

# 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
- Silicone Skin Adhesives
- Styrene Copolymers
- Thermoplastic Elastomers
- Transparent Polymers

## Medical Portfolio

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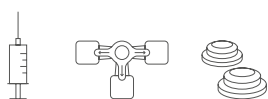
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# Our principals for medical specialities



# 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

Type	Product Description	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]
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
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\* 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



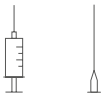
## Hydrophobic silicone dispersion for lubrication and siliconization of cutting edges and needles

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
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- 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

<b>0,65 cSt.</b>	Clear, colorless, high-purity, volatile Hexamethyldisiloxan	✓	-	✓*	**	0,65	0,76	acetone	-3
<b>1 cSt.</b>	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)

<b>7-9700</b>	Two-part (1:1 by weight), PT-catalyzed, soft fillerless elastomeric adhesive Low viscosity Transparent	500/ 320	90	0,6	0,11	✓	✓	-
<b>MG 7-9800</b>		500/ 320	90	0,6	0,11	✓	✓	✓
<b>MG 7-9850</b>		2900/ 2900	135	1,1	0,03	✓**	✓**	✓
<b>MG 7-9900</b>		5100/ 5100	140	1,9	0,05	✓**	✓**	✓
<b>MG 7-9960 ***</b>		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)

<b>MG-2401</b>	One-part, polycondensed polydimethylsiloxane/silicate resin adhesive Volatile solvent-based silicone adhesive	32%, HMDS	90	17,2*	21	✓	✓	-
<b>MG-2402</b>		64%, Ethyl-acetate	2500	17,2*	21	✓	✓	-
<b>MG-2502</b>		59%, Ethyl-acetate	2500	16,4*	16	✓	✓	-
<b>MG-2410 hotmelt</b>	One-part, polycondensed polydimethylsiloxane/silicate resin adhesive Hot-melt silicone adhesive	100%	30300 at 185°C	14,5*	9	✓	✓	-

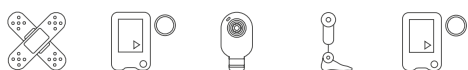
\*: @50 µm, peel force from stainless steel

\*\* : 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 [ $\mu\text{m}$ ]	Peel adhesion [2,5 g/cm <sup>2</sup> ]*	USP NF	Ph. Eur.	FDA DMF

## Liveo™ 7-4107 Silicone Elastomer Membrane

100% Biomedical Grade LSR							
75 $\mu\text{m}$ thick	10	50	75	2,5	Class VI	3.1.9 **	n.a.
Translucent, matte, soft and flexible film							

\*: @75  $\mu\text{m}$ , 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<sup>2</sup>

# 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 <sup>1</sup>	Food Grade

### Liveo™ C6-Series High Consistency Rubber (HCR)

<b>C6-135</b>	Two-part (1:1 by weight), PT-catalyzed HCR	36	8,2	1120	35,1	1,12	-	-	✓	✓	✓	✓	✓
<b>C6-150</b>		50	10,6	980	42,1	1,16	-	-	✓	✓	✓	✓	✓
<b>C6-165</b>	Enhanced tear-resistance HCR ≤ 29 day implant	61	8,0	940	42,1	1,21	-	-	✓	✓	✓	✓	✓
<b>C6-180</b>		77	7,2	610	38,6	1,21	-	-	✓	✓	✓	✓	✓
<b>C6-235</b>	One-Part HCR base Peroxide-curing agent necessary	37	7,5	810	21,1	1,12	-	-	✓	✓	✓	✓	✓
<b>C6-250</b>		49	8,2	530	26,3	1,16	-	-	✓	✓	✓	✓	✓
<b>C6-265</b>	LH: Lower hysteresis for demanding applications (e.g. peristaltic pump tubing)	66	8,2	560	35,1	1,20	-	-	✓	✓	✓	✓	✓
<b>C6-350 LH</b>		49	8,5	730	38,6	1,15	-	✓	✓	✓	✓	✓	✓

