

# DECLARATION

DICHIARAZIONE DI CONFORMITA' DEI MATERIALI E DEGLI OGGETTI DESTINATI  
A VENIRE A CONTATTO CON I PRODOTTI ALIMENTARI  
(DECLARATION OF COMPLIANCE OF MATERIALS AND ARTICLES  
INTENDED TO COME INTO CONTACT WITH FOOD)

Con la presente si dichiara che il materiale fornitoVi:  
*We hereby declare that the material supplied:*

Semilavorati e prodotti finiti realizzati in materiale fluteck™ P1000 - P1500  
Semi - finished and finished products made in fluteck™ P1000 - P1500 material

1. è conforme alla seguente legislazione dell'Unione Europea (UE):  
*is in compliance with the following European Union (EU) legislation:*

- Regolamento (CE) n°1935/2004  
*Regulation (EC) No 1935/2004*
- Regolamento (UE) n°10/2011 e s.m.i.  
*Regulation (EU) No 10/2011 as amended*
- Regolamento (CE) n°2023/2006 e s.m.i.  
*Regulation (EC) 2023/2006 as amended*

alla seguente legislazione Italiana:  
*and with the following Italian legislation:*

- Decreto Ministeriale n°21/03/1973 e s.m.i.
- D.P.R. n°777/82 e s.m.i.

2. e alla seguente legislazione americana (Food and Drug Administration):  
*and with the following american regulation (FDA):*

- FDA 21CFR 177.1550  
*FOOD AND DRUG ADMINISTRATION, VOL. 21, CAP. 177.1550.*

3. è prodotto con il seguente materiale:  
*is made by the following material:*

**PTFE** (politetrafluoroetilene/ polytetrafluoroethylene)

**fluorseals**



Company Quality System  
Uni EN ISO 9001:2015  
cert. CISQN° 061  
First issue 1994

**fluorseals S.p.A.**  
Via Tribolina, 20/22  
24064 Grumello d.M (Bg)  
Italia

P.IVA - C.F - VAT: IT00593110166  
REA: BG 158562  
Reg.Imp: BG 11004  
Cap. Soc. 1.500.000,00 €

T +39 035 4492811  
F +39 035 831410  
info@fluorseals.it  
**fluorseals.it**

# DECLARATION

## LEGISLAZIONE EUROPEA:

### European Legislation:

- sulla base delle dichiarazioni di idoneità alimentare rilasciate dai fornitori delle materie prime utilizzate, il materiale fornitoVi, contiene la seguente sostanza sottoposta a restrizione nelle legislazioni citate:  
*according to the declarations of compliance to food contact legislations received from our raw materials suppliers, the material supplied contains the following substance with restriction concerning the above- mentioned legislations:*

Sostanza (Substance)	N° riferimento CEE (Ref. No EEC)	N° CAS (CAS No)	FRF applicabile (FRF applicable)	LMS [mg]/[kg] (SML [mg]/[kg])	LMS (T) [mg]/[kg] (SML(T) [mg/kg])	Restrizioni e specifiche (Restrictions and specifications)
Tetrafluoroetilene (tetrafluoroethylene)	25120	16-14-3	no	0,05	/	/

- rispetta i limiti di migrazione globale e le restrizioni specifiche nelle seguenti condizioni di prova:  
*doesn't exceed the overall and specific migration limits under the following test conditions:*
  - 4 ore a temperatura di riflusso, 100°C, (1 ora e uso ripetuto) - simulante alimentare B (acido acetico al 3% p/v) - rapporto superficie/volume: 1 dm<sup>-1</sup>
  - 4 hours at reflux temperature, 100°C, (one hour and repeated use) - food simulant B (acetic acid 3% w/v) - surface/volume ratio: 1 dm<sup>-1</sup>
  - 4 ore a temperatura di riflusso (uso ripetuto) - simulante alimentare D1 (etanolo al 50% v/v) - rapporto superficie/volume: 1 dm<sup>-1</sup>
  - 4 hours at reflux temperature (repeated use) - food simulant D1 (ethanol 50% V/V) - surface/volume ratio: 1 dm<sup>-1</sup>
  - 2 ore a 175°C (uso ripetuto) - simulante alimentare D2 (olio vegetale) - rapporto superficie/volume: 1 dm<sup>-1</sup>
  - 2 hours at 175°C (repeated use) - food simulant D2 (vegetable oil) - surface/volume ratio: 1 dm<sup>-1</sup>
  - 6 ore a 60°C (uso ripetuto) - simulante alimentare Etanolo 95% (V/V) - rapporto superficie/volume: 1 dm<sup>-1</sup>
  - 6 hours at 60°C (repeated use) - food simulant ethanol 95% (V/V) - surface/volume ratio: 1 dm<sup>-1</sup>
  - 2 ore a 175°C (uso ripetuto) - simulante alimentare E (MPPO) - rapporto massa simulante/superficie campione: 4g/dm<sup>2</sup>
  - 2 hours at 175°C (repeated use) - food simulant E (MPPO) - weight simulant/sample surface ratio: 4g/dm<sup>2</sup>
- è conforme a quanto previsto dall'Allegato II, punti 1 e 2, del Regolamento (UE) n°10/2011 e s.m.i. (condizioni di prova: 4 ore a temperatura di riflusso, uso ripetuto - simulante alimentare B (acido acetico al 3% p/v) - rapporto superficie/volume: 1)  
*is in compliance with the Annex II, points 1 and 2, of the Regulation (EU) No 10/2011 OJ EU L12 dated 15/01/2011 as amended (test conditions: 4 hours at reflux temperature, repeated use - food simulant B (acetic acid 3% w/v) - surface/volume ratio: 1)*

