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

Date : November 2026 (1) Rev.21

We hereby confirm that the material :

PTFE G400

- **Comply with the requirements of the Regulation (EC) No. 1935/2004**

- **The material comply with Regulation (EC) No. 10/2011 and subsequent amendments, Regulation EU 2025/351 included. 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**
- **The material comply with Regulation EU/2025/351 because the material**
  - **Do not have any deterioration if properly used;**
  - **There are no observable changes of the article that may indicate the deterioration of the article or material if properly used;**
  - **Even in case specific damages or foreseeable misuse this will not increase migration or would cause the article to become otherwise unsuitable for further use in contact with food.**
- **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"**

- **Is suitable to be used in contact with foodstuffs in accordance with CHINESE Standard GB4806.1-2023, GB 4806.7-2023, GB 31604.7-2023, GB 31604.9- 2016, GB 9685.3-2016, GB 31604.2-2016, GB 9685-2016**

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D-U-N-S ® Number: 429385180

- **Comply with Regulation (EU) 2024/3190 on the use of bisphenol A (BPA) and other bisphenols and bisphenol derivatives**

- **Comply with Article 19 of 10/2011 : *Assessment of non intentionally added substances -NIAS* - not included in the Union list**

- **There are no dual-use additives present in the material.**

- **Ingredient of PTFE G400 is in "Positive List for food contact materials and articles made with synthetic resins" dated 1st June 2025 (Notification No. 324) issued by the Japanese Ministry of Health, Labour, and Welfare (MHLW) relative to list of the particular polymers and materials considered acceptable for use in food contact applications .**

*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

- Type(s) of food not intended to come into repeated contact with the material :
  Not applicable

- Test Conditions :
  Overall Migration + Colouring Migration + Specific Migration of Primary Aromatics Amines + Specific Migration Tetrafluoroethylene + Specific Migration of metals : Ba, Co, Mn, Zn, Cu, Fe, Li, Al, Ni, Sb, Hg*, As*, Cr*,Pb*, Cd*,La*, Eu*, Gd*,Tb*.
  *= according to Reg. EU 1245/20 (15th amendment)
  Simulant A : Ethanol 10% v/v - 4 hours at 100°C
  Simulant B : Acetic Acid 3% W/v in aqueous solution - 4 hours at 100°C
  Simulant D2 : Rectified olive oil - 2 hours at 175°C

  Migration test was carried out by **TOTAL IMMERSION**.
  SURFACE (dm^2): 1.0 (4 pieces)
  VOLUME (dl): 1
  LOD : 1mg/dm^2

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With reference to specific migrations, the compliance computations have been arranged assuming that 1 kg of food comes in contact with 6 dm^2 of packaging material.

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

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 December, 2012
Rev.1 – Released in April 2013- FDA suitability added
Rev.2 – Note No. 2 added
Rev.3 – References to Directive 2002/72/EC removed
Rev.4 – Note No. 3 added
Rev.5 - Validity of declaration prolonged
Rev.6 – Amendments of Reg. 10/2011 added
Rev.7 – Compliance with Chinese Food standard added
Rev.8 – Updated according Reg. EU 831/2018 amendment
Rev.9 – Declaration updated according new simulants tests performed. Ratio S/V revised.
Rev.10 – Declaration completely renewed after new tests according 15th amendment of 10/2011.
Rev. 11 – Composition Conformity to Japanese Positive List for Food contact of 1st June 2020 added
Rev. 12 – Dual-use additives concept added
Rev. 13 – Update for amendments - Reg. EU 2023/1442
Rev. 14 – Update for amendment Reg. EU 2023/1627
Rev. 15 – Japanese Positive List updated
Rev. 16 – Japanese Positive List updated up to 1st June 2025 (Notification No. 324)
Rev. 17 – Declaration updated according Reg. EU 2025/351 and Reg. EU 2024/3190
Rev. 18 – Compliance to GB 4806.7 updated to 2023
Rev. 19 - Reference to transitional measures of Reg. EU 2025/351 added
Rev. 20 – Conformity to Regulation EU 2025/351 added
Rev. 21 – References to GB Chinese norm updated

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