<sup>1</sup>: 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 <sup>1</sup>	Food Grade

## Liveo™ BioMedical Grade High Consistency Rubber (HCR)

<b>Q7-4720</b>		23	8,9	1310	31,6	1,11	✓	✓	✓	✓	✓	✓	✓
<b>Q7-4735</b>	Two-part (1:1 by weight), PT-catalyzed HCR	36	9,3	1180	36,8	1,12	✓	✓	✓	✓	✓	✓	✓
<b>Q7-4750</b>	Enhanced tear-resistance HCR > 29 day implant	50	10	930	45,6	1,16	✓	✓	✓	✓	✓	✓	✓
<b>Q7-4765</b>	Compliant to USP pyrogenicity	65	8	900	45,6	1,20	✓	✓	✓	✓	✓	✓	✓
<b>Q7-4780</b>		77	7,8	660	42,1	1,20	✓	✓	✓	✓	✓	✓	✓
<b>Q7-4535 base</b>	HCR-base, must add peroxide Enhanced tear-resistance HCR	36	8,1	830	24,6	1,12	✓	✓	✓	✓	✓	✓	✓
<b>Q7-4550 base</b>	> 29 day implant Compliant to USP pyrogenicity	48	9,3	680	31,6	1,16	-	-	✓	✓	✓	✓	✓

<sup>1</sup>: 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 <sup>1</sup>	Food Grade

## Liveo™ C6-Series liquid silicone rubber (LSR)

<b>C6-530</b>	Two-part (1:1 by weight), PT-catalyzed LSR ≤ 29 day implant	30	8,2	830	26,3	1,13	-	-	✓	✓	✓	✓	✓
<b>C6-540</b>		40	8,9	740	24,1	1,13	-	-	✓	✓	✓	✓	✓
<b>C6-550</b>		50	10,4	660	44,7	1,14	-	-	✓	✓	✓	✓	✓
<b>C6-560</b>		60	8,8	540	50,9	1,10	-	-	✓	✓	✓	✓	✓
<b>C6-570</b>		65	9,1	440	54,4	1,15	-	-	✓	✓	✓	✓	✓
<b>C6-720</b>	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	-	-	✓	✓	✓	✓	✓
<b>C6-740</b>		40	8,6	680	30,7	1,14	-	-	✓	✓	✓	✓	✓
<b>C6-750</b>		50	8,8	610	42,1	1,13	-	✓	✓	✓	✓	✓	✓
<b>C6-770</b>		67	9,3	450	42,1	1,14	-	✓	✓	✓	✓	✓	✓

<sup>1</sup>: 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 <sup>1</sup>	Food Grade

## Liveo™ BioMedical Grade liquid silicone rubber (LSR)

<b>7-6830</b>	Two-part (1:1 by weight), PT-catalyzed LSR > 29 day implant	30	8,8	790	24,1	1,13	✓	✓	✓	✓	✓	✓	✓
<b>7-6840</b>		40	9,8	700	36,8	1,13	✓	✓	✓	✓	✓	✓	✓
<b>Q7-4840</b>		44	9,4	540	36,8	1,12	✓	✓	✓	✓	✓	✓	✓
<b>Q7-4850</b>		50	10,1	630	45,1	1,15	✓	✓	✓	✓	✓	✓	✓
<b>Q7-4860</b>		60	8,8	540	50,9	1,1	✓	✓	✓	✓	✓	✓	✓
<b>Q7-4870</b>		66	9,5	420	47,4	1,15	✓	✓	✓	✓	✓	✓	✓
<b>Q7-7840</b>	Two-part (1:1 by weight), PT-catalyzed LSR > 29 day implant	40	9,3	750	30,7	1,14	✓	✓	✓	✓	✓	✓	✓
<b>Q7-7850</b>	Formulated to reduce mold fouling	50	9	660	48,2	1,13	✓	✓	✓	✓	✓	✓	✓
<b>Q7-78700</b>	Enhanced tear strength & compression set	67	9,4	415	45,6	1,14	✓	✓	✓	✓	✓	✓	✓

