

**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

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.

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