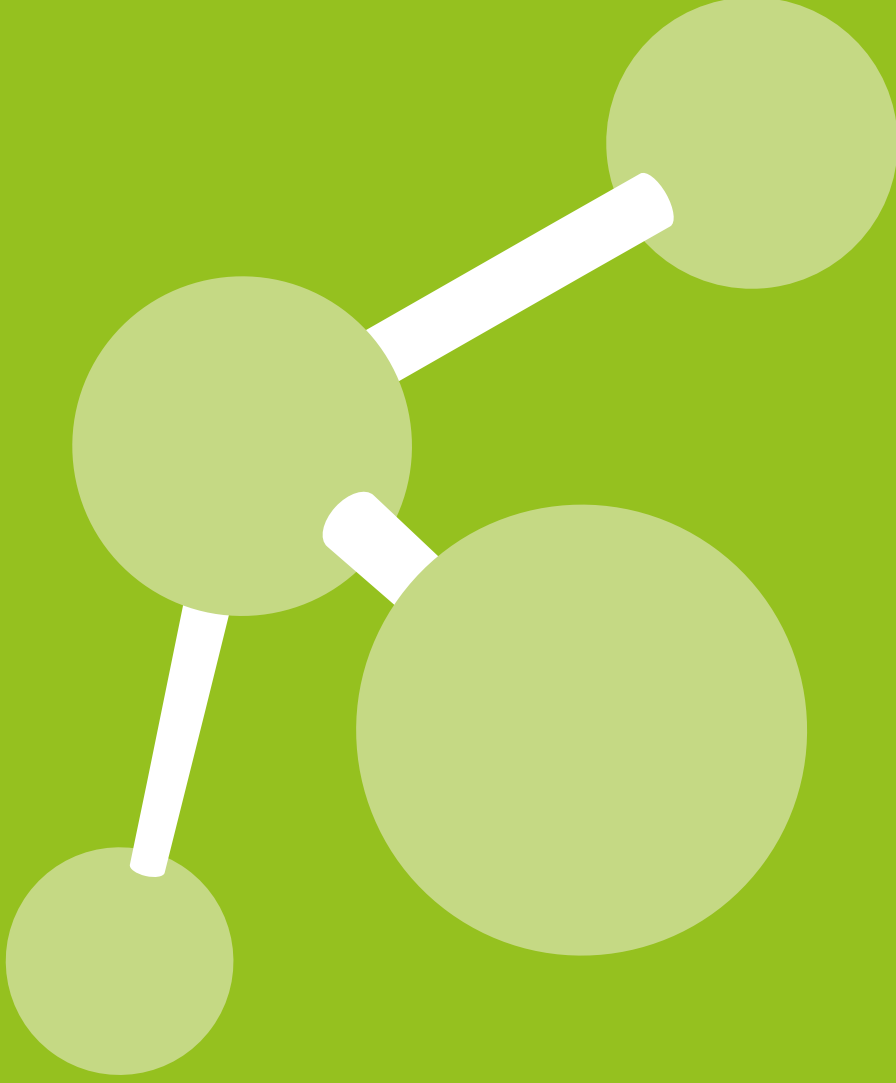


mediprene®



Sterilization Tests



General Information about the Sterilization Tests

Test Specimens for tensile tests were punched out of injection-moulded plaques. All mechanical test values refer to tensile testing of the material parallel with the flow direction. Changes reported in the tables below have been calculated by comparing values for sterilized specimens with the corresponding values for the unsterilized reference.

Gamma Sterilization

Risø National Laboratory in Denmark conducted radiation of the samples. During the exposure period the samples were placed in test tubes. The temperature was not controlled, but approximately 30°C. Samples were taken out after two different dose levels; 25 kGy and 50 kGy and material property changes when compared with the unsterilized reference were determined.

Gamma sterilization results at 25 kGy radiation dose

Mediprene Grade	Hardness change ShA	Tensile Strength Change %	Elongation at Break change %	Modulus 100 % change %	Modulus 300 % change %	Yellowness Index change units
Test method	ASTM D2240 (4mm)	ASTM D638	ASTM D638	ASTM D638	ASTM D638	ASTM D1925
500200M	-1.5	+29	+56	-17	-15	+5.5
500600M	0	+10	+24	-10	-9	+6.5
500900M	0	-11	-2	-5	-5	+10

Gamma sterilization results at 50 kGy radiation dose

Mediprene grade	Hardness change ShA	Tensile Strength Change %	Elongation at Break change %	Modulus 100 % change %	Modulus 300 % change %	Yellowness Index change units
Test method	ASTM D2240 (4mm)	ASTM D638	ASTM D638	ASTM D638	ASTM D638	ASTM D1925
500200M	-3	+58	+98	-25	-25	+9
500600M	-1.5	+10	+30	-14	-12	+10
500900M	+0.5	-17	-5	-7	-8	+13



Ethylene Oxide Sterilization (EtO)

Paperpak Sweden AB conducted ethylene oxide (EtO) Sterilization of the samples with the following process set-up and material property changes when compared with the unsterilized reference were determined.