<sup>1</sup>: 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 <sup>1</sup>	Elongation at break [%] <sup>2</sup>	Modulus at 200% [MPa] <sup>2</sup>	Tensile Strength at break [kN/m] <sup>2</sup>	Burst Pressure [bar] <sup>3</sup>	Tear Strength [kN/m] <sup>1</sup>	Specific Gravity <sup>2</sup>	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	50	795	2,1	8,7	4,1	47,3	1,14	✓	✓	✓	✓
65	3 durometer: 50, 65 and 80 High resiliency	65	775	2,8	6,8	7,7	45,5	1,22	✓	✓	✓	✓
80	Kink resistant Easily sterilizable	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 kinking 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
- The DuPont Liveo Pharma Silicone Tubing portfolio offers more than 150 standard dimensions. Get in touch!



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

Type	Product description	Physical Properties							Biocompatibility Testing			
		Durometer Shore A <sup>1</sup>	Elongation at break [%] <sup>2</sup>	Modulus at 200% [MPa] <sup>2</sup>	Tensile Strength at break [kN/m] <sup>2</sup>	Burst Pressure [bar] <sup>3</sup>	Tear Strength [kN/m] <sup>1</sup>	Specific Gravity <sup>2</sup>	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	✓	✓	✓	✓
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- 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 ultra pure 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 <sup>1</sup>	Elongation at break [%] <sup>2</sup>	Modulus at 200% [MPa] <sup>2</sup>	Tensile Strength at break [kN/m] <sup>2</sup>	Burst Pressure [bar] <sup>3</sup>	Tear Strength [kN/m] <sup>1</sup>	Specific Gravity <sup>2</sup>	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 <sup>1</sup>	2,82 <sup>1</sup>	7,94 <sup>1</sup>	41,2 <sup>1</sup>	45,5 <sup>1</sup>	1,22 <sup>1</sup>	✓	✓	✓	✓
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<sup>1</sup>: based on elastomer

<sup>2</sup>: on extruded tubing (Die D)

<sup>3</sup>: 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 [%] <sup>1,2</sup>	Modulus at 200% [MPa] <sup>1,2</sup>	Tensile Strength at break [kN/m] <sup>1,2</sup>	Burst Pressure 1 [bar] <sup>1,2</sup>	Specific Gravity <sup>1,2</sup>	ISO 11737-1	ISO 10993-5,6,10,11	USP Class VI

## Liveo™ Pharma TPE Tubing

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

<sup>1</sup>: based on tests with Liveo™ Pharma TPE Tubing 9,5 mm (inner diameter) x 15,9 mm (outer diameter)

<sup>2</sup>: properties after steam sterilization (121°C/30 min) / gamma radiation (50 kGy)

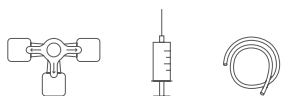
- Improved heat-welding to itself and competitive offer
- High tensile strength and burst resistance before & after welding
- Low extractables
- Good chemical resistance
- Minimal spallation after 24h of pumping
- Stable clarity after sterilization
- Manufactured in ISO Class 7 cleanroom



# 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

<b>1209-M-UR-SC</b>	ABS, PC, PCTG, PEEK, PETG, PMMA, PPO, PS, PVC, SS • self-leveling adhesive	1200	D60	15,6	170	641	✓	✓	✓	✓	✓
<b>1405-M-T-UR-SC</b>	ABS, PC, PCTG, PEI, PET, PETG, PMMA, PPO, PS, PSU, PU, PVC, SAN, TPU, SS, PCB	7000	D70	23	180	379	-	✓	-	-	-
<b>1040-M</b>	ABS, PC, PCTG, PMMA, PPO, PS, SAN, AL, BR, SS, glass • autoclavable	775	D60	18,6	8	668,8	-	✓	-	-	-
<b>1172-M-UR*</b>	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	-	✓	-	-	-

\* also for sealing, conformal coating or encapsulation of electronic circuit boards & components

## UV-curing Adhesives for Catheter Assembly



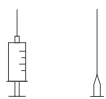
Dymax CTH-series adhesives provide a high degree of flexibility, excellent moisture and humidity resistance and meet the unique assembly challenges associated with newest catheter materials as Nylon12 and PEBA.

