59%, Ethyl-acetate	2500	16,4	16	✓*	✓*	-
MG-2410 hotmelt PSA	Formulated and packaged as spray adhesives in solvents	100%, none	30300 at 185°C	14,5	9	✓*	✓*	-

[1]: @50 µm, peel force from stainless steel

Material Type	Characteristics				Compliance		
	Tensile strength (mPa)	Share A Hard-ness	Thick-ness (µm)	Peel adhesion (2,5 g/cm) [1]	USP NF	Ph. Eur.	FDA DMF
Liveo™ 7-4107 Silicone Elastomer Membrane							
100% Biomedical Grade LSR **75 µm** **For topical application to skin, including bandages, tapes, wound dressings, medicated patches and plasters** **Translucent, soft and flexible film** **Rolled film supplied on PC carrier** **300-400 m coil, 145-155 mm width, 83-113 g/m²**	10	50	75	2,5	Class VI	3.1.9 2	n.a.

[1]: to stainless steel

[2]: selected tests; substances soluble in hexane, volatile matter

Elastomers: HCR

Type	Description	Characteristics				Compliance				
		Hardness Shore A	Tensile Strength (MPa)	Elon-gation at break (%)	Tear Strength (kN/m)	ISO 10993-3 geno	ISO 10993-4 hemo	ISO 10993-5 cyto	ISO 10993-10 Skin irri sensi	Ph. Eur. 3.1.9 [1]
Liveo™ C6-Series High Consistency Rubber (HCR)										
C6-135 HCR	Two-part (1:1 by weight), PT-catalyzed HCR Enhanced tear-resistance HCR Fabrication of extruded parts, molded medical/ surgical/diagnostic devices and components Implantation applications ≤ 29 days Food-Grade compliance USP Class V & VI compliance	36	8,2	1120	35,1	-	-	✓	✓	✓
C6-150 HCR		50	10,6	980	42,1	-	-	✓	✓	✓
C6-165 HCR		61	8,0	940	42,1	-	-	✓	✓	✓
C6-180 HCR		77	7,2	610	38,6	-	-	✓	✓	✓
C6-235 HCR	One-Part HCR base Peroxide-curing agent necessary Fabrication of extruded parts, molded medical/ surgical/diagnostic devices and components Implantation applications ≤ 29 days Food-Grade compliance USP Class V & VI compliance	37	7,5	810	21,1	-	-	✓	✓	✓
C6-250 HCR		49	8,2	530	26,3	-	-	✓	✓	✓
C6-265 HCR		66	8,2	560	35,1	-	-	✓	✓	✓
C6-350 LH HCR	Two-part (1:1 by weight), PT-catalyzed HCR Lower hysteresis for de-manding applications (e.g. peristaltic pump tubing)	49	8,5	730	38,6	-	✓	✓	✓	✓

Type	Description	Characteristics				Compliance				
		Hardness Shore A	Tensile Strength (MPa)	Elon-gation at break (%)	Tear Strength (kN/m)	ISO 10993-3 geno	ISO 10993-4 hemo	ISO 10993-5 cyto	ISO 10993-10 Skin irri sensi	Ph. Eur. 3.1.9 [1]
Liveo™ BioMedical Grade High Consistency Rubber (HCR)										
Q7-4720 BMG HCR	Two-part (1:1 by weight), PT-catalyzed HCR Fabrication of extruded parts, molded medical/surgical/diagnostic devic-es and components Consistent materials for critical applications Implantation applications ≥ 29 days Food-Grade compliance USP Class V & VI compliance USP Pyrogenicity compliance DMF (drug master file) available	23	8,9	1310	31,6	✓	✓	✓	✓	✓
Q7-4735 BMG HCR		36	9,3	1180	36,8	✓	✓	✓	✓	✓
Q7-4750 BMG HCR		50	10,0	930	45,6	✓	✓	✓	✓	✓
Q7-4765 BMG HCR		65	8,0	900	45,6	✓	✓	✓	✓	✓
Q7-4780 BMG HCR		77	7,8	660	42,1	✓	✓	✓	✓	✓
Q7-4535 BMG HCR	One-Part HCR base Peroxide-curing agent necessary DMF (drug master file) available	36	8,1	830	24,6	✓	✓	✓	✓	✓
Q7-4550 BMG HCR		48	9,3	680	31,6	✓	✓	✓	✓	✓

Elastomere LSR:

Type	Description	Characteristics				Compliance				
		Hardness Shore A	Tensile Strength (MPa)	Elon-gation at break (%)	Tear Strength (kN/m)	ISO 10993-3 geno	ISO 10993-4 hemo	ISO 10993-5 cyto	ISO 10993-10 Skin irri sensi	Ph. Eur. 3.1.9 [1]
Liveo™ C6-Series Liquid Silicone Rubber (LSR)										
C6-530 LSR	Two-part (1:1 by weight), PT-catalyzed LSR Injection molding of precision and intricate parts of class 6 medical devices Mesh or fabric coating Implantation applications ≤ 29 days Food-Grade compliance USP Class V & VI compliance	30	8,2	830	26,3	-	-	✓	✓	✓
C6-540 LSR		40	8,9	740	42,1	-	-	✓	✓	✓
C6-550 LSR		50	10,4	660	44,7	-	-	✓	✓	✓
C6-560 LSR		60	8,8	540	50,9	-	-	✓	✓	✓
C6-570 LSR		65	9,1	440	54,4	-	-	✓	✓	✓
C6-720 LSR	Two-part (1:1 by weight), PT-catalyzed LSR Injection molding of precision and intricate parts of class 6 medical devices Improved molding per-formance; reduced mold fouling, no post-cure to stabilize physical param-eters Mesh or fabric coating Implantation applications ≤ 29 days Food-Grade compliance USP Class V & VI compliance	23	6,5	750	26,0	-	-	✓	✓	✓
C6-740 LSR		40	8,6	680	30,7	-	-	✓	✓	✓
C6-750 LSR		50	8,6	610	42,1	-	✓	✓	✓	✓
C6-770 LSR		67	9,3	450	42,1	-	✓	✓	✓	✓

Type	Description	Characteristics				Compliance				
		Hardness Shore A	Tensile Strength (MPa)	Elon-gation at break (%)	Tear Strength (kN/m)	ISO 10993-3 geno	ISO 10993-4 hemo	ISO 10993-5 cyto	ISO 10993-10 Skin irri sensi	Ph. Eur. 3.1.9 [1]
Liveo™ BioMedical Grade Liquid Silicone Rubber (LSR)										
7-6830 BMG LSR	Two-part (1:1 by weight), PT-catalyzed LSR Injection molding of precision and intricate parts of medical devices, mesh or fabric coating Consistent materials for critical applications Implantation applications ≥ 29 days Food-Grade compliance USP Class V & VI compliance USP Pyrogenicity compliance	30	8,8	790	24,1	✓	✓	✓	✓	✓
7-6840 BMG LSR		40	9,8	700	36,8	✓	✓	✓	✓	✓
Q7-4840 BMG LSR		44	9,4	540	36,8	✓	✓	✓	✓	✓
Q7-4850 BMG LSR		50	10,1	630	45,1	✓	✓	✓	✓	✓
Q7-4860 BMG LSR		60	8,8	540	50,9	✓	✓	✓	✓	✓
Q7-4870 BMG LSR		66	9,5	420	47,4	✓	✓	✓	✓	✓
Q7-7840 BMG LSR	Improved molding performance; reduced mold fouling, no post-cure to stabilize physical parameters Improved mechanical properties	40	9,3	750	30,7	✓	✓	✓	✓	✓
Q7-7840 BMG LSR		50	9,0	660	48,2	✓	✓	✓	✓	✓
Q7-7840 BMG LSR		67	9,4	415	45,6	✓	✓	✓	✓	✓

DuPont Liveo™ Pharma Silicone Tubing

Type	Description	Characteristics							Compliance			
		Durometer Shore A [1]	Elongation at break (%) [2]	Modulus at 200% (MPa) [2]	Tensile Strength at break (kN/m) [2]	Burst Pressure 1 (bar) [3]	Tear Strenght (kN/m) [1]	Specific Gravity [2]	ISO 10993 3/4/5/6/10/11	USP 788/88/85/151/661	Ph. Eur. 3.1.9 & FDA 21 CFR 177.2600	JP XIV section 11
Liveo™ Pharma Tubing												
Pharma 50	Translucent, PT-cured silicone tubing For safe & secure fluid transfer in diverse filling machines 3 durometer: 50, 65 and 80 High resiliency Kind resistant Easily sterilizable	50	795	2,1	8,7	4,1	47,3	1,14	✓	✓	✓	✓
Pharma 65		65	775	2,8	6,8	7,7	45,5	1,22	✓	✓	✓	✓
Pharma 80		80	570	3,9	7,0	13,2	42	1,22	✓	✓	✓	✓
Liveo™ Pharma Advanced Pump Tubing												
Pharma APT 50 Increased tubing pump life Superior resiliency		50	590	3	8,9	3,4	40,3	1,14	✓	✓	✓	✓
Liveo™ Pharma 65 Reinforced Tubing												
Pharma 65 RFT Polyester-fiber reinforced silicone tubing for improved burst strength Resistant to collapse under vacuum		65	890 [1]	2,82 [1]	7,94 [1]	41,2 [1]	45,5 [1]	1,22 [1]	✓	✓	✓	✓

[1]: based on elastomer

[2]: on extruded tubing (Die D)

[3]: burst pressure for tubing dimension is available in product information sheet (PRI)

