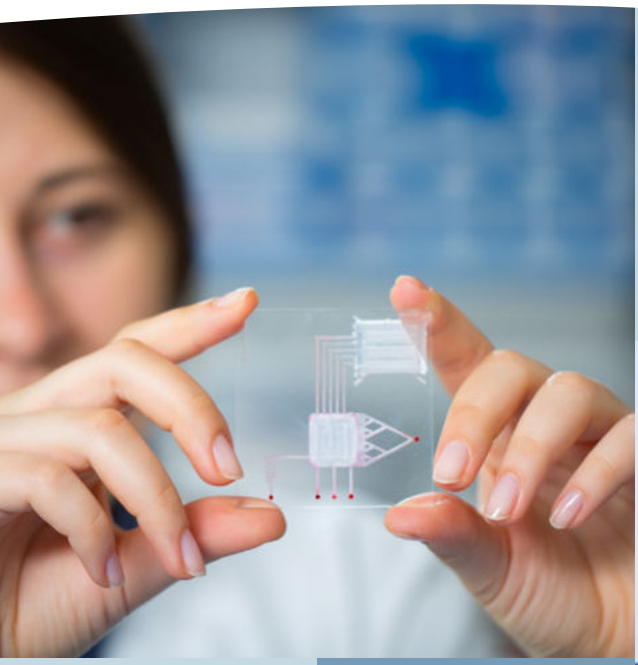
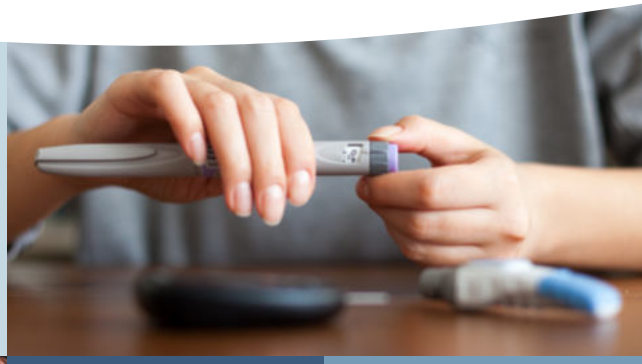
Biesterfeld
Competence in Solutions

Your supplier for medical plastics and specialties


- Engineering polymers
- High-performance polymers
- Polyolefins
- Product adhesives and encapsulants
- Silicone coatings and lubricants
- Silicone elastomers
- Silicone HCR& LSR
- Silicone hoses
- Silicone skin adhesives
- Silicone & TPE tubings
- Styrene copolymers
- Thermoplastic elastomers
- Transparent polymers
- UV-curing structural adhesives & encapsulants

Medical Portfolio

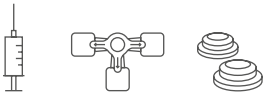
Contents

Specialty chemicals

Polymers

Our principals for medical specialities

Medical Fluids for Device Lubrication and Siliconization



Hydrophobic lubricants for glass, metals, plastics and rubbers

Type	Product Description	Regulatory Status				Physical Properties			
		INCI	USP NF	Ph. Eur.	DMF	Viscosity [cSt., 25°C]	Specific Gravity [at 25°C]	Refractive Index [at 25°C]	Flash Point, closed cup [°C]
Liveo™ 360 Medical Fluid									
20 cSt.	Clear, colourless, PDMS liquid (Polydimethylsiloxan)	✓	✓	✓	✓	20	0,951	1,4018	>100
100 cSt.		✓	✓	✓	✓	100	0,967	1,4032	>100
350 cSt.		✓	✓	✓	✓	350	0,971	1,4042	>100
1000 cSt.		✓	✓	✓	✓	1000	0,972	1,4046	>100
12500 cSt.		✓	✓	✓	✓	12500	-	1,4047	>100

- High water repellency/hydrophobicity
- Excellent lubricating characteristics

Waterborne silicone emulsion for lubrication and siliconization of glass-made parenteral container

Product Description	Regulatory Status				Physical Properties			
	INCI	USP NF	Ph. Eur.	DMF	Viscosity [cSt., 25°C]	Specific Gravity [at 25°C]	Drying Rate similar to	pH
Liveo™ 366 35% Dimethicone NF Emulsion								
White, liquid emulsion containing 35% Dimethicone	✓*	✓*	✓*	✓	350	0,99	water	5,0

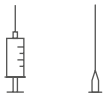
* no monograph exists for the Liveo™ 366 35% Dimethicone NF Emulsion but PDMS used in the production is compliant

- Excellent lubricating and release characteristics
- Not formulated with OPE-surfactant
- Not formulated with parabens

Hydrobhobic silicone dispersion for lubrication and siliconization of cutting edges and needles

Product Description	Regulatory Status				Physical Properties			
	INCI	USP NF	Ph. Eur.	DMF	Viscosity [cSt., 25°C]	Drying Rate similar to	Refractive Index [at 25°C]	Flash Point, closed cup [°C]
Liveo™ MDX4-4159 50% Medical Grade Dispersion								
Colorless to slightly hazy liquid, amino-functional silicone dispersion with 50% active ingredients	-	-	-	✓	130	Mineral spirits	1,4089	13,3