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

<b>209-CTH</b>	ABS, CAP, PC, PCTG, PET, PET-G, PMMA, PS, SAN, SS, NiTi	300	D70	17	120	300	✓	✓	✓	✓	✓
<b>215-CTH-SV01-UR-SC</b>	ABS, PA, PC, PCTG, PEBA, PEEK, PEI, PET, PETG; PMMA, PS, PSU, PU, PVC, TPU	1100	D53	11,7	300	105,4	✓	✓	✓	✓	✓
<b>215-CTH-LV-UR-SC</b>	ABS, PA, PC, PCTG, PEBA, PEEK, PEI, PET, PETG; PMMA, PS, PSU, PU, PVC, TPU	450	D53	11	300	117	✓	✓	✓	✓	✓
<b>250-CTH</b>	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	✓	✓	✓	✓	✓

## 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

<b>1406-M</b>	ABS, PC, PCTG, PE, PETG, PS, PVC, SAN, TPU, SS, PCB	150	D70	15	120	419	-	✓	-	-	-
<b>1405-M-UR-SC</b>	ABC, PC, PCTG; PEI, PET, PETG, PMMA, PPO, PS, PU, SAN, SS PCB	150	D70	18,6	150	397	-	✓	-	-	-
<b>1501-M-UR</b>	ABS, CAP, PC, PETG, PP (st), PVC, SAN, SS • for shadowed areas/colored plastics	80	D70	180	80	397	-	✓	-	-	-
<b>1045-M*</b>	ABS, PC, SS, glass • very low extractables • autoclavable	525	D78	23,4	20	1861,6	✓	✓	✓	✓	✓

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

## 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

<b>108-MSK</b>	CAP, PC, PEEK, PMMA, PS, PU, PVC, SAN, TPU	600	D75	25	70	388	-	✓	-	✓	-
<b>104-MSK-Gel</b>	ABS, PCTG, PETG, PU, PVC, SAN	23500	D60	19	205	147	-	✓	-	-	-
<b>111-MSK</b>	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

<b>2022-MW</b>	ABS, PC, PETG, PI, PU, SAN, AL, SS, glass	700	D60	19,3	25	620,5	-	✓	-	-	-
<b>2101-MW-UR</b>	ABS, PC, PCTG, PETG,PVC, SAN, TPU	5500	D80	24,8	80	1020,4	-	✓	-	✓	-
<b>1901-M</b>	CAP, PS, TPU, PCB (flexible & rigid) • for sealing, conformal coating or encapsulation of electronic circuit boards & components	3000	A67	2	45	3	-	✓	-	-	-
<b>2103-MW-UR*</b>	PC, ABS, PVC, PEBA, SS	5500	D70	18,6	23	641,2	-	✓	-	✓	-

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



## Dymax Nomenclature

LV = Low Viscosity

T = Thick

SV = Special Viscosity

VT = Very Thick

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

UR<sup>®</sup> = Ultra-Red (Patented Color-Change Technology)



# Our principals for medical plastics



## INEOS Olefins & Polymers – Polypropylene (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

<b>100-MG03</b>	3	1450	FDA; (EU) 10/2011; GMP	-	VI	3.1.3 ; 3.1.6	✓	121°C 1hr	✓	-	-
<b>100-MG12</b>	12	1400		5	[87]; VI	3.1.3 ; 3.1.6	✓		✓	-	-
 <b>100-MG25</b>	25	1200		-	VI	3.1.3 ; 3.1.6	✓		✓	-	-

