

Sterilization Results

Ultracur3D® RG 35

This document is intended to provide guidance for manufacturers regarding sterilization of the 3D printed materials. BASF3D Printing Solutions GmbH has performed specific sterilization tests for the materials 3D printed employing Ultracur3D® RG 35. Indications on material changes that can occur during the sterilization process were studied. It remains the responsibility of the device manufacturers and/or end-users to determine the suitability of all printed parts for their respective application.

Material

Material
Ultracur3D® RG 35

Print scene and Test Specimens

Three different test parts were chosen, to help determine the impact of the sterilization.

1. *Color disc* (Figure 1) to measure the color of the material before and after sterilization.
2. *Cytotoxicity disc* (Figure 2) to be able to assess the cytotoxic potential
3. *Tensile Bars* (Figure 3) to check possible changes in mechanical properties.

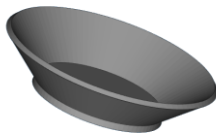


Figure 1 Color disc 2 mm

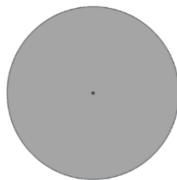


Figure 2 Cytotoxicity disc



Figure 3 ASTM D638 Type IV – Tensile Bar

Overall, the following amount of specimens were printed for each test:

- 10 Tensile Bars
- 1 Color disc
- 3 Cytotoxicity disc

The test specimens were provided to the external laboratory (Steris GmbH) for E-Beam, Gamma and EtO sterilization treatment. Steam Sterilization was performed internally.

Gamma Sterilization:

The samples were exposed to 37.1 – 37.5 kGy gamma radiation (measured via dosimeter). When exposed to gamma sterilization, Ultracur3D® RG 35 demonstrates a 73% reduction in elongation at break and a 19% increase in E - modulus. The samples also show a 25% decrease in ultimate strength. The test specimens show some **reddish color** post-sterilization.

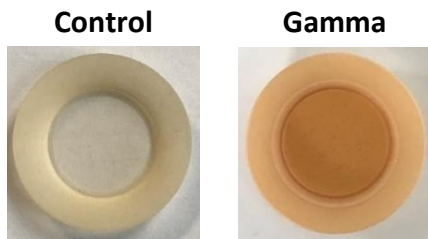


Figure 4 Color discs before and after Gamma sterilization

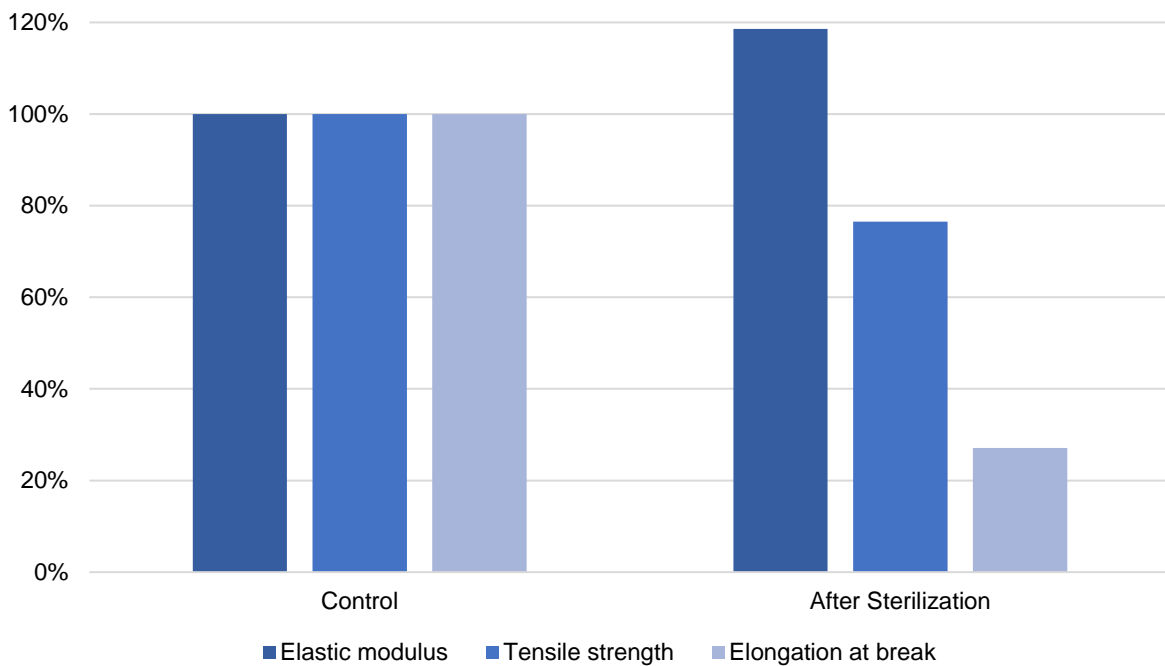


Figure 5 Tensile properties comparison of the Gamma-treated samples

Gamma Sterilization it is not recommend for Ultracur3D® RG 35.

E-Beam Sterilization

The samples were exposed to 36.04 – 39.26 kGy (calculated dose).