DuPont Liveo™ Pharma TPE Tubing

Material Type	Properties[1]					Compliance			
	Hardness Shore A	Maximum Elongation [2] %	Modulus at 200% elongation [2] MPa	Maximum tensile strength [2]	Specific Gravity	ISO 10993 5/6/11/23	USP 85/665/ 788/151	Ph. Eur. 3.1.9 & FDA 21 CFR 177.2600	JP XIV section 11
Liveo™ Pharma TPE Tubing									
Pharma TPE 65 Thermoplastic elastomer (TPE) tubing For fluid, media solvent transport, single-use processing, peristaltic pump applications in biopharmaceutical processes and biotechnology Improved heat-welding to itself and competitive offers Low extractables Good chemical resistance Minimal spallation after 24h of pumping Stable clarify after sterilization Manufactured in ISO Class 7 cleanroom	65	1,134/ 1,031	2,7/ 2,6	9,4/ 7,4	0,9	✓	✓	✓	✓

[1]: based on tests with Livep Pharma TPE Tubing 9,5 mm (inner diameter) x 15,9 mm (outer diameter)

[2]: properties after steam sterilization (121°C/30 min) / gamma radiation (50 kGy)

Type	Recommended substrates / specific features	Characteristics				Compliance				
		Visco-sity [cP]	Duro-meter Hard-ness	Tensile break [MPa]	Elon-gation at break [%]	ISO 10993-4 geno	ISO 10993-5 hemo	ISO 10993-6 cyto	ISO 10993-10 Skin irri sensi	ISO 10993-11 Sys-temic toxicity
Dymax 1000-series multipurpose adhesives										
1209-M-UR-SC	ABS, PC, PCTG, PEEK, PETG, PMMA, PPO, PS, PVC, SS	1200	D60	15,6	170	✓	✓	✓	✓	✓
1405-M-T-UR-SC	ABS, PC, PCTG,PEI, PET, PETG, PMMA, PPO, PS, PSU, PU, PVC, SAN, TPU, SS, PCB	7000	D70	23	180	-	✓	-	-	-
1040-M	ABS, PC, PCTG, PMMA, PPO, PS, SAN, AL, BR, SS, glass › autoclavable	775	D60	18,6	8	-	✓	-	-	-
1172-M-UR	ABC, COC, COP, EVA, PA, PC, PCTG, PEBA, PEI, PET, PETG, PMMA, PS, PSU, PVC, SAN, TPU, CER, AL, SS	1100	A70	4,1	600	-	✓	-	-	-
Dymax CTH-series adhesives for catheter assembly										
209-CTH	ABS, CAP, PC, PCTG, PET, PETG,PMMA, PS, SAN, SS, NiTi	300	D70	17	120	✓	✓	✓	✓	✓
215-CTH-SV01-UR-SC	ABS, PA, PC, PCTG, PEBA, PEEK, PEI, PET, PETG; PMMA, PS, PSU, PU, PVC, TPU	1100	D53	11,7	300	✓	✓	✓	✓	✓
215-CTH-LV-UR-SC	ABS, PA, PC, PCTG, PEBA, PEEK, PEI, PET, PETG; PMMA, PS, PSU, PU, PVC, TPU	450	D53	11	300	✓	✓	✓	✓	✓
250-CTH	ABS, CAP, PC, PCTG, PEI, PETG, PS, PU, PVC, SAN, glass, PCB › complete heat-curing at 80-85°C	58000	D90	51,7	2	✓	✓	✓	✓	✓
Dymax 1400-, 1500- and 1045-series adhesives for needle assembly										
1406-M	ABS, PC, PCTG, PE, PETG, PS, PVC, SAN, TPU, SS, PCB	150	D70	15	120	-	✓	-	-	-
1405-M-UR-SC	ABC, PC, PCTG; PEI, PET, PETG, PMMA, PPO, PS, PU, SAN, SS PCB	150	D70	18,6	150	-	✓	-	-	-
1501-M-UR	ABS, CAP, PC, PETG, PP (st), PVC, SAN, SS	80	D70	180	80	-	✓	-	-	-
1045-M	ABS, PC, SS, glass	525	D78	23,4	20	✓	✓	✓	✓	✓

Type	Recommended substrates / specific features	Characteristics				Compliance				
		Visco-sity [cP]	Duro-meter Hard-ness	Tensile break [MPa]	Elon-gation at break [%]	ISO 10993-4 geno	ISO 10993-5 hemo	ISO 10993-6 cyto	ISO 10993-10 Skin irri sensi	ISO 10993-11 Sys-temic toxicity
Dymax MSK-series adhesives for bonding respiratory devices										
108-MSK	CAP, PC, PEEK, PMMA, PS, PU, PVC, SAN, TPU	600	D75	25	70	-	✓	-	✓	-
104-MSK-Gel	ABS, PCTG, PETG, PU, PVC, SAN	23500	D60	19	205	-	✓	-	-	-
111-MSK	ABS, PC, PI, PMMA, PS, PU, PCC, SAN, SEBS, TPU	250	D55	6,9	400	-	✓	-	-	-
Dymax 2000-MW series adhesives for wearable medical device assembly										
2022-MW	ABS, PC, PETG, PI, PU, SAN, AL, SS, glass	700	D60	19,3	25	-	✓	-	-	-
2101-MW-UR	ABS, PC, PCTG, PETG,PVC, SAN, TPU	5500	D80	24,8	80	-	✓	-	✓	-
1901-M	CAP, PS, TPU, PCB (flexible & rigid)	3000	A67	2	45	-	✓	-	-	-
2103-MW-UR	PC, ABS, PVC, PEBA, SS	5500	D70	18,6	23	-	✓	-	✓	-

