

# Product Compliance Declaration

NonOilen®



Hulin, 7<sup>th</sup> September 2020

The company **Fillamentum Manufacturing Czech s.r.o.** declares that the products **Fillamentum NonOilen®** (3D printing filaments) are manufactured according to:

- a) the requirements of the European Parliament
- b) the Council Regulation (EC) No 1935/2004 on Materials and Articles intended to come into contact with food
- c) the Commission Regulation (EU) No 10/2011 on Plastic Materials and Articles intended to come into contact with food and subsequent amendments up to 2019/988

and they may be used for contact with foodstuffs.

The input material used for the production is only the bioplastic polymer compound of polylactic acid (PLA) and polyhydroxy butyrate (PHB). According to the Commission Regulation (EU) No 10/2011, the polymer is suitable for food-contact applications. The products can be used in the direct contact with these food types:

- foods that have a hydrophilic character
- foods that have a lipophilic character
- foods which have a pH below 4,5
- foods with alcohol content up to 70 %

for cold and hot filling.

The primary input materials used for production do not contain the substances restricted by the specific migration limit (SML) listed in Annex I and II of the Commission Regulation (EU) No 10/2011. According to the EU regulation, the overall migration limit shall not exceed 10 mg/dm<sup>2</sup> of the food contact surface or 60 mg/kg.

The production is based on the Good Manufacturing Practice according to the Commission Regulation (EC) No 2023/2006. The company guarantees that all the products placed on the market are in accordance with the technical documentation and the basic product requirements.

The declaration is based on the present knowledge and experience of the material suppliers. According to the Commission Regulation (EU) No 10/2011, it is necessary to determine the migration limits for the final article, that is intended to come into contact with food.