

**DECLARATION OF COMPLIANCE FOR MATERIALS AND ARTICLES
INTENDED TO COME INTO CONTACT WITH FOOD**

Date : February 2022 ⁽¹⁾

Rev.1

We hereby confirm that the material :

TEKFILM® FEP 2000E Clear

- Comply with the requirements of the Regulation (EC) No. 1935/2004
- The material comply with Regulation (EC) No. 10/2011 and subsequent amendments. It can be used as specified below* based on migration tests (overall migration as well as the specific migration) performed on material with simulants below identified
- Is manufactured following the indications of Good Manufacturing Practice (GMP) as set out in Regulation (EC) No. 2023/2006
- Is suitable to be used in contact with foodstuffs in accordance with U.S. legislation – FDA 21 CFR 177.1550 “Perfluorocarbon resins”

*Specifications on the intended use :

- Type(s) of food intended to come into repeated contact with the material :
All types of food : aqueous, acidic, alcoholic, oily or fatty foodstuffs (Simulants A, B and D2)
- Type(s) of food not intended to come into repeated contact with the material :
Not applicable
- Time and temperature of treatment and storage when in contact with food :
Tested in Acetic Acid 3% W/v in aqueous solution (4 hours at 100°C), Ethanol 10% v/v in aqueous solution (4 hours at 40°C) and in Rectified olive oil (2 hours at 175°C)



- Ratio of food contact surface area to volume (S/V) used to establish the compliance of the material :

$$S/V = 1$$

The following substances subject to restriction under Regulation EC No. 10/2011 are used in the material :

Chemical name of the substances	CAS No.	Restrictions
Tetrafluoroethylene	0000116-14-3	SML = 0,05 mg/kg
Hexafluoropropylene	0000116-15-4	SML = ND

Notes

It remains the responsibility of the customer use the plastic article manufactured from the product into the intended use, to assess the final suitability of the plastic material for the intended food contact application . i.e. checking if the physical properties of plastic material make it suitable for the intended application, checking compliance of the finished plastic article with the relevant migration limits, checking for possible influence of the plastic material on the composition and/or organoleptic properties of the contacting foodstuff, etc.

(1) - This Declaration will expire 3 years after the date of this issue

- Finished food contact articles shall be manufactured such that the surface skin(s) of semifinished product is (are) taken away.
- In accordance to GMP the food contact articles shall be thoroughly cleaned prior their first use in contact with food.
- It is the responsibility of the buyer to assure traceability of the material during any further downstream use up to and including the finished machined part as well as the equipment in which it is assembled.

Note No. 2 : The customer must always specify in the Orders when an approval / certification stated in this document is necessary. This because the approved material follow a different internal procedure with respect to the standard material.

Note No. 3 : the present declaration It is not valid unless accompanied by a certificate showing the identification (Lot No.) of material supplied

Rev.0 –First issue - Released in February 2019

Rev.1 –renewal of the declaration - Released in February 2022

