

January 2021

## **FDA DECLARATION OF CONFORMITY FOR PLACTIVE™**

**Copper3D** is an EPA Registered Company, number 99079.

**Copper3D** declares that under regulations administered by the U.S. Food and Drug Administration (FDA), the raw materials for the natural version of the filament are in compliance under a specific Food Contact Notification as appropriately regulated indirect additive.

The Food Contact Notification Number is not mentioned as it gives special information on the origin of the material and is confidential information.

The product's fabrication process meets the requirements of 21CFR174.5 on good manufacturing practice for materials and devices intended to come into contact with food.

Further, as stated in 21CFR174.5, it is the responsibility of the end-use device manufacturers to ensure that the device is appropriate for its intended food-contact use, and that its use does not cause adulteration of food.



Claudio Soto Angelo, MD  
Medical Director  
Copper3D Inc.



Andrés Acuña Velásquez  
CEO & Legal Representative  
Copper3D Inc.

Copper3D Inc.

[www.copper3d.com](http://www.copper3d.com)

3929 Harney Street, Omaha, Nebraska, USA.