- High adhesion to metal, providing durability
- Only to be used diluted in Liveo™ Q7-9180 0,65 cSt. or 1 cSt. or non-polar solvents to an active content of 1-5%
- 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



Diluting solvent for Liveo™ 360 Medical Fluid and Liveo™ MDX4-4159 50% Medical Grade Dispersion

Type	Product Description	Regulatory Status				Physical Properties			
		INCI	USP NF	Europ. Techn. file	VOC	Viscosity [cSt., 25°C]	Specific Gravity [at 25°C]	Drying Rate similar to	Flash Point, closed cup [°C]
Liveo™ Q7-9180 Silicone Fluid									
0,65 cSt.	Clear, colorless, high-purity, volatile Hexamethyldisiloxan	✓	-	✓*	**	0,65	0,76	acetone	-3
1 cSt.	Clear, colorless, high-purity, volatile Octamethyltrisiloxan	✓	-	✓*	**	1	0,82	isopropanol	34

* DuPont has the capabilities to provide safety data sheets to meet requirements

** VOC Exempted in U.S. by EPA

Silicone Skin Adhesives

Non-sensitizing, gentle adhesion to skin for wound care and scar therapies as well as wearable device fixation

Type	Product Description	Physical Properties				Biocompatibility Testing		
		Viscosity Part A & B [mPa/s] at 25°C	Penetration after Cure [mm/10]	Peel Adhesion [N/2,5 cm]*	Release [N/2,5 cm]	ISO 10993-5	ISO 10993-10/11	DMF
Liveo™ MG Series Soft Skin Adhesives (SSA)								
7-9700	Two-part (1:1 by weight), PT-catalyzed, soft fillerless elastomeric adhesive Low viscosity Transparent	500/ 320	90	0,6	0,11	✓	✓	-
MG 7-9800		500/ 320	90	0,6	0,11	✓	✓	✓
MG 7-9850		2900/ 2900	135	1,1	0,03	✓**	✓**	✓
MG 7-9900		5100/ 5100	140	1,9	0,05	✓**	✓**	✓
MG 7-9960 * **		5000/ 5000	145	2,8	0,06	✓**	✓**	-

*: @ 250 µm, peel force from polycarbonate

**: based on biocompatibility test data from analogous materials

***: meets SVHC (substance of very high concern) threshold for concerned cyclosiloxanes (>0,1%) according REACH regulation (EC) 1907/2006

- High tack, gentle removal from skin, repositionable from skin
- High gas and moisture permeability
- Application method: Knife over roll coating is recommended

Non-sensitizing adherence of medical devices as stoma-appliances, surgical dressings/pads, external prosthetics and wearable medical devices

Type	Product Description	Physical Properties				Biocompatibility Testing		
		% solid content in solvent type	Viscosity [mPa/s] at 25°C	Peel Adhesion [N/2,5 cm]*	Shear [kg]	ISO 10993-5**	ISO 10993-10**	DMF
Liveo™ MG Series Pressure Sensitive Adhesives (PSA)								
MG-2401	One-part, polycondensed poly-dimethylsiloxane/silicate resin adhesive Volatile solvent-based silicone adhesive	32%, HMDS	90	17,2*	21	✓	✓	-
MG-2402		64%, Ethyl-acetate	2500	17,2*	21	✓	✓	-
MG-2502		59%, Ethyl-acetate	2500	16,4*	16	✓	✓	-
MG-2410 hotmelt	One-part, polycondensed polydimethyl-siloxane/silicate resin adhesive Hot-melt silicone adhesive	100%	30300 at 185°C	14,5*	9	✓	✓	-

*: @50 µm, peel force from stainless steel

**: based on test results on adhesive solids

- Medium to very high tack
- High adhesion and conformity to skin for extended wear time
- High gas and moisture permeability
- Application methods (1) formulated and packaged as spray adhesive, (2) conventional tape coating equipment (transfer coating, brushing), (3) printing/dispensing using specific nozzles provided by Nordson EFC

PSA/SSA Accessories for Silicone Skin Adhesives

For topical application to skin, including bandages, tapes, wound dressings, medicated patches and plasters

Product Description	Physical Properties				Biocompatibility Testing		
	Tensile strength [mPa]	Shore A Hardness	Thick-ness [µm]	Peel adhesion [2,5 g/cm]*	USP NF	Ph. Eur.	FDA DMF
Liveo™ 7-4107 Silicone Elastomer Membrane							
100% Biomedical Grade LSR 75 µm thick Translucent, matte, soft and flexible film	10	50	75	2,5	Class VI	3.1.9 **	n.a.

*: @75 µm, peel force from stainless steel

**: based on test results on adhesive solids

- Rolled film supplied on PC carrier
- Conforms to curved surfaces
- 300-400 m coil, 145-155 mm width, 83-113 g/m^2

Silicone Elastomers

High Consistency Rubber (HCR)

Millable thermoset silicone elastomers for extruded parts or fabrication of molded medical/ surgical/diagnostic devices and components

Type	Product Description	Physical Properties					Biocompatibility Testing						
		Hardness Shore A	Tensile Strength [MPa]	Elongation at break [%]	Tear Strength [kN/m]	Relative Density	ISO 10993-3	ISO 10993-4	ISO 10993-5	ISO 10993-10	Ph. Eur. 3.1.9 [1]	Food Grade	USP Class V &VI
Liveo™ C6-Series High Consistency Rubber (HCR)													
C6-135	Two-part (1:1 by weight), PT-catalyzed HCR Enhanced tear-resistance HCR ≤ 29 day implant	36	8,2	1120	35,1	1,12	-	-	✓	✓	✓	✓	✓
C6-150		50	10,6	980	42,1	1,16	-	-	✓	✓	✓	✓	✓
C6-165		61	8,0	940	42,1	1,21	-	-	✓	✓	✓	✓	✓
C6-180		77	7,2	610	38,6	1,21	-	-	✓	✓	✓	✓	✓
C6-235	One-Part HCR base Peroxide-curing agent necessary ≤ 29 day implant LH: Lower hysteresis for demanding applications (e.g. peristaltic pump tubing)	37	7,5	810	21,1	1,12	-	-	✓	✓	✓	✓	✓
C6-250		49	8,2	530	26,3	1,16	-	-	✓	✓	✓	✓	✓
C6-265		66	8,2	560	35,1	1,20	-	-	✓	✓	✓	✓	✓
C6-350 LH		49	8,5	730	38,6	1,15	-	✓	✓	✓	✓	✓	✓

[1]: Selected Ph. Eur. 3.1.9: substances soluble in hexane & volatile matter

- Manufactured in dedicated healthcare facility

Liveo™ BioMedical Grade High Consistency Rubber (HCR)

Type	Product Description	Physical Properties					Biocompatibility Testing						
		Hardness Shore A	Tensile Strength [MPa]	Elongation at break [%]	Tear Strength [kN/m]	Relative Density	ISO 10993-3	ISO 10993-4	ISO 10993-5	ISO 10993-10	Ph. Eur. 3.1.9 [1]	Food Grade	USP Class V &VI
Q7-4720	Two-part (1:1 by weight), PT-catalyzed HCR Enhanced tear-resistance HCR > 29 day implant Compliant to USP pyrogenicity	23	8,9	1310	31,6	1,11	✓	✓	✓	✓	✓	✓	✓
Q7-4735		36	9,3	1180	36,8	1,12	✓	✓	✓	✓	✓	✓	✓
Q7-4750		50	10	930	45,6	1,16	✓	✓	✓	✓	✓	✓	✓
Q7-4765		65	8	900	45,6	1,20	✓	✓	✓	✓	✓	✓	✓
Q7-4780		77	7,8	660	42,1	1,20	✓	✓	✓	✓	✓	✓	✓
Q7-4535 base	HCR-base, must add peroxide Enhanced tear-resistance HCR > 29 day implant Compliant to USP pyrogenicity	36	8,1	830	24,6	1,12	✓	✓	✓	✓	✓	✓	✓
Q7-4550 base		48	9,3	680	31,6	1,16	-	-	✓	✓	✓	✓	✓

[1]: Selected Ph. Eur. 3.1.9: substances soluble in hexane & volatile matter

- Manufactured in dedicated healthcare facility

Liquid Silicone Rubber (LSR)

Injection molding of precise and intricate parts of medical devices as o-rings, stoppers, closures or mesh and fabric coating

Type	Product Description	Physical Properties					Biocompatibility Testing						
		Hardness Shore A	Tensile Strength [MPa]	Elongation at break [%]	Tear Strength [kN/m]	Relative Density	ISO 10993-3	ISO 10993-4	ISO 10993-5	ISO 10993-10	Ph. Eur. 3.1.9 [1]	Food Grade	USP Class V &VI
Liveo™ C6-Series liquid silicone rubber (LSR)													
C6-530	Two-part (1:1 by weight), PT-catalyzed LSR ≤ 29 day implant	30	8,2	830	26,3	1,13	-	-	✓	✓	✓	✓	✓
C6-540		40	8,9	740	24,1	1,13	-	-	✓	✓	✓	✓	✓
C6-550		50	10,4	660	44,7	1,14	-	-	✓	✓	✓	✓	✓
C6-560		60	8,8	540	50,9	1,10	-	-	✓	✓	✓	✓	✓
C6-570		65	9,1	440	54,4	1,15	-	-	✓	✓	✓	✓	✓
C6-720	Two-part (1:1 by weight), PT-catalyzed LSR ≤ 29 day implant Reduced mold fouling Enhanced tear strength & compression set No post-cure to stabilize physical properties	23	6,5	750	26	1,14	-	-	✓	✓	✓	✓	✓
C6-740		40	8,6	680	30,7	1,14	-	-	✓	✓	✓	✓	✓
C6-750		50	8,8	610	42,1	1,13	-	✓	✓	✓	✓	✓	✓
C6-770		67	9,3	450	42,1	1,14	-	✓	✓	✓	✓	✓	✓