Our principals for medical plastics

INEOS Olefins & Polymers – Polypropylen (PP)

INEOS

Properties Eltex® MED – outstanding optical properties, high transparency, low odour, high purity

Medical applications Inhalation components, syringe barrels and plungers, thin-walled containers for pharmaceutical applications, blow-fill-seal (BFS) (bottles and ampoules) - * PP terpolymer for film applications, medical IV bags

Type	MFR (230°C/2.16 kg) (g/10min)	Bend elast. modulus (MPa)	Food compliance	Medical approvals				Sterilisation			
				10993	USP	EP	DMF	Steam	EtO	Gamma	E-Beam
Eltex® MED HPP											
100-MG03	3	1450	FDA; (EU) 10/2011; GMP	-	VI	3.1.3 ; 3.1.6	✓	121°C 1hr	✓	-	-
100-MG12	12	1400		5	[87]; VI	3.1.3 ; 3.1.6	✓		✓	-	-
100-MG25	25	1200		-	VI	3.1.3 ; 3.1.6	✓		✓	-	-
Eltex® MED RCP											
200-MG02	1,8	900	FDA; (EU) 10/2011; GMP	-	VI	3.1.3 ; 3.1.6	✓	121°C 1hr	✓	-	-
240-MS23	23	980		-		-	-		✓	-	-
Terpolymer											
KS357	5	620	FDA; (EU) 10/2011; GMP	-	VI	3.1.3	-	✓	(✓)	-	-

(√) auf Anfrage

INEOS Olefins & Polymers – Polyethylen mit hoher Dichte (HDPE)

INEOS

Eigenschaften

Eltex® MED – schnellfließend, gute Dimensionsstabilität, hohe Reinheit
Eltex® – gute Chemikalienresistenz, herausragende organoleptische Eigenschaften

Medizinische Anwendungen

Spritzen (Spritzenkolben), dünnwandige Behälter für pharmazeutische Anwendungen, Kappen und Verschlüsse

Type	MFR (190°C/2,16kg) (g/10min)	Density (kg/m³)	Food compliance	Medical approvals				Sterilisation			
				10993	USP	EP	DMF	Steam	EtO	Gamma	E-Beam
Eltex® MED HDPE											
HD5226EA-M	26	953	FDA; (EU) 10/2011; GMP	5	[87]; VI	3.1.3 ; 3.1.5	✓	✓	✓	-	-
HD5502M	0,2	954	FDA; (EU) 10/2011; GMP	-	-	3.1.3 ; 3.1.5	✓	✓	✓	-	-
Eltex®											
CAP508	1,8	953	FDA; (EU) 10/2011; GMP	-	[661.1]	3.1.3 ; 3.1.5	-	(✓)	(✓)	-	-
HD5211EA-B	11	951	FDA; (EU) 10/2011	-	-	3.1.3	-	(✓)	(✓)	-	-
HD6070EA-B	7,6	960		-	-	3.1.3 ; 3.1.5	-	(✓)	(✓)	-	-

INEOS Olefins & Polymers – Polyethylen mit niedriger Dichte (LDPE)

INEOS

Eigenschaften Eltex® MED – gute Fließeigenschaften, gute Dimensionsstabilität, hoher Reinheitsgrad

Medizinische Anwendungen BFS - Blow Fill Seal (Flaschen und Ampullen), medizinische Schläuche, Folienanwendungen

Type	MFR (190°C/2,16kg) (g/10min)	Density (kg/m³)	Food compliance	Medical approvals				Sterilisation			
				10993	USP	EP	DMF	Steam	EtO	Gamma	E-Beam
Eltex® MED LDPE											
PH19N630	7,5	920	FDA; (EU) 10/2011; GMP	5	[661.1]; [87]	3.1.3; 3.1.4	-	-	(✓)	50kGy	-
PH22D630	0,3	922		5	[661]; [87]; USPVI		(✓)	-	(✓)	-	-
PH23H630	2	923		-	[661.1]; VI		(✓)	-	(✓)	-	-
PH23T630	22	923		-	VI		(✓)	-	(✓)	50kGy	-
PH27D630	0,3	927		-	[661.1]; VI		(✓)	108°C 1hr	(✓)	-	-
PH30D630	0,3	930		-	[661.1]; VI		(✓)	112°C 1hr	(✓)	-	-

SK CHEMICALS – Polyethylenterephtalat (PET) / Polycyclohexylen-Dimethylenterephthalat (PCTG)

