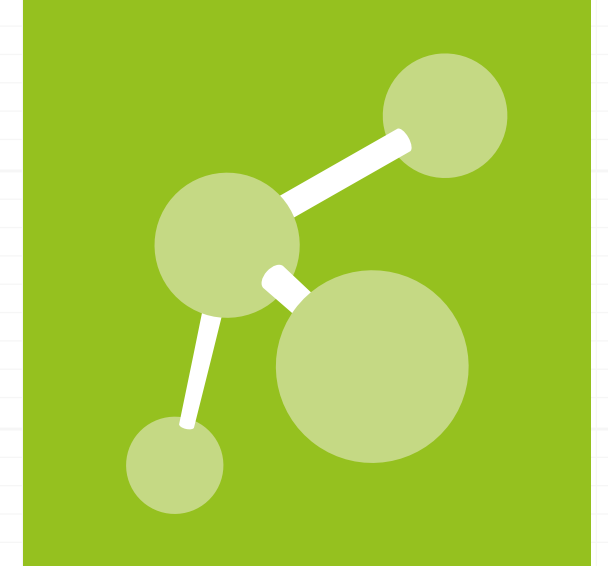


Mediprene®

Sterilization Tests



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GENERAL INFORMATION ABOUT 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 in this guide have been calculated by comparing values for sterilized specimens with the corresponding values for the unsterilized reference.

Please [contact us](#) for further information

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 Shore A	Tensile Strength Change %	Stress at 100% Strain Change %	Stress at 300% Strain Change %	Elongation at Break Change %	Yellowness Index Change units
Test Method	ASTM D2240 (4mm)	ASTM D638	ASTM D638	ASTM D638	ASTM D638	ASTM D1925
500200M	-1.5	+29	-17	-15	+56	+5.5
500600M	0	+10	-10	-9	+24	+6.5
500900M	0	-11	-5	-5	-2	+10

Gamma sterilization results at 50 kGy radiation dose

Mediprene Grade	Hardness Change Shore A	Tensile Strength Change %	Stress at 100% Strain Change %	Stress at 300% Strain Change %	Elongation at Break Change %	Yellowness Index Change units
Test Method	ASTM D2240 (4mm)	ASTM D638	ASTM D638	ASTM D638	ASTM D638	ASTM D1925
500200M	-3	+58	-25	-25	+98	+9
500600M	-1.5	+10	-14	-12	+30	+10
500900M	+0.5	-17	-7	-8	-5	+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	1 h 25 min
Relative humidity	> 50% RH
Gas concentration, pressure rise	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 Shore A	Tensile Strength Change %	Stress at 100% Strain Change %	Stress at 300% Strain Change %	Elongation at Break Change %	Yellowness Index Change units
Test Method	ASTM D2240 (4mm)	ASTM D638	ASTM D638	ASTM D638	ASTM D638	ASTM D1925
500200M	0	+2	+3	+2	+1	+1.5
500600M	+1	-4	+7	+4	-9	+1.5
500900M	+0.5	-3	+7	+4	-8	+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 were determined.

SUB-PROCESS	TIME
Vacuum	3 minutes
Sterilization at 134°C	7 minutes
Vacuum	5 minutes

Steam sterilization results :

Mediprene 500200M

Number of Cycles	Hardness Change Shore A	Tensile Strength Change %	Stress at 100% Strain Change %	Stress at 300% Strain Change %	Elongation at Break Change %
Test Method	ASTM D2240 (4mm)	ASTM D638	ASTM D638	ASTM D638	ASTM D638
1	-0.5	-10	-18	-19	+13
10	-1.5	-2	-20	-23	+31
25	-1.5	-7	-23	-23	+29
50	-2	-1	-22	-27	+40

Steam sterilization results :

Mediprene 500600M

Number of Cycles	Hardness Change Shore A	Tensile Strength Change %	Stress at 100% Strain Change %	Stress at 300% Strain Change %	Elongation at Break Change %
Test Method	ASTM D2240 (4mm)	ASTM D638	ASTM D638	ASTM D638	ASTM D638
1	+2	-1	+11	+13	-19
10	+1	+1	+11	+14	-18
25	+1	+3	+11	+14	-15
50	+1	+5	+14	+17	-15

Steam sterilization results :

Mediprene 500900M

Number of Cycles	Hardness Change Shore A	Tensile Strength Change %	Stress at 100% Strain Change %	Stress at 300% Strain Change %	Elongation at Break Change %
Test Method	ASTM D2240 (4mm)	ASTM D638	ASTM D638	ASTM D638	ASTM D638
1	+1.5	+5	+28	+29	-20
10	0	+6	+30	+34	-26
25	+1.5	+6	+33	+36	-29
50	+1.5	+7	+33	+37	-27

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mediprene@hexpolTPE.com

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All the 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 full-scale tests to determine the suitability of the material for the intended applications. You assume all risk and liability arising from your use of the information and/or use or handling of any product. Figures are indicative and can vary depending on the specific grade selected and the production site. HEXPOL TPE makes no representations, guarantees, or warranties of any kind with respect to the information contained in this document about its accuracy, suitability for particular applications, or the results obtained or obtainable using the information. Some of the information arises from laboratory work with small-scale equipment which may not provide a reliable indication of performance or properties obtained or obtainable on larger-scale equipment. We retain the right to make changes without prior notice. HEXPOL TPE makes no warranties or guarantees, express or implied, respecting suitability of HEXPOL TPE's products for your process or end-use application. Mediprene® is a registered trademark, property of the HEXPOL TPE group of companies.