### Eltex® MED RCP

 <b>200-MG02</b>	1,8	900	FDA; (EU) 10/2011; GMP	-	VI	3.1.3 ; 3.1.6	✓	121°C 1hr	✓	-	-
 <b>240-MS23</b>	23	980		-		-	-		✓	-	-

### Terpolymer

 <b>KS357</b>	5	620	FDA; (EU) 10/2011; GMP	-	VI	3.1.3	-	✓	(✓)	-	-
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(✓) auf Anfrage



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

## 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




<b>HD5226EA-M</b>	26	953	FDA; (EU) 10/2011; GMP	5	[87]; VI	3.1.3; 3.1.5	✓	✓	✓	-	-	
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## Eltex® HDPE

<b>HD5502M</b>	0,2	954	FDA; (EU) 10/2011; GMP	-	-	3.1.3; 3.1.5	✓	✓	✓	-	-	
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(✓) auf Anfrage

## Eltex® organoleptic HDPE

<b>CAP508</b>	1,8	953	FDA; (EU) 10/2011; GMP	-	[661.1]	3.1.3; 3.1.5	-	(✓)	(✓)	-	-	
<b>HD5211EA-B</b>	11	951	FDA; (EU) 10/2011	-	-	3.1.3	-	(✓)	(✓)	-	-	
<b>HD6070EA-B</b>	7,6	960		-	-	3.1.3; 3.1.5	-	(✓)	(✓)	-	-	

(✓) auf Anfrage

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



**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

<b>PH19N630</b>	7,5	920	FDA; (EU) 10/2011; GMP	5	[661.1]; [87]	3.1.3; 3.1.4	-	-	(✓)	50kGy	-
<b>PH22D630</b>	0,3	922		5	[661]; [87]; USPVI		(✓)	-	(✓)	-	-
<b>PH23H630</b>	2	923		-	[661.1]; VI		(✓)	-	(✓)	-	-
<b>PH23T630</b>	22	923		-	VI		(✓)	-	(✓)	50kGy	-
<b>PH27D630</b>	0,3	927		-	[661.1]; VI		(✓)	108°C 1hr	(✓)	-	-
<b>PH30D630</b>	0,3	930		-	[661.1]; VI		(✓)	112°C 1hr	(✓)	-	-

(✓) auf Anfrage

# 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	✓	-	-	-
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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		-			-	-			



## Solvay Specialty Polymers – Polyphenylsulfone (PPSU)

### 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/cm <sup>3</sup> )	Food compliance	Medical approvals			Sterilisation		
				10993	USP	DMF	Steam	EtO	Gamma

### Radel®

<b>R-5000</b>	14-20	1,29	FDA; (EU) 10/2011; GMP	5; 10; 11; 18	VI	-	134°C 18min 1.000x	✓ 100x	40kGy
<b>R-5100</b>	17	1,30				-			
<b>R-5500</b>	12-17	1,29				-			
<b>R-5800</b>	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.



## Solvay Specialty Polymers – Polyethersulfone (PESU)

### 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/cm <sup>3</sup> )	Food compliance	Medical approvals			Sterilisation		
				10993	USP	DMF	Steam	EtO	Gamma

### Veradel® HC

<b>HC-A301 NT</b>	30	1,37	FDA; (EU) 10/2011; GMP	5; 10; 11; 18	VI	-	134°C 18min 100x	✓ 100x	40kGy
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## Solvay Speciality Polymers – Polysulfone (PSU)

### 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/cm <sup>3</sup> )	Food compliance	Medical approvals			Sterilisation		
				10993	USP	DMF	Steam	EtO	Gamma

### Udel®

<b>GF-110</b>	5-9	1,33	FDA		-	-			
<b>GF-120</b>	5-9	1,40			-	-			
<b>P-1700</b>	5-9	1,24	FDA; (EU) 10/2011	5; 10; 11; 18	VI	-	134°C 18min 500x	✓ 100x	40kGy
<b>P-3500 LCD</b>	5-9	1,24				-			
<b>P-3703</b>	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.

