

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

Place, Date : Castelli Calepio , October 2025 ⁽¹⁾

Rev.2

Based on Test Report FC230465.01 dated 23rd August 2023 and Test Report FC240179.01 dated 02nd April 2024, we hereby confirm that products in :

PTFE SC1400

- 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 and subsequent amendments.
- Comply with requirements of the Regulation (EC) No. 1895/2005 and subsequent amendments.
- 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.
- Is suitable to be used in contact with foodstuffs in accordance with U.S. legislation – FDA 21 CFR 177.1550 “Perfluorocarbon resins”

- Ingredients of SC1400 are 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 :
Aqueous foodstuffs

- Test Conditions :

Overall Migration

3 attacks - 10 days at 40°C – Simulant : Water

Specific Migration of Primary Aromatics Amines

3 attacks – 1h. at 100°C – Simulant : Water , followed by 10 Days at 60°C

Specific Migration of heavy and lanthanides metals

Ba, Co, Mn, Zn, Cu, Fe, Li, Al, Ni, Pb, Hg, Cd, As, Cr, Sb, La, Eu, Gd, Tb.

3 attacks – 1h. at 100°C – Simulant : Water , followed by 10 Days at 60°C

Specific Migration of Tetrafluoroethylene

3 attacks – 1h. at 100°C – Simulant : Water , followed by 10 Days at 60°C

Migrations test was carried out by **TOTAL IMMERSION**.

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

The validity of this declaration starts from the date indicated above. The declaration remains valid as long as no substantial changes occur in the composition and/or production process of the material and/or component such as to entail the modification of the conformity requirements, or as long as the legislative references cited in it do not undergo modifications or updates such as to require the issuing of a new declaration of conformity.

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.

- 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 September 2023
Rev. 1 – Conformity to FDA 177.1550 added
Rev.2 – Conformity to Japanese positive list added



Marco Nocera

Quality & Customer Care Mgr.



GUARNIFLON SPA
(Società Soggetta all'attività di direzione e coordinamento
ex art. 2497 bis C.C. da parte di Mazza Holding S.p.A.)

Sede Legale
Via Soave 7 - 20135 (MI) ITALY
VAT N. IT01406020162 - C.F. 01406020162
REG. IMPRESE DI MI - REA 2726605
CAPITALE SOCIALE €10.000.000 INTERAMENTE VERSATO
Sede Operativa
Via T. Tasso n° 12 - 24060 Castelli Calepio (BG) ITALY
REG. IMPRESE DI BG - REA 203233

www.guarniflon.com - info@guarniflon.com
UE 2018/851 : <https://www.guarniflon.com/it/imballaggi>

Phone +39.035.4494311

D-U-N-S® Number: 429385180