[1]: Selected Ph. Eur. 3.1.9: substances soluble in hexane & volatile matter

- Manufactured in dedicated healthcare facility

Type	Product Description	Physical Properties					Biocompatibility Testing						
		Hardness Shore A	Tensile Strength [MPa]	Elongation at break [%]	Tear Strength [kN/m]	Relative Density	ISO 10993-3	ISO 10993-4	ISO 10993-5	ISO 10993-10	Ph. Eur. 3.1.9 [1]	Food Grade	USP Class V &VI
Liveo™ BioMedical Grade liquid silicone rubber (LSR)													
7-6830	Two-part (1:1 by weight), PT-catalyzed LSR > 29 day implant	30	8,8	790	24,1	1,13	✓	✓	✓	✓	✓	✓	✓
7-6840		40	9,8	700	36,8	1,13	✓	✓	✓	✓	✓	✓	✓
Q7-4840		44	9,4	540	36,8	1,12	✓	✓	✓	✓	✓	✓	✓
Q7-4850		50	10,1	630	45,1	1,15	✓	✓	✓	✓	✓	✓	✓
Q7-4860		60	8,8	540	50,9	1,1	✓	✓	✓	✓	✓	✓	✓
Q7-4870		66	9,5	420	47,4	1,15	✓	✓	✓	✓	✓	✓	✓
Q7-7840	Two-part (1:1 by weight), PT-catalyzed LSR > 29 day implant Formulated to reduce mold fouling Enhanced tear strength & compression set	40	9,3	750	30,7	1,14	✓	✓	✓	✓	✓	✓	✓
Q7-7850		50	9	660	48,2	1,13	✓	✓	✓	✓	✓	✓	✓
Q7-78700		67	9,4	415	45,6	1,14	✓	✓	✓	✓	✓	✓	✓

[1]: Selected Ph. Eur. 3.1.9: substances soluble in hexane & volatile matter

- Manufactured in dedicated healthcare facility

Silicone Pharma Tubing

Translucent, platinum-cured silicone tubing for safe, secure and ultrapure fluid transfer and filling. Available in 3 durometer

Type	Product description	Physical Properties							Biocompatibility Testing			
		Durometer Shore A [1]	Elongation at break [%] [2]	Modulus at 200% [MPa] [2]	Tensile Strength at break [kN/m] [2]	Burst Pressure [bar] [3]	Tear Strenght [kN/m] [1]	Specific Gravity [2]	ISO 11737-1 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												
50	Translucent, PT-cured silicone tubing 3 durometer: 50, 65 and 80 High resiliency Kink resistant Easily sterilizable	50	795	2,1	8,7	4,1	47,3	1,14	✓	✓	✓	✓
65		65	775	2,8	6,8	7,7	45,5	1,22	✓	✓	✓	✓
80		80	570	3,9	7,0	13,2	42	1,22	✓	✓	✓	✓

- Shore A 50 durometer: suitable for most applications and for short term pumping operations
- Shore A 65 durometer: offers kink-resistance and higher pressure resistance
- Shore A 80: cost effective alternative to Liveo™ reinforced tubing for moderate to high pressure or vacuum applications. Offers the highest kink-resistance.
- BPOG extractable testing available based on elastomer
- USP665 tests available upon request
- The DuPont Liveo Pharma Silicone Tubing portfolio offers more than 150 standard dimensions. Get in touch!

High purity Shore A 50 translucent silicone tubing for ultrapure fluid transfer. Low-Hysteresis technology provides extended peristaltic pump performance, long pump life & outstanding filling accuracy.

Type	Product description	Physical Properties							Biocompatibility Testing			
		Durometer Shore A [1]	Elongation at break [%] [2]	Modulus at 200% [MPa] [2]	Tensile Strength at break [kN/m] [2]	Burst Pressure [bar] [3]	Tear Strenght [kN/m] [1]	Specific Gravity [2]	ISO 11737-1 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 Advanced Pump Tubing												
APT 50		50	590	3	8,9	3,4	40,3	1,14	✓	✓	✓	✓

- Pump life up to four times higher than Liveo™ pharma tubing
- Superior resiliency
- Easily sterilizable
- Kink resistant

High-purity Shore A 65 silicone tubing for ultrapure fluid transfer. Polyester fiber-reinforced pharmaceutical grade silicone tubing for applications requiring high kink, high pressure or high vacuum resistance

Type	Product description	Physical Properties							Biocompatibility Testing			
		Durometer Shore A [1]	Elongation at break [%] [2]	Modulus at 200% [MPa] [2]	Tensile Strength at break [kN/m] [2]	Burst Pressure [bar] [3]	Tear Strenght [kN/m] [1]	Specific Gravity [2]	ISO 11737-1 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 65 Reinforced Tubing												
Pharma 65 RFT		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)

- Reinforced for improved burst strength
- Resistant to collapse under vacuum
- High resiliency
- Easy sterilizable

DuPont Liveo™ TPE Pharma Tubing

High-purity Shore A 65 Pharma TPE tubing for fluid, media and solvent transport, single-use processing or peristaltic pump applications in biopharmaceutical processes and biotechnology