## DuPont – 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

<b>SC631</b>	Low to medium flow properties								
<b>SC655</b>	Medium flow properties								
<b>RASC655</b>	Medium flow properties	FDA; (EU) 10/2011; GMP	5; 11	VI	-	87°C +3min 134°C <25 cycles	50°C 2hr. 1x	-	-
<b>SC690</b>	High flow properties								
<b>SC968</b>	High flow properties (filled with silicone oil)								
<b>RASC698</b>	High flow properties (filled with silicone oil)								

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



**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

<b>SC956</b>	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
<b>SC969</b>	Shore 63D								
<b>SC976</b>	Shore 72D								
<b>SC988</b>	Shore 82D								

\*Please contact your contact person for more information.

## Celanese – Polybutylene Terephthalat (PBT)



**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

<b>SC164</b>	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
<b>SC193</b>	30% glass fibre- reinforced, low warpage								

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

## 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®

<b>FGFE5171 NC010</b>	PA 6.6. 33% glassfibre reinforced	FDA; (EU) 10/2011; GMP	5; 11	VI	-	87°C +3min 134°C <25-100 cycles*	50°C 2hr. 1x	40kGy 1x*	50kGy 1x*
<b>SC310</b>	PA 6.6. high flowability								
<b>SC315</b>	PA 6.12. high flowability							-	*

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

## Celanese – Thermoplastic vulcanisate (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	Colour	Hardness	Food compliance	Medical approvals			Sterilisation		
				10993	USP	DMF	Steam	EtO	Gamma

### Santoprene®

<b>181-55MED</b>	bk	Shore 59A	5; 6; 10; 11	VI	-	✓	✓	50kGY
<b>281-55MED</b>	nc	Shore 60A						
<b>8281-35MED</b>	nc	Shore 38A						
<b>8281-45MED</b>	nc	Shore 49A						
<b>8281-55MED</b>	nc	Shore 59A						
<b>8281-65MED</b>	nc	Shore 68A						
<b>8281-75MED</b>	nc	Shore 79A						
<b>8281-90MED</b>	nc	Shore 93A						
<b>8281-55B1MED</b>	colourable	Shore 57A						
<b>8181-55B1MED</b>	bk	Shore 57A						

## CHIMEI – Polycarbonate (PC)

### 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/cm <sup>3</sup> )	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 F17111 (blue tint)	17	1,2	FDA	3; 4; 5; 6; 10;11	-	-	-	✓	50kGy

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

### 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/cm <sup>3</sup> )	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 – Styrene Acrylonitrile Copolymer (SAN)

### 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®

<b>PN-107 L125FG</b>	58	1,06	FDA; (EU) 10/2011; GMP	-	VI	-	-	✓	-
<b>PN-127 L150</b>	17	1,06	FDA; (EU) 10/2011; GMP	-	VI	-	-	✓	-

## CHIMEI – Acrylonitrile Butadiene Styrene (ABS)

### 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®

<b>ABS PA-704LRP (milky white)</b>	18	1,05	FDA	5; 10	-	-	-	✓	-
<b>ABS PA-757F (milky white)</b>	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®

Type	Hardness	Food compliance	Medical approvals	DMF	Steam	EtO	Gamma	
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						
TR 557	23	1,09		-	VI	-	-	✓	-
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/cm <sup>3</sup> )	Food compliance	Medical approvals			Sterilisation		
				10993	USP	DMF	Steam	EtO	Gamma

## Tarflon®

Type	MFR (g/10min)	Density (g/cm <sup>3</sup> )	Food compliance	10993	USP	DMF	Steam	EtO	Gamma
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/cm <sup>3</sup> )	Food compliance	Medical approvals			Sterilisation		
				10993	USP	DMF	Steam	EtO	Gamma

## ViviOn®

Type	MFR (g/10min)	Density (g/cm <sup>3</sup> )	Food compliance	10993	USP	DMF	Steam	EtO	Gamma
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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## Legal notice

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