When exposed to E-Beam sterilization, Ultracur3D® RG 35 demonstrates a 17% increase in elongation at break and 37% increases in E-modulus. The samples also show a 18% increase in ultimate strength. The specimens show some **reddish color** post-sterilization.

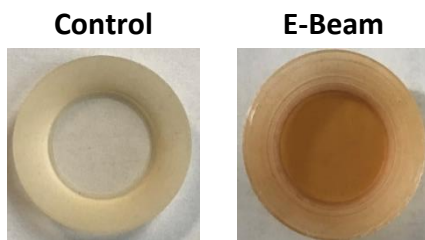


Figure 6 Color discs before and after E-Beam sterilization

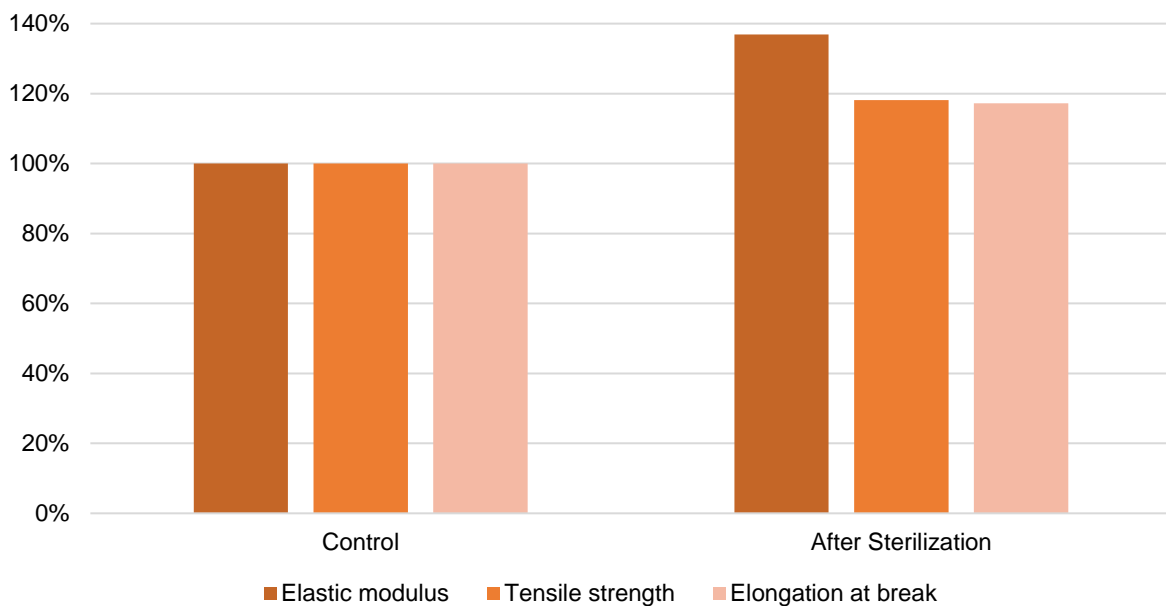


Figure 7 Tensile properties comparison of the E-Beam-treated samples

E-Beam Sterilization is recommended for Ultracur3D® RG 35, but the color and mechanical property changes need to be taken into consideration by the user.

Ethylene Oxide (EtO) Sterilization

Table 1 Testing conditions Ethylene Oxide

	Amount		Amount		Amount
Preconditioning temperature	48 °C	Chamber temperature	45 °C	Postconditioning time	48 hours
Preconditioning humidity	60 %	Vacuum	75 mbar A	Postconditioning temperature	45 °C
Preconditioning time	8 hours	EO dwell time	3 hours		
		EO concentration (calculated)	610 mg/l		

When exposed to EtO sterilization, Ultracur3D® RG 35 demonstrates a 12 % increase in elongation at break and 15 % increases in modulus. The samples also show a 14 % increase in ultimate strength. The test specimens show a small color change but become **lighter and more clear** post-sterilization. EtO residuals level after exposure were not recorded.