Type	Product description	Physical Properties						Biocompatibility Testing			
		Durometer Shore A	Elongation at break [%] [1,2]	Modulus at 200% [MPa] [1,2]	Tensile Strength at break [kN/m] [1,2]	Burst Pressure 1 [bar] [1,2]	Specific Gravity [1,2]	ISO 11737-1	ISO 10993-5,6,10,11	USP Class VI	USP 85/151/ 232/665/788
Liveo™ Pharma TPE Tubing											
Pharma TPE 65		65	1134[1]	2,7[1]	9,4[1]	87[1]	0,9[1]	✓	✓	✓	✓

[1]: based on tests with Liveo TM 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)

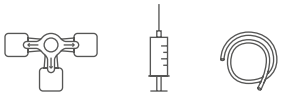
- Improved heat-welding to itself and competitive offer
- High tensile strength and burst resistance before & after welding
- Low extractables
- Good chemical resistance
- Minimal spallation after 24h of pumping
- Stable clarify after sterilization
- Manufactured in ISO Class 7 cleanroom

Interested in low-temperature compatible TPE tubings?

Get in touch!

Medical Grade UV-curing adhesives

Multipurpose UV-curing adhesives



Dymax 1000-series adhesives are ideal for bonding a wide variety of substrates found in reservoirs and housing, respiratory devices, needles & syringes, transducers, tube sets & fittings, wearable devices and other medical disposables.

Type	Recommended substrates / specific features	Physical Properties					Biocompatibility Testing				
		Viscosity [cP]	Durometer Hardness	Tensile break [MPa]	Elongation at break [%]	Modulus of elasticity [Mpa]	ISO 10993-4	ISO 10993-5	ISO 10993-6	ISO 10993-10	ISO 10993-11
Dymax 1000-series multipurpose adhesives											
1209-M-UR-SC*	ABS, PC, PCTG, PEEK, PETG, PMMA, PPO, PS, PVC, SS • self-leveling adhesive	1200	D60	15,6	170	641	✓	✓	✓	✓	✓
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	379	-	✓	-	-	-
1040-M	ABS, PC, PCTG, PMMA, PPO, PS, SAN, AL, BR, SS, glass • autoclavable	775	D60	18,6	8	668,8	-	✓	-	-	-
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	8,8	-	✓	-	-	-

*TPO free alternatives under development. Please reach out to receive your sample!

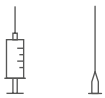
UV-curing Adhesives for Catheter Assembly

Dymax CTH-series adhesives provide a high degree of flexibility, excellent moisture and humidity resistance and meet the unique assembly challenges associated with newest catheter materials as Nylon12 and PEBA.

Type	Recommended substrates / specific features	Physical Properties					Biocompatibility Testing				
		Viscosity [cP]	Durometer Hardness	Tensile break [MPa]	Elongation at break [%]	Modulus of elasticity [Mpa]	ISO 10993-4	ISO 10993-5	ISO 10993-6	ISO 10993-10	ISO 10993-11
Dymax CTH-series adhesives for catheter assembly											
209-CTH	ABS, CAP, PC, PCTG, PET, PET-G,PMMA, PS, SAN, SS, NiTi	300	D70	17	120	300	✓	✓	✓	✓	✓
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	105,4	✓	✓	✓	✓	✓
215-CTH-LV-UR-SC*	ABS, PA, PC, PCTG, PEBA, PEEK, PEI, PET, PETG; PMMA, PS, PSU, PU, PVC, TPU	450	D53	11	300	117	✓	✓	✓	✓	✓
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	1425	✓	✓	✓	✓	✓

*TPO free alternatives under development. Please reach out to receive your sample!

UV-Curing adhesives for Needle Assembly



Dymax 1400- and 1500-series adhesives are ideal for automated high-speed assembly lines for cannula bonding to hubs, various hypodermic- and biopsy needles, syringes and winged infusion sets. They provide fast-cure, fluorescing properties and allow bonding of UV-blocking or heavily tinted plastics.

Type	Recommended substrates / specific features	Physical Properties					Biocompatibility Testing				
		Viscosity [cP]	Durometer Hardness	Tensile break [MPa]	Elongation at break [%]	Modulus of elasticity [Mpa]	ISO 10993-4	ISO 10993-5	ISO 10993-6	ISO 10993-10	ISO 10993-11
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	419	-	✓	-	-	-
1405-M-UR-SC*	ABC, PC, PCTG; PEI, PET, PETG, PMMA, PPO, PS, PU, SAN, SS PCB	150	D70	18,6	150	397	-	✓	-	-	-
1501-M-UR	ABS, CAP, PC, PETG, PP (st), PVC, SAN, SS • for shadowed areas/colored plastics	80	D70	180	80	397	-	✓	-	-	-
1045-M*	ABS, PC, SS, glass • very low extractables • autoclavable	525	D78	23,4	20	1861,6	✓	✓	✓	✓	✓

*TPO free alternatives under development. Please reach out to receive your sample!

UV-Curing Adhesives for Respiratory Devices

Dymax MSK-series adhesives are formulated for bonding a variety of (highly plasticized) substrates within respiratory devices such as anaesthesia masks, resuscitator bags and breathing circuits.

