

## Declaration of Compliance – EU Food Contact

Date: 15 April 2017

Version: 1.0

### To whom it may concern,

According to the provisions of Article 13 (Declaration for trading) and detailed in Annex VII of RD 866/2008 of May 23<sup>rd</sup> (n° 131 B.O.E Friday, May 30<sup>th</sup>, 2008) and taking into account the amendments to the R. D. 103/2009 of February the 6<sup>th</sup> (B.O.E no. 41 from Tuesday, February the 17<sup>th</sup> of 2009):

**SMART MATERIALS 3D PRINTING S.L** with address in Polígono Industrial El Retamar Calle Tomillo number 7 Vial G, CP: 23680 Alcalá la Real (Jaén), **DECLARE:**

That materials specificate in Table 1 meet the manufacturing requirements of plastic materials intended to come into contact with any type of food, meeting the requirements set by EU and national legislation:

- **Article 16 of Regulation (EC) n°1935/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27<sup>th</sup> October 2004 on materials and articles intended to come into contact with food.**
- **R.D 866/2008 (amended by RD 103/2009).**
- **Regulation (EU) n°10/2011 COMMISSION of 14<sup>th</sup>, January of 2011 and subsequent amendments.**
- **ROYAL DECREE 846/2011.**
- **ROYAL DECREE 847/2011, of June 17<sup>th</sup>, on the positive list of permitted substances for the manufacture of polymeric materials intended to come into contact with food.**
- **Regulation (EU) n° 202/2014 of 3<sup>rd</sup> March of 2014 on plastic materials and articles intended to come into contact with food and repealing Directive 2002/72 / EC,**
- **REGULATION (EU) 2015/174 OF THE COMMISSION of 5<sup>th</sup> February of 2015.**

Table 1

Product	Color
<b>SMARTFIL PETG</b> (Polyethylene Terephthalate Glycol)	NATURAL, IVORY WHITE, TRUE BLACK

The components present in the composition are listed in the above Directives.

On the other hand, we can confirm that the material has not intentionally aluminium, styrene, and phenols or not allowed phthalates or heavy metals, according to Directive 2008/39 / EC and their incorporation into Spanish law through R.D 103/2009.

With regards to the substance Bisphenol A (BPA): This substance is not intentionally used in the manufacture of such products or by SMART MATERIALS 3D PRINTING S.L or their suppliers.

In addition, SMART MATERIALS 3D PRINTING S.L works with its raw material suppliers to ensure they comply with the good manufacturing practice for materials and articles intended to come into contact with food laid down in Regulation (EC) No. 2023/2006 of 22<sup>th</sup> December 2006 and the provisions of Law 11/1997 on "packaging and packaging waste" (which includes the 94/62/EC).

In our production process, we also comply with Regulation (EC) No. 2023/2006 of 22<sup>th</sup> December of 2006 on good manufacturing practice for materials and articles intended to come into contact with food, and its subsequent amendments, REGULATION (EC) No. 282/2008 of 27<sup>th</sup>

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March of 2008, guaranteeing the absence of pathogens and other contamination during the manufacturing process.

The Smart Materials 3d Printing products listed in Table 1 contain the following monomers, which are listed in ANNEX 1 of (EU) 10/2011:

Table 2

Nº EC	Substance name	SML(T) [mg/kg]
46880	Monoethyl-3,5-di-tert-butyl-4-hydroxybenzylphosphonic acid, calcium salt	6
	Zin stearate	5
93440	titanium dioxide	Without limit specific migrations
227	ethyleneglycol	30
785	Terephthalic acid	7,5
210	1,4-bis(hydroxymethyl) cyclohexane	ND (not detectable)
364	1,4:3,6-dianhydrosorbitol	5

### Use of dual additives:

In the manufacture of our product, we use substances that are authorized both as additives in plastics as food additives. These substances are included in the list of "EuPC STUDY ON DUAL USE ADDITIVES" Updated February the 3<sup>rd</sup> of 2006).

Since SMART MATERIALS 3D is a filament manufacture for 3d Printing has neither influence or control, on the subsequent processes until obtaining the final product, and it does not know the type of food with which it will be in contact with the duration of the notice, the manufacturer is responsible to carry out the migration tests according to the conditions of use (temperature, time, simulants) of the article in its finished form or other different tests on the finished product and under normal conditions of use. Smart Materials 3d does not know these specific conditions and therefore are not under their control.

**SMART MATERIALS 3D PRINTING S.L**



**Antonio Peláez Moya**  
April 2017