Sub-process	Value
Initial deep vacuum end value	40 mbar
Humidification time at pressure 65 - 90 mbar	h 25 min
Relative Humidity	> 50 %RH
Gas concentration, pressure rice	From 68 mbar – 426 mbar
Sterilization pressure	425 - 435 mbar
Chamber temperature during sterilization phase	48.6 - 49.2 °C
Sterilization time	3 h
Gas evacuation from sterilization pressure to 45 mbar	45 min
Gas evacuation, continued pressure reduction	1 h 40 min

Ethylene Oxide Sterilization Results

Mediprene grade	Hardness change ShA	Tensile Strength Change %	Elongation at Break change %	Modulus 100 % change %	Modulus 300 % change %	Yellowness Index change units
Test method	ASTM D2240 (4mm)	ASTM D638	ASTM D638	ASTM D638	ASTM D638	ASTM D1925
500200M	0	+2	+1	+3	+2	+1.5
500600M	+1	-4	-9	+7	+4	+1.5
500900M	+0.5	-3	-8	+7	+4	+2

Steam Sterilization (autoclave)

Nolato Medical Conducted steam sterilization of the samples with the process cycle described in the table below. Samples were taken out after 1, 10, 25, and 50 cycles respectively and material property changes when compared with the unsterilized reference where determined.

Sub-process	Time
Vacuum	3 min
Sterilization at 134°C	7 min
Vacuum	5 min



Steam sterilization results – Mediprene® 500200M

Number of cycles	Hardness change ShA	Tensile Strength Change %	Elongation at Break change %	Modulus 100 % change %	Modulus 300 % change %
Test method	ASTM D2240 (4mm)	ASTM D638	ASTM D638	ASTM D638	ASTM D638
1	-0.5	-10	+13	-18	-19
10	-1.5	-2	+31	-20	-23
25	-1.5	-7	+29	-23	-27
50	-2	-1	+40	-22	-27

Steam sterilization results – Mediprene® 500600M

Number of cycles	Hardness change ShA	Tensile Strength Change %	Elongation at Break change %	Modulus 100 % change %	Modulus 300 % change %
Test method	ASTM D2240 (4mm)	ASTM D638	ASTM D638	ASTM D638	ASTM D638
1	+2	-1	-19	+11	+13
10	+1	+1	-18	+11	+14
25	+1	+3	-15	+11	+14
25	+1	+5	-15	+14	+17

Steam sterilization results – Mediprene® 500900M

Number of cycles	Hardness change ShA	Tensile Strength Change %	Elongation at Break change %	Modulus 100 % change %	Modulus 300 % change %
Test method	ASTM D2240 (4mm)	ASTM D638	ASTM D638	ASTM D638	ASTM D638
1	+1.5	+5	-20	+28	+29
10	0	+6	-26	+30	+34
25	+1.5	+6	-29	+33	+36
50	+1.5	+7	-27	+33	+37

For further information about our Mediprene TPE compounds please contact mediprene@elasto.se

All the above information about chemical and physical properties consists of values measured in tests on injection moulded test specimens. We provide written and illustrated advice in good faith. This should only be regarded as being advisory and does not absolve the customers from doing their own tests and trials, to determine the suitability of the material for the intended applications. We retain the right to make changes without prior notice.

HEXPOL TPE

About us

The HEXPOL TPE family is a leader in the development and manufacture of thermoplastic elastomers (TPE) and complimentary compounds.

With a strong heritage in the TPE market our companies include established names such as ELASTO and Müller Kunststoffe. We deliver a trusted combination of material know-how, R&D, production capability and comprehensive technical services. As part of the HEXPOL group of companies, we share an extensive global footprint covering EU, Asia-Pacific and NAFTA, enabling us to support our customers worldwide.

A comprehensive TPE product portfolio includes TPS, TPO, TPV, TPU and cork compounds and is led by global brands Dryflex®, Mediprene®, EPSeal®, Lifoprene® and Lifocork®. We support OEMs, moulders and designers at all stages of product development in the medical, electronic, automotive, caps & closures, construction and consumer markets.

Contact us...

This product guide serves as an overview of our products; we are continuously testing ingredients to create new material combinations with enhanced characteristics. Use this guide as an introduction to our products, if you do not see what you are looking for, please contact us and we will be happy to discuss your specific requirements.

HEXPOL TPE

info@hexpolTPE.com

China

HEXPOL TPE China
t +86 757 2291 5100
info.fsc@hexpolTPE.com

Germany

Müller Kunststoffe
t +49 9571 94894 0
info@mueller-kunststoffe.com

Sweden

ELASTO Sweden
t +46 532 60 75 00
info@elasto.se

UK

ELASTO UK
t +44 161 914 7341
info@elasto.co.uk

Belgium

ELASTO sales office
(DACH & BeNeLux contact for medical)
t +32 87 59 54 48
info@elasto.se

France

Sales Office
t +33 1 60 43 17 17
info.fr@elastotpe.com



www.hexpolTPE.com



@hexpolTPE



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