Type	Recommended substrates / specific features	Physical Properties					Biocompatibility Testing				
		Viscosity [cP]	Durometer Hardness	Tensile break [MPa]	Elongation at break [%]	Modulus of elasticity [Mpa]	ISO 10993-4	ISO 10993-5	ISO 10993-6	ISO 10993-10	ISO 10993-11
Dymax MSK-series adhesives for bonding respiratory devices											
108-MSK	CAP, PC, PEEK, PMMA, PS, PU, PVC, SAN, TPU	600	D75	25	70	388	-	✓	-	✓	-
104-MSK-Gel	ABS, PCTG, PETG, PU, PVC, SAN	23500	D60	19	205	147	-	✓	-	-	-
111-MSK	ABS, PC, PI, PMMA, PS, PU, PCC, SAN, SEBS, TPU	250	D55	6,9	400	400	-	✓	-	-	-

UV-Curing Adhesives for Wearable Medical Device Assembly


Dymax 2000-series adhesives are uniquely designed for assembly of wearable medical devices. Formulated without skin-irritants, the series provides strong bonds and dependable performance against moisture and thermal shock.

Type	Recommended substrates / specific features	Physical Properties					Biocompatibility Testing				
		Viscosity [cP]	Durometer Hardness	Tensile break [MPa]	Elongation at break [%]	Modulus of elasticity [Mpa]	ISO 10993-4	ISO 10993-5	ISO 10993-6	ISO 10993-10	ISO 10993-11
Dymax 2000-MW series adhesives for wearable medical device assembly											
2022-MW	ABS, PC, PETG, PI, PU, SAN, AL, SS, Glas	700	D60	19,3	25	620,5	-	✓	-	-	-
2101-MW-UR	ABS, PC, PCTG, PETG,PVC, SAN, TPU	5500	D80	24,8	80	1020,4	-	✓	-	✓	-
2103-MW-UR*	PC, ABS, PVC, PEBA, SS	5500	D70	18,6	23	641,2	-	✓	-	✓	-

* limited release, full commercialization expected Q1 2023, samples available upon request

Curing with light and contact/moisture

A revolutionary patented adhesive platform, HLC™ (Hybrid Light-Curable) technology, combines the best qualities of anionic and free radical chemistries. Cure with UV/Visible light or a combination of light and contact/moisture. The contact curing feature allows bonding to a broad range of substrates, including opaque and light-blocking materials, and in shadow areas.

Type	Recommended substrates / specific features	Physical Properties					Biocompatibility Testing				
		Viscosity [cP]	Durometer Hardness	Tensile break [MPa]	Elongation at break [%]	Modulus of elasticity [Mpa]	ISO 10993-4	ISO 10993-5	ISO 10993-6	ISO 10993-10	ISO 10993-11
HLC™ (Hybrid Light-Curable)											
HLC-M-1000	ABS, PC, PCTG, PEBA, PETG, PMMA, PS, SAN, SS	3	D80	49	4	2144,3	✓	✓	✓	-	✓

Dymax Nomenclature

LV = Low Viscosity

T = Thick

SV = Special Viscosity

VT = Very Thick

SC = See-Cure (Patented Color-Change Technology)

UR® = Ultra-Red (Patented Color-Change Technology)

Our principals for medical plastics

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							

Celanese – Polyamide (PA)

Properties Zytel® – high mechanical strength, combines rigidity and impact strength

Medical applications Forceps, applicator guns, medical valves, filters, syringe barrels

Type	Description	Food compliance	Medical approvals			Sterilisation			
			10993	USP	DMF	Steam	EtO	Gamma	E-Beam
Zytel®									
SC315	PA 6.12. Hohe Fließfähigkeit	FDA; (EU) 10/2011; GMP	5; 11	VI	-	87°C +3min 134°C <25-100 cycles*	50°C 2hr. 1x	-	*

*Please contact your contact your sales or technical person for more information.

Celanese – Polybutylene Terephthalat (PBT)

Celanese
The chemistry inside innovation™

Properties: Crastin® – exceptional surface finishes, good dyeing performance, chemical resistance

Medical applications: Components for insulin syringes

Type	Description	Food compliance	Medical approvals			Sterilisation			
			10993	USP	DMF	Steam	EtO	Gamma	E-Beam
Crastin® SC									
SC164	Non-reinforced, low viscosity	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% glass fibre-reinforced, low warpage								

*Please contact your sales or technical person for more information.

Celanese – Thermoplastic Polyester-Elastomer (TPC)

Celanese
The chemistry inside innovation™

Properties: Hytrel® – good flexibility, sterilisation resistance, chemical resistance, low material fatigue, high resistance to long-term stress

Medical applications: Tubing with high resistance to long-term stress, wrist protection, foot prostheses

Type	Hardness	Food compliance	Medical approvals			Sterilisation			
			10993	USP	DMF	Steam	EtO	Gamma	E-Beam
Hytrel® SC									
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.