Eigenschaften

SKYPET® BR (PET, bzw. PETG) – hohe Transparenz, ausgezeichnete chemische Beständigkeit, leicht recycelbar, RIC 1 kompatibel
SKYGREEN® S2008 (PETG) – hohe Transparenz, gute Schlagfestigkeit, leichtes Thermoformen, gute Bedruckbarkeit

Medizinische Anwendungen

Blisterverpackungen, Einwegspritzen, medizinische Schalen und Behälter, Probengreifer

Type	Density (g/cm³)	Food compliance	Medical approvals				Sterilisation		
			10993	USP	EP	DMF	Steam	EtO	Gamma
SKYPET®									
SKYPET® BT (Transparent)	1,33	FDA; (EU) 2023/2006; GMP	-	[87]; VI	3.1.15	✓	-	-	-

Type	Density (g/cm³)	Food compliance	Medical approvals				Sterilisation			
			10993	USP	EP	DMF	Steam	ETO	Gamma	E-Beam
SKYGREEN®										
SKYGREEN® S2008	1,27	FDA; (EU) 2023/2006; GMP	3; 4; 5: 6; 10; 11	[661]; [87]; VI	3.1.15	✓	-	50°C 50% 5hr.	50kGy 30min	50kGy 24hr.
SKYGREEN® MP200	1,27		-	VI	-	-	-			
SKYGREEN@ MJ200	1,23		-	VI	-	-	-			
ECOZEN®										
ECOZEN® MT5G (Transparent)	1,25	FDA; (EU) 10/2011; GMP	-	VI	-	-	-	50°C 50% 5hr	50kGy 30min	50kGy 24hr
ECOZEN® MT10 (Transparent)	1,27		-			-	-			
ECOZEN® MT10G (Transparent)	1,27		-			-	-			

Solvay Specialty Polymers – Polyphenylsulfon (PPSU)

Eigenschaften

Radel® – Unglaublich zäher, transparenter Kunststoff mit einer Wärmeformbeständigkeitstemperatur (HDT) von 207°C, ausgezeichnete chemische Beständigkeit und die Fähigkeit, mehr als 1.000 Zyklen der Dampfsterilisation ohne signifikanten Verlust der Eigenschaften zu überstehen. In durchgefärbten und transparenten Farben erhältlich.

Medizinische Anwendungen

Sterilisationsbehälter und -tabletts, orthopädische Geräte, medizinische und zahnmedizinische Instrumente

Type	MFR (g/10min)	Density (g/cm³)	Food compliance	Medical approvals			Sterilisation		
				10993	USP	DMF	Steam	EtO	Gamma
Radel®									
R-5000	14-20	1,29	FDA; (EU) 10/2011; GMP	5; 10; 11; 18	VI	-	134°C 18min 1.000x	✓ 100x	40kGy
R-5100	14-20	1,29				-			
R-5500	14-20	1,29				-			
R-5800	14-20	1,29				-			

* Das Basis Polymer ist konform. Bitte prüfen Sie mit Ihrem Vertriebsmitarbeiter, ob die von Ihnen bezogene Farbe zugelassen ist.

Solvay Specialty Polymers – Polyethersulfon (PESU)

Eigenschaften

Veradel® HC - ein steifes, transparentes Hochtemperatur-Polymer, das für den Einsatz in hochleistungsfähigen Anwendungen im Gesundheitswesen angeboten wird. Das Material ist von Natur aus schwer entflammbar und hochgradig beständig gegen eine Vielzahl von Reinigungsmitteln im Gesundheitswesen und Sterilisationsmitteln. Es behält seine Transparenz, seine mechanischen Eigenschaften und seine Formbeständigkeit sowohl in feuchten Umgebungen, als auch bei hoher Hitze. Es ist verträglich in der Sterilisation mit Ethylenoxid, Wasserstoffperoxid-dampf, Gammastrahlung und Wasserdampf.

Medizinische Anwendungen

Medizinische Gerätegehäuse

Type	MFR (g/10min)	Density (g/cm³)	Food compliance	Medical approvals			Sterilisation		
				10993	USP	DMF	Steam	EtO	Gamma
Veradell® HC									
HC-A301 NT	30	1,37	FDA; (EU) 10/2011; GMP	5; 10; 11; 18	VI	-	134°C 18min 100x	✓ 100x	40kGy

Solvay Speciality Polymers – Polysulfon (PSU)

Eigenschaften

Udel® – Nahezu kristallklarer transparenter Kunststoff mit einer Wärmeformbeständigkeit (HDT) von 174°C, hohe Festigkeit, gute chemische Beständigkeit und ausgezeichneter Dimensionsstabilität bei Einwirkung von Dampf und Oxidationsmitteln. In durchgefärbten Farben, in transparent und in glasfasergefüllten Qualitäten erhältlich.

