Steam Sterilization Results
Ultracur3D® EL 60

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® EL 60. 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® EL 60 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® EL 60

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. *Dimensional accuracy* (Figure 2) will be used to check the dimension/accuracy and weight changes before and after.
3. *Chess Figure* (Figure 3) will be used for checking accuracy before and after.
4. *Shore A Hardness part* (Figure 4) to check possible changes in mechanical properties.
5. *Tensile Bars* (Figure 5) will be used for checking any change in mechanical properties.

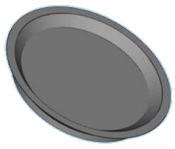


Figure 1 Color disc 2 mm

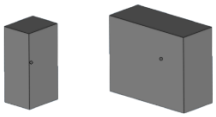


Figure 2 Dimensional accuracy

Figure 3 Chess Figure

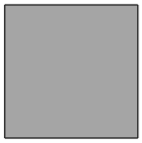


Figure 4 ASTM 2240 - Shore A Part

Figure 5 ASTM D412 C - 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 no significant color change post-sterilization.

Control **Steam Sterilization**

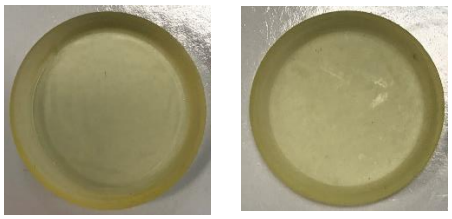


Figure 6 Color discs before and after Steam sterilization

Dimensional accuracy Weight Changes

Table 2 Dimensional weight changes

Weight Comparison	Dimensional accuracy Weight
Before	2.95
After	2.91
	In tolerance

Dimensional Changes

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

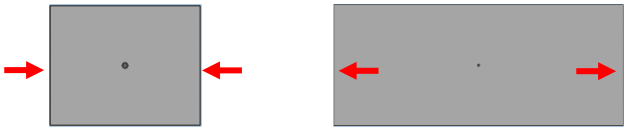


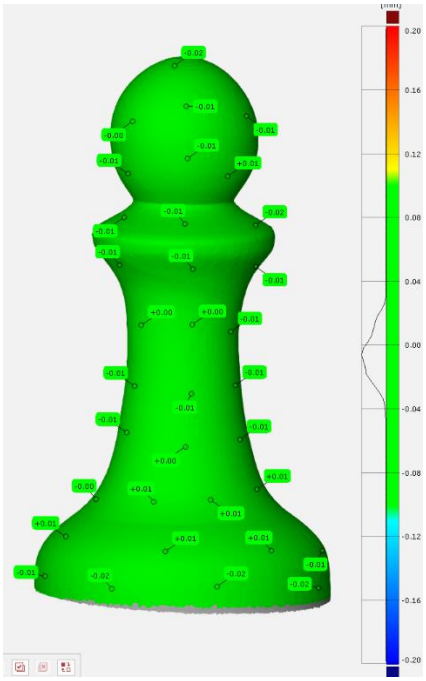
Figure 7 Dimensional accuracy measurement

Table 3 Dimensional accuracy changes

Dimension	A 1	A 2	A 3	B
Before	4.10	4.13	4.13	12.26
After	4.02	4.04	4.04	12.09
	decrease 1.95 %	*decrease 2.18 %*	*decrease 2.18 %*	*decrease 1.39 %*

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**

Mechanical Properties Comparison

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

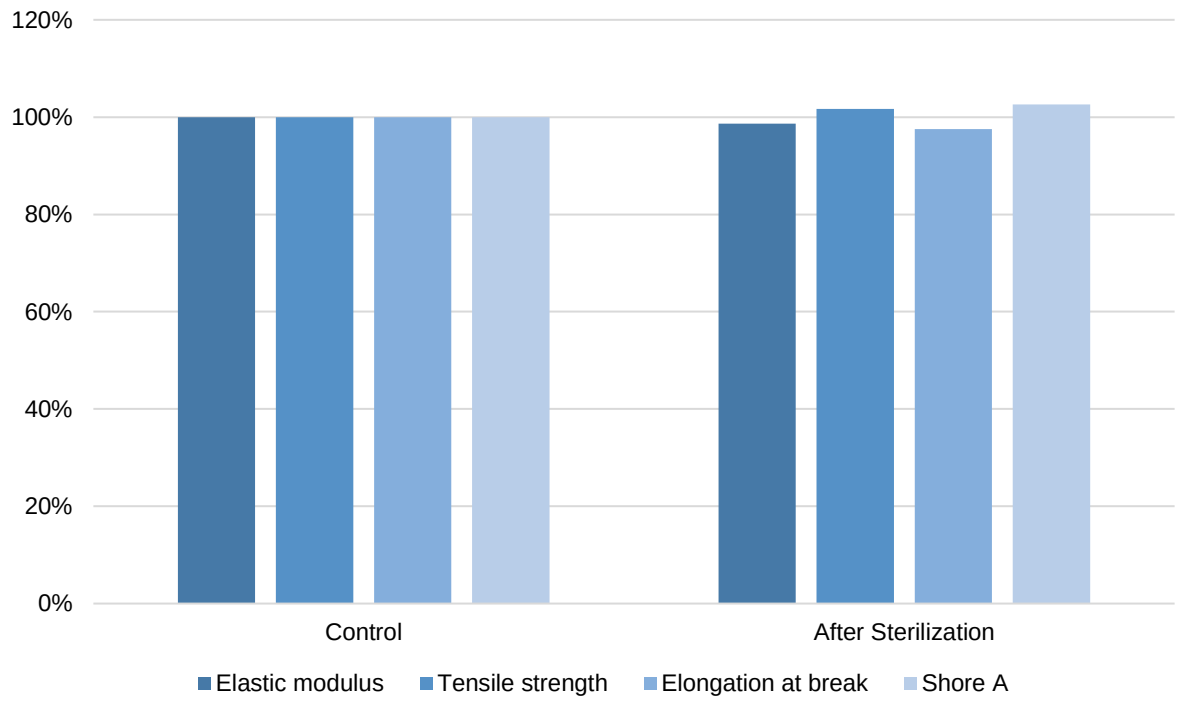


Figure 8 Mechanical properties comparison of the treated samples

Conclusion

The color change in the samples before and after steam sterilization treatment was not noticeable. Even though there was a small variation in the measured dimension of the cubes, the scanning of a simple part did not reveal any dimensional changes. The mechanical properties are, close to the control properties. The results of the performed tests show that Ultracur3D® EL 60 can be steam sterilized with no significant change in color but vaguely effect on mechanical-, surface- properties and accuracy performance.