Celanese – Thermoplastic vulcanisate (TPV)

Celanese
The chemistry inside innovation™

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	Colour	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	colourable	Shore 57A							
8181-55B1MED	bk	Shore 57A							

bk = black, nc = natural color

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®									
PA-703TRP	2,3	1,08	FDA	5; 10	-	-	-	✓	-
PA-758	3,0	1,08	FDA; (EU) 10/2011; GMP	-	VI	-	-	✓	-

CHIMEI – Acrylonitrile Butadiene Styrene (ABS)

CHIMEI a step up

Properties Polylac® is an impact-resistant, high-gloss ABS that is suitable for a wide range of applications. The material can be processed by injection molding as well as extrusion. In addition to good flowability, which facilitates processing in many applications, Polylac® 757F also meets the requirements of EU Directive 10/2011 and is therefore suitable for contact with food.

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 (milky white)	18	1,05	FDA	5; 10	-	-	-	✓	-
ABS PA-757F (milky white)	18	1,05	FDA; (EU) 10/2011; GMP	-	VI	-	-	✓	-

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	15	1,2	FDA	3; 4; 5; 6; 10;11	-	-	-	✓	-
PC-115P F01 (slight blue tint)	17	1,2	FDA	5; 10	-	-	-	✓	-
PC-115P F17111C1 (blue tint)	17	1,2	FDA	3; 4; 5; 6; 10;11	-	-	-	✓	50kGy

CHIMEI – Styrene Acrylonitrile Copolymer (SAN)

CHIMEI a step up

Properties Kibisan® is a transparent material with very good processing properties. Another important feature is the material's good chemical resistance, which is a prerequisite for many applications in the medical sector. In addition, both grades listed meet the requirements of EU Directive 10/2011 and are therefore also ideally suited for contact with food.

Medical applications Syringe covers

Type	MFR (g/10min)	Density (g/cm³)	Food compliance	Medical approvals			Sterilisation		
				10993	USP	DMF	Steam	EtO	Gamma
Kibisan®									
PN-107 L125FG	58	1,06	FDA; (EU) 10/2011; GMP	-	VI	-	-	✓	-
PN-127 L150FG	17	1,06	FDA; (EU) 10/2011; GMP	-	VI	-	-	✓	-

Delrin – Polyoxymethylen-Homopolymer (POM)

Properties: Delrin® – high abrasion resistance, good durability, dimensional stability

Medical applications: Injector pens, inhalers, dosing systems

Type	Description	Food compliance	Medical approvals			Sterilisation			
			10993	USP	DMF	Steam	EtO	Gamma	E-Beam
Delrin® SC; Delrin® RASC									
SC631	Low to medium flow properties	FDA; (EU) 10/2011; GMP	5; 11	VI	-	87°C +3min 134°C <25 cycles	50°C 2hr. 1x	-	-
SC655	Medium flow properties								
RASC655	Medium flow properties								
SC690	High flow properties								
SC698	High flow properties (filled with silicone oil)								
RASC698	High flow properties (filled with silicone oil)								

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							

bio based recycling (mechanical & chemical)

INEOS Olefins & Polymers – Polyethylene with low density (LDPE)

INEOS

Properties — Eltex® MED – good flow properties, good dimensional stability, high purity

Medical applications — Blow-fill-seal (BFS) bottles and ampoules, medical tubing, film applications

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	(✓)	-	-

(√) on request

INEOS Olefins & Polymers – Polyethylene with high density (HDPE)

Properties

Eltex® MED – fast-flowing, good dimensional stability, high purity
Eltex® – good chemical resistance, outstanding organoleptic properties

Medical applications

Syringes (syringe plungers), thin-walled containers for pharmaceutical applications, caps and closures

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	✓	✓	✓	-	-
Eltex® HDPE											
HD5502M	0,2	954	FDA; (EU) 10/2011; GMP	-	-	3.1.3; 3.1.5	✓	✓	✓	-	-
Eltex® organoleptic HDPE											
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	-	(✓)	(✓)	-	-

(√) auf Anfrage

(√) on request

bio based recycling (mechanical & chemical)

INEOS Olefins & Polymers – Polypropylene (PP)

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 1 hr	✓	-	-
201-MG02	1,8	900		-		3.1.3 ; 3.1.6	✓		✓	-	-
240-MS23	23	980		-		-	-		✓	-	-
Terpolymer											
KS357	5	620	FDA; (EU) 10/2011; GMP	-	VI	3.1.3	-	✓	(✓)	-	-

(√) on request

bio based recycling (mechanical & chemical)

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							

SK CHEMICALS – Polyethylene terephthalate (PET); Polyethylene terephthalate glycol modified (PETG); Polycyclohexylene dimethylene terephthalate (PCTG)

Properties

SKYPET® PET BR – high transparency, excellent chemical resistance, easy to recycle
SKYGREEN® PETG S2008 – high transparency, good impact strength, easy thermoforming, good printability

Medical applications

Blister packs, disposable syringes, medical dishes and containers, sample grippers

Type	Density (g/cm³)	Food compliance	Medical approvals				Sterilisation		
			10993	USP	EP	DMF	Steam	EtO	Gamma
SKYPET®									
SKYPET® BR	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	1,25	FDA; (EU) 10/2011; GMP	-	VI	-	-	-	50°C 50% 5hr	50kGy 30min	50kGy 24hr
ECOZEN® MT10	1,27		-			-	-			
ECOZEN® MT10G	1,27		-			-	-			
ECOTRIA®										
ECOTRIA® S2008-CR	1,27	FDA; (EU) 2023/2006; GMP	3; 4; 5: 6; 10; 11	[661]; [87]; VI	3.1.15	✓	-	50 °C 50 % 5 hr	50 kGy 30 min	50 kGy 24 hr

bio based recycling (mechanical & chemical)

Syensqo – Polyaryletherketone (PAEK)

Properties

AvaSpire® PAEK (polyaryletherketone) is a family of high-performance polyketones tailored to close cost and performance gaps between PEEK and other high-performance polymers. For example, ductility and toughness can be significantly improved over comparable PEEK grades, resulting in 20% higher elongation at yield and twice the elongation at break.

