

Byoxene® TEST REPORT

SCOPE

The purpose of this test is to evaluate the performances of Byoxene lens material after sterilization cycles with gamma rays.

STERILIZATION METHOD

Samples are sterilized by exposure to gamma rays with a dose of 25kGy for each cycle.

Samples were sterilized for the following amount of cycles: 5 – 10 – 15 – 20 – 25 and 30 cycles

An irradiation certificate guarantees the ray dose exposure for each cycle.

TEST METHOD

All samples are tested according the following test of EN166:2001:

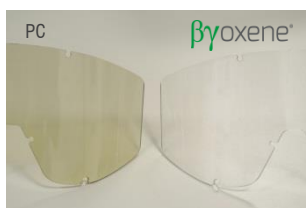
- Luminous transmittance
- Diffusion of light
- Protection against high-speed particles – Medium energy impact (B)

SAMPLE PICTURES

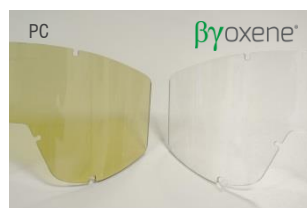


Reference sample – Not sterilized

Here below are reported pictures which highlight the difference between PC and Byoxene exposed to the same amount of sterilization cycles.



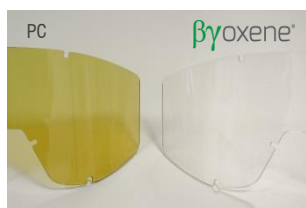
After 5 cycles



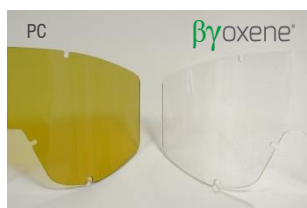
After 10 cycles



After 15 cycles



After 20 cycles



After 25 cycles



After 30 cycles

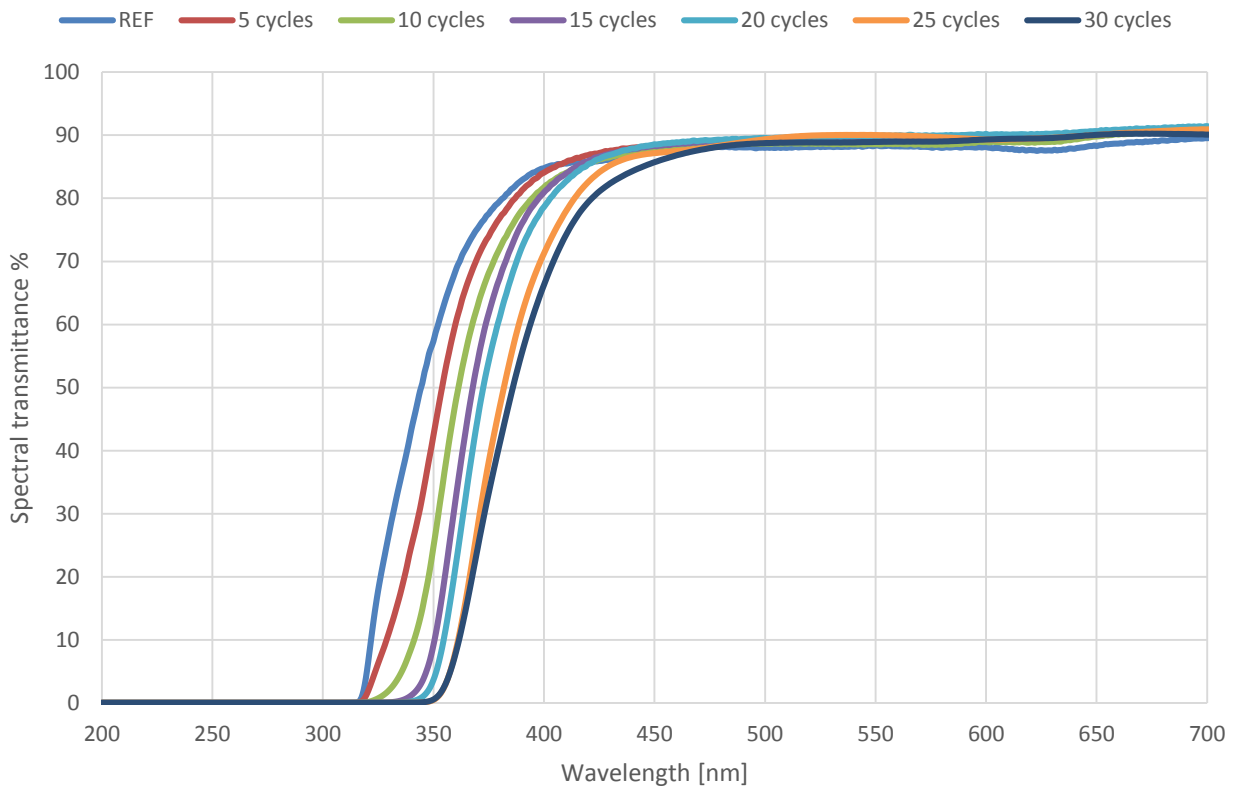
TEST RESULTS

LUMINOUS TRANSMITTANCE

§ EN166, clause 7.1.2.2

REF. SAMPLE	After 5 cycles	After 10 cycles	After 15 cycles	After 20 cycles	After 25 cycles	After 30 cycles
89.1%	88.7%	88.7%	88.5%	88.3%	88.1%	87.8
Variation	-0.4%	-0.4%	-0.6%	-0.8%	-1.1%	-1.4%

Here below are reported the spectrums of the samples:



DIFFUSION OF LIGHT

§ EN166, clause 7.1.2.3

The maximum value of the reduced luminance factor shall be $0.75 \frac{cd}{m^2 \cdot lx}$

REF. SAMPLE	After 5 cycles	After 10 cycles	After 15 cycles	After 20 cycles	After 25 cycles	After 30 cycles
0.22	0.26	0.60	0.67	0.49	0.19	0.42
