

# Steam Sterilization Results

## Ultracur3D® RG 35

This document is intended to provide guidance for manufacturers regarding steam sterilization of the 3D printed materials. BASF3D Printing Solutions GmbH has performed specific steam 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.

### Test Description

The compatibility of Ultracur3D® RG 35 with a commonly used steam sterilization is going to be evaluated. In this evaluation, compatibility was evaluated based on change in weight, color, dimension and tensile properties.

### Material

Material
Ultracur3D® RG 35

### Test Specimens

Six different test parts were chosen, to help determine the impact of the steam 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. *Dimensional accuracy* (Figure 3) to check the dimension/accuracy and weight changes before and after treatment.
4. *Chess Tower* (Figure 4) to check accuracy before and after treatment.
5. *Tensile Bars* (Figure 5) to check possible changes in mechanical properties.

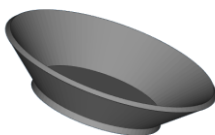


Figure 1 Color disc 2 mm

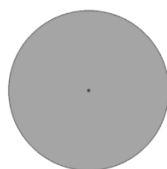


Figure 2 Cytotoxicity disc

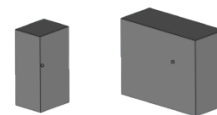


Figure 3 Dimensional accuracy



Figure 4 Chess Tower



Figure 5 ASTM D638 Type IV – Tensile Bar

## Procedure

Following steps and set up parameters were conducted for the steam sterilization tests.

*Table 1 Testing conditions Steam Sterilization*

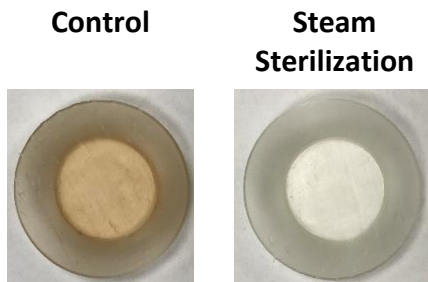
Steam Sterilization Parameters	Settings
Vacuum pulses	4
Temperature	134°C
Pressure	210 kPa
Holding time	4 minutes
Drying time	20 minutes

Samples were maintained in the autoclave until the program was completely finished.

## Results

### Color and Dimensional accuracy Comparison

The Color disc specimens show a significant color change but become **lighter and more clear** post-sterilization.



*Figure 6 Color discs before and after Steam sterilization*

### Dimensional accuracy Weight Changes

*Table 2 Dimensional weight changes*

Weight Comparison	Dimensional accuracy Weight
Before	3.01
After	3.01
	<i>Stable</i>

## Dimensional Changes

The small test samples were measured three times and the big one once at the points shown in Figure 7.

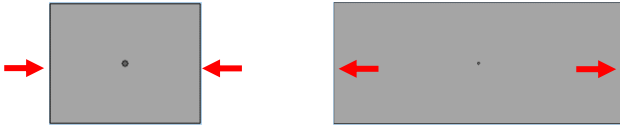


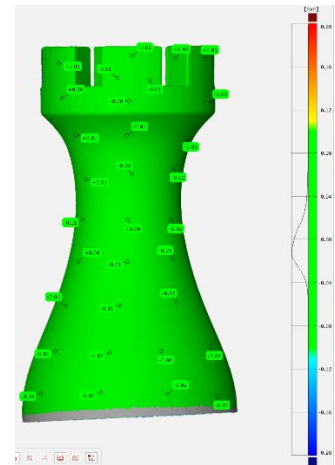
Figure 7 Dimensional accuracy measurement

Table 3 Dimensional accuracy changes

Dimension	A 1	A 2	A 3	B
Before	3.99	4.00	4.00	11.96
After	3.99	4.01	4.00	11.96
	0%	0.25% increase	0%	0%

## Accuracy post steam sterilization

For measuring the accuracy of the part after steam sterilization the test specimen was scanned and compared with the scan of the actual 3D printed part before sterilization. The change in dimension of the part after sterilization may vary depending on the design and construction, this could be considered at an early stage of the design. Different designs may show different behavior during the sterilization process.



In Tolerance set to +/- 100µm

## Cytotoxicity Post-Steam Sterilization

After steam sterilization, samples were tested, for in vitro cytotoxicity. The results show that post-sterilization, there is **no observed cytotoxicity**.

## Mechanical Properties Comparison

The following tensile properties of the samples before and after treatment were obtained.

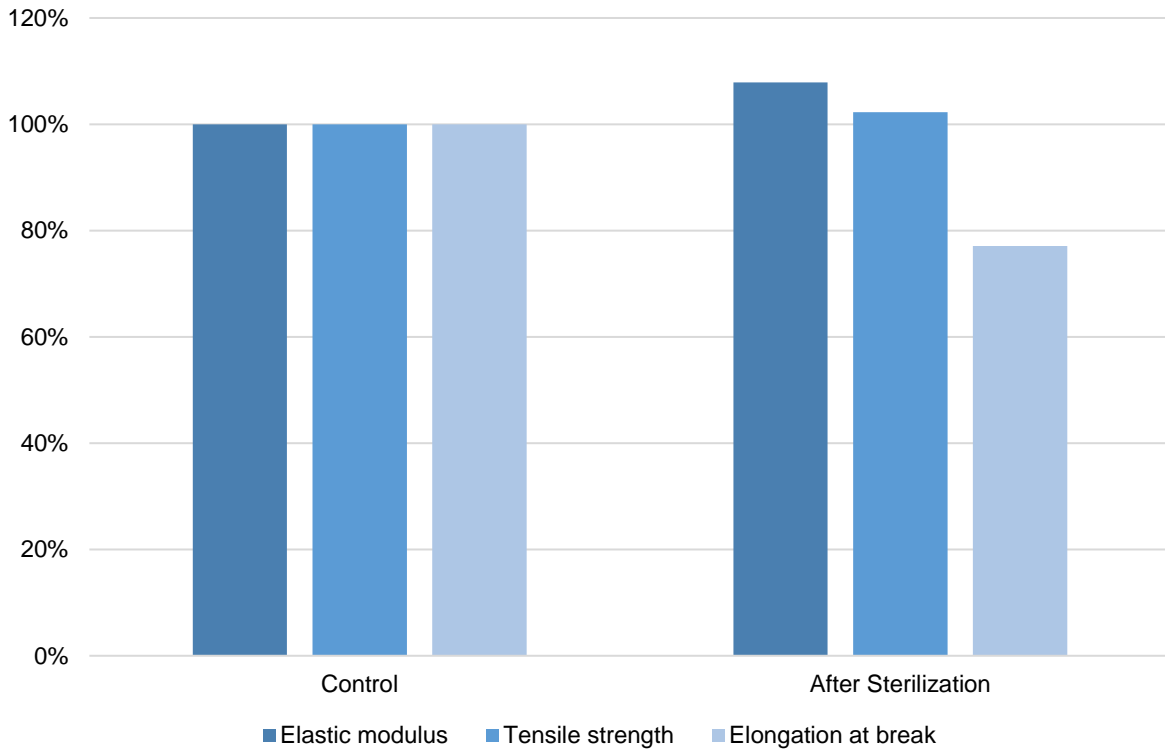


Figure 8 Tensile properties comparison of the treated samples

## Conclusion

There was a notable color change in the samples before and after steam sterilization treatment. There was no significant variation in dimension observed. The mechanical properties are, as well, close to the control properties. The results of the performed tests show that Ultracur3D® RG 35 can be steam sterilized with just minimal or neglectable effect on mechanical-, accuracy-, surface- and color properties.

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