Medical applications

Medical and dental instruments, sterilisation cases and trays, operating theatre equipment, diagnostic equipment; reusable medical equipment

Type	MFR (g/10min)	Density (g/cm³)	Food compliance	Medical approvals			Sterilisation		
				10993	USP	DMF	Steam	EtO	Gamma
AvaSpire®									
AV-621 NT	5	1.29	FDA / (EU) 10/2011	5; 10; 11	-	-	134°C 18min 500x	500x	40kGy
AV-621 GF30	2	1.55	FDA						
AV-650 BG15	25	1.3	FDA	-					
AV-651 NT	25	1.29	FDA / (EU) 10/2011	5; 10; 11					
AV-651 BG15	25	1.29	FDA / (EU) 10/2011						
AV-651 BK95	25	1.29	FDA / (EU) 10/2011						
AV-651 CF30	4,5	1.42	-						
AV-651 GF30 BG20	9	1.52	FDA						
AV-651 GF30 BK95	9	1.52	-						

Syensqo – Polyetheretherketone (PEEK)

SYENSQO

Properties

KetaSpire® PEEK are polyetheretherketones for highly demanding applications. The high-performance plastics are characterised in particular by an outstanding combination of fatigue strength and chemical resistance.

Medical applications

Medical and dental instruments, sterilisation cases and trays, operating theatre equipment, diagnostic equipment; reusable medical devices.

Type	MFR (g/10min)	Density (g/cm³)	Food compliance	Medical approvals			Sterilisation		
				10993	USP	DMF	Steam	EtO	Gamma
KetaSpire®									
KT-820 NT	3.0	1.30	FDA; (EU) 10/2011	5; 10; 11; 18	VI	-	134°C 18min 500x	500x	40kGy
KT-820 CF30	1.1	1.41	FDA	5; 10; 11	-				
KT-820 FP	3.0	1.30	FDA; (EU) 10/2011	5; 10; 11; 18					
KT-820 GF30	0.7	1.53	FDA						
KT-820 P	3.0	1.30	FDA; (EU) 10/2011						
KT-820 SL30	2.4	1.45		-					
KT-880 NT	36	1.30	FDA; (EU) 10/2011	5; 10; 11; 18	VI				
KT-880 CF30	11	1.41	FDA		-				
KT-880 GF30	14	1.53	FDA						

KT-820 CF30, KT-820 GF30, KT-880 CF30 and KT-880 GF30 are not "EU Food" compliant.

Syensqo – Polyethersulfone (PESU)

SYENSQO

Properties

Veradel® HC - a rigid, transparent high-temperature polymer for use in high-performance healthcare applications. The material has inherent flame resistance and is highly resistant to a wide range of cleaning agents used in healthcare as well as sterilising agents. It retains its transparency, mechanical properties and dimensional stability in both humid and very hot environments. In sterilisation it is compatible with ethylene oxide, vaporized hydrogen peroxide, gamma radiation and steam.

Medical applications

Medical device housings

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

Syensqo – Polyphenylsulfone (PPSU)

SYENSQO

Properties

Radel® – Incredibly tough, transparent plastic with a heat deflection temperature (HDT) of 207°C, excellent chemical resistance and the ability to withstand over 1000 steam sterilisation cycles without significant loss of properties. Available in solid and transparent colours.

Medical applications

Sterilisation containers and trays, orthopaedic devices, medical and dental instruments

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	17	1,30				-			
R-5500	12-17	1,29				-			
R-5800	20-28	1,29				-			

The polymer base is compliant. Please check with a member of the sales team whether the colour you require is approved.

Syensqo – Polysulfone (PSU)

SYENSQO

Properties

Udel® – Almost crystal-clear transparent plastic with a heat deflection temperature (HDT) of 174°C, high strength, good chemical resistance and excellent dimensional stability in the presence of steam and oxidising agents. Available in solid colours, transparent and glass fibre-filled grades.

Medical applications

Medical and dental instruments, vacuum flasks, tube connectors, device housings, haemodialysis membranes

Type	MFR (g/10min)	Density (g/cm³)	Food compliance	Medical approvals			Sterilisation		
				10993	USP	DMF	Steam	EtO	Gamma
Udel®									
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				-			

The polymer base is compliant. Please check with a member of the sales team whether the colour you require is approved.

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							
0645 (High TG)	6	0,94							
1608 (Flex. Shore D 65)	3	0,92							
0510HFE (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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