Result	PASS	PASS	PASS	PASS	PASS	PASS

PROTECTION AGAINST HIGH SPEED PARTICLES

§ EN166, clause 7.2.2

Samples shall withstand the impact of a 6mm diameter steel ball striking at a speed of 120 m/s - Medium energy impact (B).

REF. SAMPLE	After 5 cycles	After 10 cycles	After 15 cycles	After 20 cycles	After 25 cycles	After 30 cycles
120.1 m/s	121.3 m/s	120.8 m/s	122.2 m/s	120.6 m/s	120.9 m/s	121.2 m/s
Result	PASS	PASS	PASS	PASS	PASS	PASS

VISUAL INSPECTION

PARAMETER	NOTE
Overall inspection	Samples maintain their integrity even after 30 cycles. There are no deformations or visible defects on all the components. Lenses are firmly placed in the housing.
Frame	There are no visible degradation of the material. The material maintains its elasticity and softness. There is no sticky effect on the surfaces. A little discoloration of rubber appears after 15 cycles.
Headband	There are no visible degradation of the material. There is no sticky effect. The material lose its elasticity after 15 cycles.
Vision	Vision capabilities of the operator are still guaranteed, as confirmed by optical tests of spectral transmittance and diffusion of light.

CONCLUSIONS

Univet new β yxene material offers a very good resistance to gamma rays sterilization.

Lens doesn't suffer the yellowing effect as like as polycarbonate material, and they guarantee a perfect vision up to 30 sterilization cycles.

Very low values of diffusion of light are the confirmation of the clarity of the lens, which allows the best acuity to the operator's vision.

The frame material doesn't degrade and maintains its performances in terms of fitting and comfort.

Mechanical resistance is guaranteed even after 30 sterilization cycles.

Suggested lifecycle of this product is the following:

