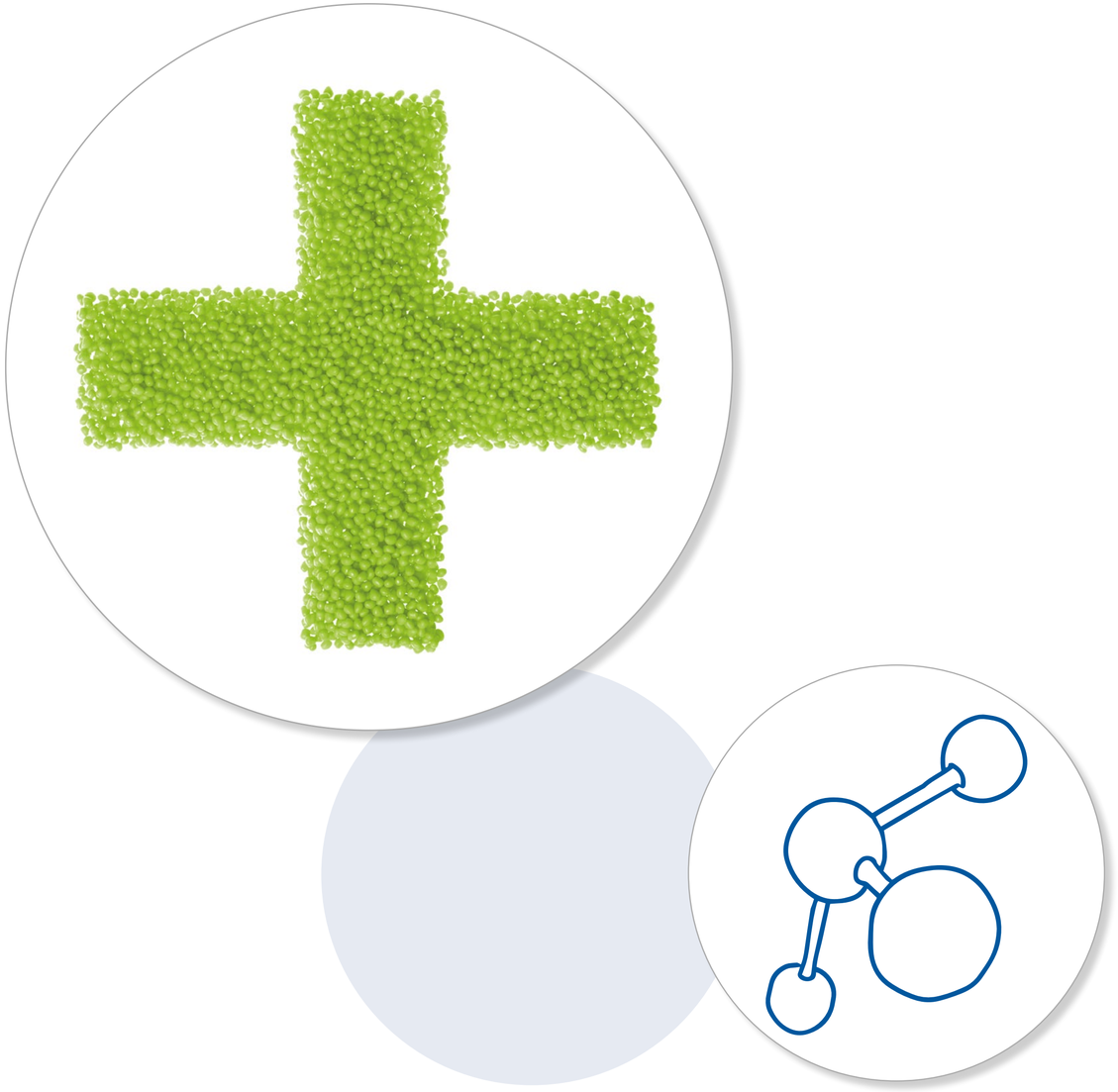

A Material Difference

Mediprene®

Sterilization Tests

HEXPOL® TPE

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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

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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Plunger Seal Series

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Mediprene® BM

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