Medizinische Anwendungen

Medizinische und zahnärztliche Instrumente, Saugflaschen, Schlauchverbindungen, Gerätegehäuse, Hämodialysemembranen

Type	MFR (g/10min)	Density (g/cm³)	Food compliance	Medical approvals			Sterilisation		
				10993	USP	DMF	Steam	EtO	Gamma
Udel® HC									
GF-110	5-9	1,33	FDA	5; 10; 11; 18	-	-	134°C 18min 500x	✓ 100x	40kGy
GF-120	5-9	1,40	FDA; (EU) 10/2011		-	-			
P-1700	5-9	1,24			VI	-			
P-3500 LCD	5-9	1,24				-			
P-3703	14-20	1,24				-			

* Das Basis Polymer ist konform. Bitte prüfen Sie mit Ihrem Vertriebsmitarbeiter, ob die von Ihnen gekaufte Farbe zugelassen ist.

DuPont – Polyoxymethylen-Homopolymer (POM)

Eigenschaften

Delrin® – hohe Abriebfestigkeit, gute Widerstandsfähigkeit, Dimensionsstabilität

Medizinische Anwendungen

Injektor-Stifte, Inhalator, Dosiereinheiten

Type	Description	Food compliance	Medical approvals			Sterilisation			
			10993	USP	DMF	Steam	EtO	Gamma	E-Beam
DELRIN®									
SC631	Niedrige bis mitlere Fließfähigkeit	FDA; (EU) 10/2011; GMP	5; 11	VI	-	87°C +3min 134°C <25 cycles	50°C 2hr. 1x	-	-
SC655	Mittlere Fließfähigkeit								
RASC655	Mittlere Fließfähigkeit								
SC690	Hohe Fließfähigkeit								
SC968	Hohe Fließfähigkeit (mit Silikonöl gefüllt)								
RASC698	Hohe Fließfähigkeit (mit Silikonöl gefüllt)								

DuPont – Thermoplastisches Polyester-Elastomer (TPC-ET)

Eigenschaften Hytrel® – gute Flexibilität, Sterilisationsbeständigkeit, chemische Beständigkeit, geringe Materialermüdung, hohe Dauerbeanspruchbarkeit

Medizinische Anwendungen hohe dauerbelastbare Schläuche, Handgelenkschutz, Fußprothesen

Type	Hardness	Food compliance	Medical approvals			Sterilisation			
			10993	USP	DMF	Steam	EtO	Gamma	E-Beam
HYTREL®									
SC956	Shore 55D	FDA; (EU) 10/2011; GMP	5; 11	VI	-	87°C +3min 134°C <25-100 cycles*	50°C 2hr. 1x	40kGy 1x	50kGy 1x
SC969	Shore 63D								
SC976	Shore 72D								
SC988	Shore 82D								

*Please contact your contact person for more information.

DuPont – Polybutylen Terephthalat (PBT)

Eigenschaften Crastin® – ausgezeichnete Oberflächenbeschaffenheit, gute Einfärbbarkeit, chemische Beständigkeit

Medizinische Anwendungen Komponenten für Insulinspritzen

Type	Description	Food compliance	Medical approvals			Sterilisation			
			10993	USP	DMF	Steam	EtO	Gamma	E-Beam
CRASTIN®									
SC164	Unverstärkt, hohe Fließfähigkeit	FDA; (EU) 10/2011; GMP	5; 11	VI	-	87°C +3min 134°C <25 cycles*	50°C 2hr. 1x	40kGy 1x	50kGy 1x
SC193	30% Glasfaserverstärkt verzugsarm								

*Please contact your contact person for more information.

DuPont – Polyamid (PA)

Eigenschaften: Zytel® – hohe mechanische Festigkeit, gleichzeitige Steifigkeit und Schlagfestigkeit

Medizinische Anwendungen: Zangen und Applikatorpistolen, medizinische Ventile, Filter, Spritzenkörper

Type	Description	Food compliance	Medical approvals			Sterilisation			
			10993	USP	DMF	Steam	EtO	Gamma	E-Beam
ZYTEL®									
FGFE5171 NC010	PA6.6. 33% glasfaserverstärkt	FDA; (EU) 10/2011; GMP	5; 11	VI	-	87°C +3min 134°C <25-100 cycles*	50°C 2hr. 1x	40kGy 1x*	50kGy 1x*
SC310	PA6.6. hohe Fließfähigkeit								
SC315	PA6.12. hohe Fließfähigkeit							-	*

*Please contact your contact person for more information.

Celanese – Thermoplastisches Vulkanisat (TPV)

Properties: Santoprene is a thermoplastic vulcanizate with excellent long-term compression set and stress relaxation for sealing performance

Medical applications: Syringe tips, plunger Stopper, soft grip, seals

Type	Farbe	Hardness	Food compliance	Medical approvals			Sterilisation		
				10993	USP	DMF	Steam	EtO	Gamma
Santoprene®									
181-55MED	bk	Shore 59A		5; 6; 10; 11	VI	-	✓	✓	50kgY
281-55MED	nc	Shore 60A							
8281-35MED	nc	Shore 38A							
8281-45MED	nc	Shore 49A							
8281-55MED	nc	Shore 59A							
8281-65MED	nc	Shore 68A							
8281-75MED	nc	Shore 79A							
8281-90MED	nc	Shore 93A							
8281-55B1MED	colorable	Shore 57A							
8181-55B1MED	bk	Shore 57A							

CHIMEI – Polycarbonate (PC)

CHIMEI
a step up

Properties Wonderlite® is a transparent material suitable for a wide range of applications. Polycarbonate has very good temperature resistance combined with high impact strength and transparency.

