

DECLARATION OF COMPLIANCE (DoC)

Material/article intended to come into contact with food

Manufacturer:

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Product: inFil PETG MDT (polyethylene terephthalate glycol – PETG)

1. Compliance statement

The above-mentioned product is manufactured in accordance with:

- **Regulation (EC) No. 1935/2004**, Articles 3 and 17.
- **Regulation (EC) No. 2023/2006** on Good Manufacturing Practice.
- **Regulation (EU) No. 10/2011** on plastic materials intended to come into contact with food, including all amendments up to **Reg. (EU) 2020/1245**.

The raw materials, monomers, additives and colorants used in the manufacturing of this product are listed in the **Union List** (Annex I of Reg. 10/2011), and comply with the corresponding **specific migration limits (SML)**.

2. Substances subject to restrictions / SML

Substance	FCM No	Ref. No	CAS No	SML (mg/kg food)
Terephthalic acid	785	24910	100-21-0	7.5 (as terephthalic acid)
Ethylene glycol	227	16990 / 53650	107-21-1	30 (as ethylene glycol)
2,2-dimethyl-1,3-propanediol	310	16390 / 22437	126-30-7	0.05
Diethylene glycol	263	13326 / 15760 / 47680	111-46-6	30 (as ethylene glycol; group restriction)
Acetaldehyde	128	10060	75-07-0	6
Antimony	—	—	—	0.04
Copper	—	—	—	5

There are **no functional barrier layers** in this material.

3. Dual-use additives (Reg. (EC) 1333/2008 and Reg. (EC) 1334/2008)

The following substances present in the formulation are authorised as dual-use additives:

- Sodium, potassium and calcium salts of fatty acids (E470a)
- Titanium dioxide (E171) (*)
- Iron oxides and hydroxides (E172)
- Phosphoric acid (E338)

(*) Titanium dioxide is not authorised as a food additive, but its use as a colorant in plastic materials is permitted under Reg. 10/2011.

4. Conditions of use

The manufacturer of the **final article** must verify compliance via migration testing under real or worst-case conditions. The material itself does not guarantee food-contact suitability unless validated in the finished product.

Recommended testing conditions:

- **Food contact types:** all food categories except those incompatible with PETG under extreme temperatures.
- **Contact temperature:** up to 70–80 °C depending on final product geometry.
- **Contact time:** short-term or repeated long-term; to be defined by final use.
- **Surface/volume ratio:** must be defined by the processor of the final article.

Migration must be assessed according to **Annex V of Reg. 10/2011** (which replaces Dir. 82/711/EEC and 97/48/EC).

Users must check restrictions in **Annex II** of Reg. 10/2011, particularly for **metals** and **primary aromatic amines (PAA)**.

5. Responsibility for conformity of the final article

This Declaration applies only to the **material as supplied**.

3DFILAMENTS S.L. does not control the manufacturing conditions of the final article and therefore **does not guarantee** that the printed or processed product will comply with food-contact requirements without additional validation.

The entity placing the final article on the market is responsible for ensuring:

- Correct use of the material
- Compliance with SML and OML via migration testing
- Suitability under intended end-use conditions

6. Signature

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