**fluorseals**



Company Quality System  
Uni EN ISO 9001:2015  
cert. CISQN° 061  
First issue 1994

**fluorseals S.p.A.**  
Via Tribolina, 20/22  
24064 Grumello d.M (Bg)  
Italia

P.IVA - C.F - VAT: IT00593110166  
REA: BG 158562  
Reg.Imp: BG 11004  
Cap. Soc. 1.500.000,00 €

T +39 035 4492811  
F +39 035 831410  
info@fluorseals.it  
**fluorseals.it**

# DECLARATION

Il materiale fornitoVi è idoneo a qualsiasi condizione di contatto a una temperatura superiore a 40°C, uso ripetuto, con i prodotti alimentari per i quali vengono assegnati i simulanti A, B, C o D1 (alimenti acidi, alcolici e lattiero-caseari) e con i cibi grassi per applicazioni ad alta temperatura (>121°C) compresa la Categoria 01.04 della tabella 2 del Reg.10/2011/UE.

*the material supplied is suitable for any contact condition at a temperature exceeding 40°C, repeated use and with food covered by simulants A, B, C or D1 (acid, alcoholic food and milk products) and with fatty food for high temperature application (>121°C), included 01.04 Category of table 2 Reg.10/11/EU.*

## SPECIFIC MIGRATION OF BA, CO, MN, ZN, CU, FE, LI, AL, NI

Determination of the specific migration of Ba, Co, Mn, Zn, Cu, Fe, Li, Al, Ni according to Reg. EU 10/2011 from the tested material into the simulants by ICP (Inductively Coupled Plasma) technique. The quantitative evaluation was carried out by external calibration of the elements in the same liquid simulants.

Ba - SML: 1 mg/kg; LOD: 0.02 mg/kg; Average value: <0,02 mg/kg  
Co - SML: 0.05 mg/kg; LOD: 0.02 mg/kg; Average value: < 0,02 mg/kg  
Mn - SML: 0.6 mg/kg; LOD: 0.02 mg/kg; Average value: < 0,02 mg/kg  
Li - SML: 0.6 mg/kg; LOD: 0.02 mg/kg; Average value: < 0,02 mg/kg  
Zn - SML: 5 mg/kg; LOD: 0.02 mg/kg; Average value: < 0.02 mg/kg  
Cu - SML: 5 mg/kg; LOD: 0.02 mg/kg; Average value: < 0.02 mg/kg  
Fe - SML: 48 mg/kg; LOD: 0.02 mg/kg; Average value: < 0.02 mg/kg  
Al - SML: 1 mg/kg; LOD: 0.02 mg/kg; Average value: < 0.06 mg/kg  
Ni - SML: 0,02 mg/kg; LOD: 0.02 mg/kg; Average value: < 0.015 mg/kg

## QUANTITATIVE DETERMINATION OF PRIMARY AROMATIC AMINES: METHOD L.00.00-6 (LMBG § 35)

The procedure used to quantify the primary aromatic amines was a spectrophotometer method, based on the colour complex formed by a diazotization and a coupletization reaction. The solution was further concentrated and eluted on a solid phase column. The final solution was photometrically detected at 550 nm (Method BGVV § 64 LFGB, L.00.00-6 dated 1995, updated 2002). An external calibration curve detected at 550 nm was used to quantify the primary aromatic amines. An aniline standard solution 0, 0.5, 1.0, 1.5, 2.0, 3.0, 4.0, 6.0 g in acetic acid 3% was detected.

LOD: 0.2 µg /100 ml or LOD: 0.002 mg/kg or LOD: 0.0003 mg/dm<sup>2</sup> (the limit is originally expressed in mg/kg; it is possible to convert the measure unit by dividing for the factor 6 to express them in mg/dm<sup>2</sup>.)

LMS: 0.01 mg/kg (according to 10/2011)  
Average value: <0,002 mg/kg

## SPECIFIC MIGRATION OF TETRAFLUOROETHYLENE

Determination of the specific migration of tetrafluoroethylene (CAS No. 000116-14-3 - Ref No. 25120) made simulants arising from the release test by HS-GC/MS technique. The quantification is performed by an external calibration of tetrafluoroethylene in the same simulants.