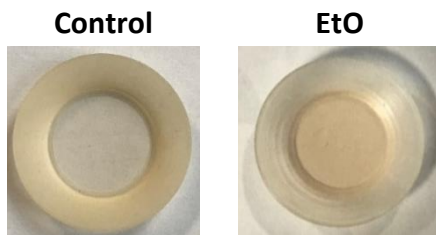


Figure 8 Color discs before and after EtO sterilization

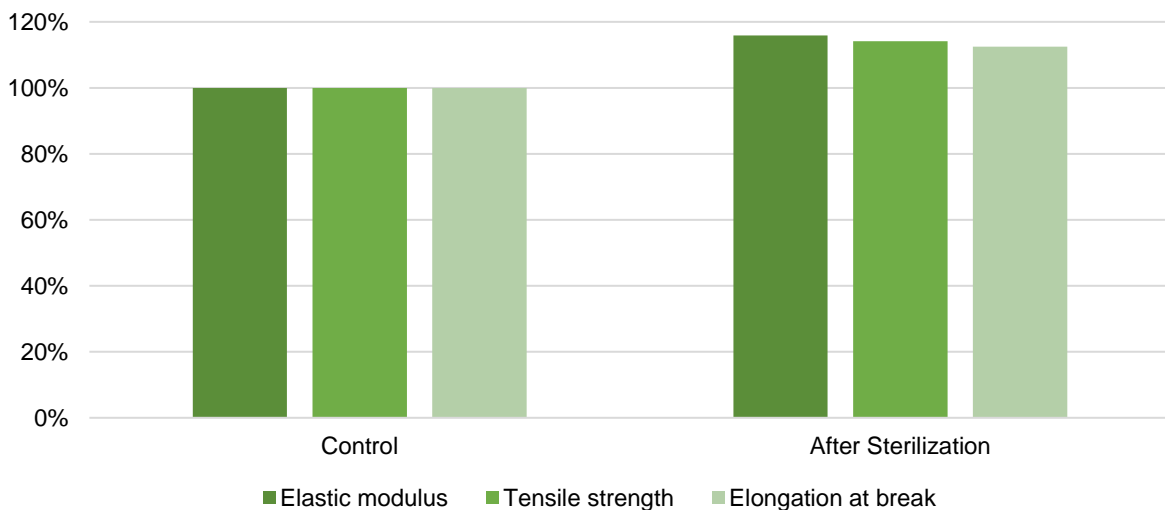


Figure 9 Tensile properties comparison of the EtO-treated samples

EtO sterilization can be suitable for Ultracur3D® RG 35, but the color and mechanical property changes need to be taken into consideration by the user.

Steam Sterilization

Table 2 Testing conditions Steam Sterilization

Steam Sterilization Parameters	Settings
Vacuum pulses	4
Temperature	134°C
Pressure	210 kPa
Holding time	4 minutes
Drying time	20 minutes

When exposed to steam sterilization, Ultracur3D® RG 35 demonstrates a 23 % decrease in elongation at break and 8 % increases in modulus. The samples also show a 2 % increase in ultimate strength. The test specimens show a color change but become **lighter and clear** post-sterilization.

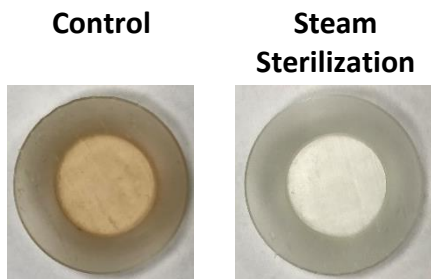


Figure 10 Color discs before and after Steam sterilization

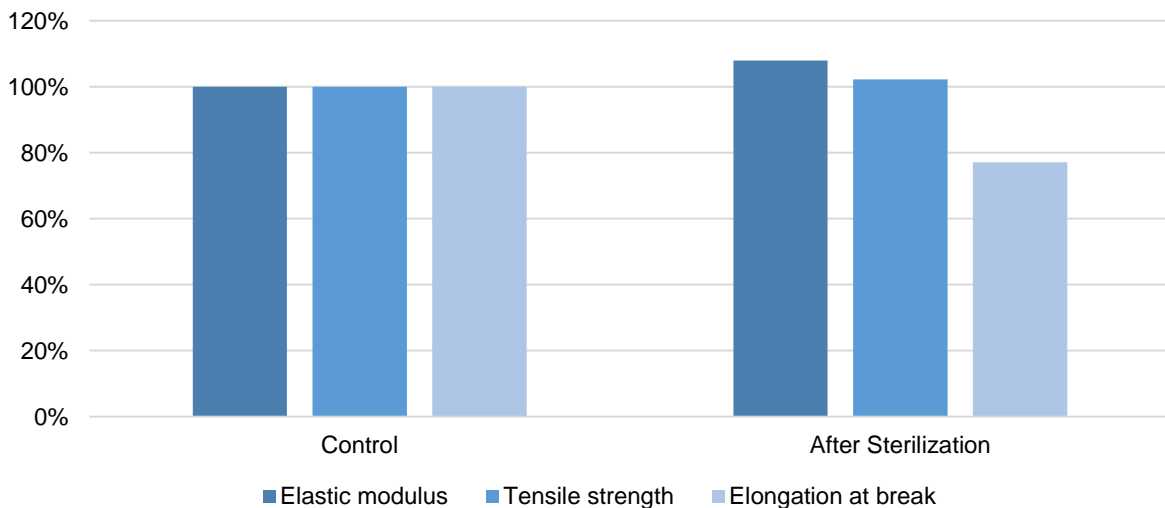


Figure 11 Tensile properties comparison of the Steam-treated samples

Steam sterilization can be suitable for Ultracur3D® RG 35, but the color and mechanical property changes need to be taken into consideration by the user.

Conclusion

The results of the performed tests show that **Ultracur3D® RG 35** can be summarized in the table below.

Sterilization Method	Ultracur3D® RG 35
Gamma	☹️ not recommended
E-Beam	😊 recommended, but depend on the final application case
EtO	😊 recommended
Steam*	😊 recommended

*Additional information available in a separate document on demand.

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Version 2.1