Medical applications Infusion valves, infusion tubes, dialysers

Type	MFR (g/10min)	Density (g/cm³)	Food compliance	Medical approvals			Sterilisation		
				10993	USP	DMF	Steam	EtO	Gamma
Wonderlite®									
PC-115P (transparent)	15	1,2	FDA	3; 4; 5; 6; 10;11	-	-	-	✓	-
PC-115P F01 (transparent with slight blue tint)	17	1,2	FDA	5; 10	-	-	-	✓	-
PC-115P F17111 (transparent blue)	17	1,2	FDA	3; 4; 5; 6; 10;11	-	-	-	✓	50kGy

CHIMEI – Methyl Methacrylate Acrylonitrile Butadiene Styrene (M-ABS)

CHIMEI
a step up

Properties M-ABS exhibits high transparency and offers good impact strength and chemical resistance. It is also easy to process.

Medical applications Syringe covers

Type	MFR (g/10min)	Density (g/cm³)	Food compliance	Medical approvals			Sterilisation		
				10993	USP	DMF	Steam	EtO	Gamma
POLYLAC®									
M-ABS PA-703TRP (transparent)	2,3	1,08	FDA	5; 10	-	-	-	✓	-
M-ABS PA-758 (transparent)	3,0	1,08	FDA; (EU) 10/2011; GMP	-	VI	-	-	✓	-

CHIMEI – Styrene Acrylonitrile Copolymer (SAN)

CHIMEI a step up

Properties

Kibisan® is a transparent material suitable for a wide range of applications, which can be used for injection moulding and extrusion. Kibisan® PN-107FG L125 can be used for food contact applications in accordance with EU Directive 10/2011; Kibisan® offers good chemical resistance combined with very good processing characteristics.

Medical applications

Syringe covers

Type	MFR (g/10min)	Density (g/cm³)	Food compliance	Medical approvals			Sterilisation		
				10993	USP	DMF	Steam	EtO	Gamma
KIBISAN®									
SAN PN-107 L125FG (transparent)	58	1,06	FDA; (EU) 10/2011; GMP	-	VI	-	-	✓	-
SAN PN-127 L150 (transparent)	17	1,06	FDA; (EU) 10/2011; GMP	-	VI	-	-	✓	-

CHIMEI – Acrylonitrile Butadiene Styrene (ABS)

CHIMEI a step up

Properties

Polylac® is a high-gloss ABS suitable for a wide range of applications. The material can be used for injection moulding and extrusion. Polylac® 757F can be used for food contact applications in accordance with EU Directive 10/2011. Polylac® offers good impact strength and flow properties.

Medical applications

IV regulators

Type	MFR (g/10min)	Density (g/cm³)	Food compliance	Medical approvals			Sterilisation		
				10993	USP	DMF	Steam	EtO	Gamma
POLYLAC®									
ABS PA-704LRP (milchig weiß)	18	1,05	FDA	5; 10	-	-	-	✓	-
ABS PA-757F (milchig weiß)	18	1,05	FDA; (EU) 10/2011; GMP	-	VI	-	-	✓	-

BASF – Thermoplastic Polyurethane (TPU)

Properties Elastollan is a thermoplastic polyurethane with excellent hydrolysis resistance, good resistance to microorganisms and excellent transparency.

Medical applications Infusion systems, redon-drains, stool drainage systems, hollow fibre membranes for oxygenator, wound coverings, general catheters (single- and multi-lumen), tracheal tubes

Type	Hardness	Food compliance	Medical approvals			Sterilisation		
			10993	USP	DMF	Steam	EtO	Gamma
ELASTOLLAN®								
1170 A 10 FC	Shore 70 A	FDA; (EU) 10/2011; GMP	5; 10		-	-	✓	✓
1180 A 10 FC	Shore 80 A							
1185 A 10 FC	Shore 85 A			VI				
1190 A 10 FC	Shore 90 A							
1195 A 10 FC	Shore 95 A							
1198 A 10 FC	Shore 98 A							
1154 D 10 FC	Shore 54 D							
1174 D 10 FC	Shore 74 D							

LG – Methyl Methacrylate Acrylonitrile Butadiene Styrene (M-ABS)

Properties Exceptional transparency similar to PMMA or PC, impact strength, rigidity and ease of processing; well balanced properties; LG TR ABS exhibits good Izod impact strength and good results in the falling weight test, similar to a standard ABS; the material also does not fracture under low impact energy.