LMS: 0.05mg/kg (according to 10/2011)  
Average value: <0,05 mg/kg

## OLFACTORY ORGANOLEPTIC TEST

According to sensory analysis it is in compliance with article 3, point 1c, of the Regulation (EC) No 1935/2004 OJ EC

Standard deviation: 0.5  
Average score: < 1.5

**fluorseals**



Company Quality System  
Uni EN ISO 9001:2015  
cert. CISQN° 061  
First issue 1994

**fluorseals S.p.A.**  
Via Tribolina, 20/22  
24064 Grumello d.M (Bg)  
Italia

P.IVA - C.F - VAT: IT00593110166  
REA: BG 158562  
Reg.Imp: BG 11004  
Cap. Soc. 1.500.000,00 €

T +39 035 4492811  
F +39 035 831410  
info@fluorseals.it  
**fluorseals.it**

# DECLARATION

## LEGISLAZIONE AMERICANA (FDA):

### American Legislation (FDA):

Il materiale rispetta i limiti e le specifiche delle analisi sotto riportate, in accordo ai requisiti del regolamento FDA 21 CFR 177.1550:

*The material respects the limits and the specifications of the following analysis, according to FDA Regulation 21 CFR 177.1550 requirements:*

- Verifica degli estratti totali ed estratti specifici (fluoruri) alle seguenti condizioni di prova:  
*Verify the total extracts and specific extracts (fluorides) under the following test condition:*
  - 2 ore a temperatura di riflusso in Acqua distillata  
*2 hours at reflux temperature – in distilled water*
  - 2 ore a temperatura di riflusso in Etanolo 50% (V/V)  
*2 hours at reflux temperature – in ethanol 50% (V/V)*
  - 2 ore a temperatura di riflusso in n-eptano  
*2 hours at reflux temperature – in n-heptane*
  - 2 ore a temperatura di riflusso in etilacetato  
*2 hours at reflux temperature – in ethylacetate*

## Fluoruri estratti

Determinazione di fluoruri tramite elettrodo ionoselettivo nei simulanti sopraelencati

### *Fluoride extractives (specific extracts)*

*The determination of the fluoride in the sample has been made by ionoselective electrode in the following stimulant: distilled water, ethanol 50% v/v, n-heptane and ethyl-acetate:*

- *Distilled water: < 0.01 (Limit Value 0.03)*
- *Ethanol 50 % v/v: < 0.01 (Limit Value 0.03)*
- *n-heptane: < 0.01 (Limit Value 0.03)*
- *Ethyl-acetate: < 0.01 (Limit Value 0.03)*

# DECLARATION

Attenzione:

Attention:

- ✓ questa Dichiarazione di Conformità è valida esclusivamente per il materiale da noi fornito e non può essere estesa ad un'eventuale trasformazione dello stesso
- ✓ *this Declaration of Compliance refers only to the material supplied*
- ✓ a supporto di quanto indicato in questo documento, l'azienda dichiara di avere a disposizione delle Autorità competenti i rapporti di prova effettuati, le dichiarazioni di conformità dei fornitori di materia prima e tutto il materiale ausiliario
- ✓ *appropriate documentation is available to the competent authorities to demonstrate what is stated in this DoC*
- ✓ questa Dichiarazione di Conformità è redatta in conformità alla legislazione sopra citata ed è destinata a:
- ✓ *this Declaration of Compliance was drawn up in compliance with the above-mentioned legislations and it is addressed to:*

## Diflon Technology

Registered Office: Piazza Castello, 26 - 20121 - Milano – Italy  
Factory: Via Sicilia, 8 - 24060 - Carobbio Degli Angeli - BG – Italy  
Phone: 0039.035.4491137  
Fax: 0039.035.4491419

- ✓ questa Dichiarazione di Conformità ha validità a partire dalla data sotto riportata e sarà sostituita nel caso in cui intervengano cambiamenti sostanziali nella produzione del materiale in oggetto in grado di mutare alcuni requisiti essenziali ai fini della conformità o quando i riferimenti legislativi citati nella presente dichiarazione saranno modificati ed aggiornati in modo da richiedere una nuova verifica ai fini della conformità.
- ✓ *this Declaration of Compliance is valid from the date indicated at the bottom of this document and it will be renewed if significant changes in the production process, able to negatively affect the compliance of the material supplied, occur or if amendments or updates to the above-mentioned legislations require further or different verifications.*


The user of the material, intended for contact with food, has the responsibility to inform the manufacturer if there are any restrictions related to the compositional features in the foodstuffs (presence of additives and aromas).

Furthermore, the user must verify that the finished item, machined from the semi-finished product, would be technically suitable for the requested application and it may not cause any modification to the organoleptic properties of the foodstuff. The technological suitability of the material, it is assigned to, must be guaranteed.

For each foreign country market, where the items are introduced into, it is responsibility of the user to determine whether both material than items would comply with the applicable laws and regulations.

Data:04/2019  
Date: 04/2019

Firma QAM:  
Signature:



fluorseals S.p.A. QA Dpt

## fluorseals



Company Quality System  
Uni EN ISO 9001:2015  
cert. CISQN° 061  
First issue 1994

**fluorseals S.p.A.**  
Via Tribolina, 20/22  
24064 Grumello d.M (Bg)  
Italia

P.IVA - C.F - VAT: IT00593110166  
REA: BG 158562  
Reg.Imp: BG 11004  
Cap. Soc. 1.500.000,00 €

T +39 035 4492811  
F +39 035 831410  
info@fluorseals.it  
**fluorseals.it**