Type	MFR (g/10min)	Density (g/cm³)	Food compliance	Medical approvals			Sterilisation		
				10993	USP	DMF	Steam	EtO	Gamma
LG TR ABS									
TR 556	5	1,09	FDA; (EU) 10/2011; GMP	-	VI	-	-	✓	-
TR 557	23	1,09							
TR 558A	24	1,01							

Idemitsu – Polycarbonate (PC)

Properties

As well as the impact strength implied in the product name, this material offers additional outstanding properties such as transparency, heat resistance and dimensional accuracy, making it suitable for a variety of applications.

Medical applications

Laboratory equipment, medical packaging

Type	MFR (g/10min)	Density (g/cm³)	Food compliance	Medical approvals			Sterilisation		
				10993	USP	DMF	Steam	EtO	Gamma
TARFLON®									
IR 1700	27	1,20	FDA; (EU) 10/2011; GMP	-	VI	-	134°C (no load)	✓	✓*
IR1900	19	1,20							
IR 2200	12	1,20							
IR 2500	8	1,20							

USI – Cyclic Block Copolymer (CBC)

Properties

The key properties of CBC include high transparency, exceptional purity, low extractable substances, exceptional chemical resistance, low moisture absorption, low autofluorescence and exceptional UV-vis transmittance.

Medical applications

Bio-diagnostic devices, syringes, bottles, laboratory equipment, medical packaging, dental applications, microtitre plates

Type	MFR (g/10min)	Density (g/cm³)	Food compliance	Medical approvals			Sterilisation		
				10993	USP	DMF	Steam	EtO	Gamma
ViviOn®									
1325 / 1325 EUT*	13	0,94	FDA; (EU) 10/2011; GMP	4; 5; 6; 10; 11	[661]; VI	3.1.3	✓	✓	50kGy
0510 / 0510 EUT*	5	0,94							
8210 / 8210 EUT*	200	0,94							
0510 HF (high flow)	13	0,94							

*improved UV characteristics

Approvals

FDA - The Food and Drug Administration (FDA) is a U.S. public health agency that provides a range of health-related services and sets standards for food packaging and labelling. All drugs and medical devices approved for use in the U.S. must be tested by the FDA and must satisfy the agency's standards.

ISO 10993 - ISO 10993, regulated by the International Organization for Standardization (ISO), is a series of standards for the biological evaluation of medical products. The standard covers the biological evaluation of the biocompatibility of materials with the human body.

Test	Method
Genotoxicity	ISO 10993-3
Cytotoxicity	ISO 10993-5
Bone and muscle implant tests	ISO 10993-6
Sensitisation	ISO 10993-10
Intracutaneous toxicity	ISO 10993-10
Acute systemic toxicity	ISO 10993-11
Subchronic toxicity	ISO 10993-11
Full characterisation(1)	ISO 10993-18
Physicochemical	ISO 10993-18

(1) Including exhaustive extractions and risk assessment

DMF - A Drug Master File (DMF) is a confidential, detailed document describing the active ingredients contained in a medical product. It is submitted by manufacturers to the U.S. Food and Drug Administration (FDA). A DMF details the chemistry, manufacturing processes and checks that apply to a component of a drug. There is no regulatory requirement to create and file a DMF.

USP - The United States Pharmacopeia (USP) defines standards that guarantee the quality and purity of drugs and health technologies worldwide. It includes tests for the biological reactivity of elastomers, plastics and other polymer materials that come into direct or indirect contact with people. USP Class VI is the most stringent test and is accepted throughout the industry.

EP - The European Pharmacopoeia (EP) defines quality testing for medicines in Europe. All drugs and medical devices manufactured in European countries must satisfy these standards. EP quality standards (Europe)

EP 3.1.3	Release of medicinal products from some additives
EP 3.1.4	Release of pharmaceuticals from PE without additives
EP 3.1.5	Release of pharmaceuticals from PE with additives (additives are tested for compatibility of pharmaceuticals)
EP 3.1.6	Release of medicinal products from PP with additives (additives are tested for compatibility of pharmaceuticals)
EP 3.1.9	Silicone elastomer for closures and tubing

EFSA - The European Food Safety Authority (EFSA) is a European agency which provides information and scientific advice on existing and emerging risks in the food chain. It deals with all issues relating directly or indirectly to food and animal feed safety, including animal health and welfare, plant protection, plant health and nutrition.

Classification	Definition
Biotolerant materials	are recognised as foreign by the surrounding tissue and are enclosed by a layer of connective tissue but not rejected.
Bioinert materials	do not form any chemical bonds when in contact with surrounding tissue.
Bioactive materials	are capable of chemical and biological interaction with tissues such as bone.

Contact time	Description
Short-term	Medical devices with one-off or repeated use or contact time likely to last up to 24 hours
Longer-term	Medical devices with one-off, repeated or long-term use or contact time likely to last more than 24 hours but not longer than 30 days
Permanent	Medical devices with one-off, repeated or long-term use or contact time lasting more than 30 days

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