

DECLARATION OF CONFORMITY OF MATERIALS AND ARTICLES
INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

TUBIGOMMA DEREGIBUS SRL A SOCIO UNICO declares that, under the foreseen and foreseeable conditions of use and in the state in which the articles are marketed:

TUFLUOR PTFE PHARM

Ref. Invoice/Delivery Note: /

complies with

Following European requirements:

- **Reg. (CE) 1935/2004** and subsequent modifications and integrations;
- **Reg. (CE) 2023/2006** and subsequent modifications and integrations;
- **Reg. (CE) 10/2011** and subsequent modifications and integrations;

And following National requirements:

- **Decreto Presidente Repubblica (DPR) 777/82** and subsequent modifications and integrations;
- **Decreto Legislativo 29/2017**
- **Decreto Ministeriale 21/03/1973** and subsequent modifications and integrations
- **FDA CFR 21 177.1550**

The liner of the products are made of:

PTFE

This declaration is supported by tests performed:

Test Conditions:

4 hours at 100°C

	Limits:
Overall migration ethanol 10%	10 mg/dm ²
Overall migration in acetic acid 3%	10 mg/dm ²
Overall migration in oil	10 mg/dm ²
Primary aromatic amines specific migration	0.01 mg/kg
9 Metals specific migration:	
Aluminum	1 mg/kg
Barium	1 mg/kg
Cobalt	0.05 mg/kg
Iron	48 mg/kg

Lithium	0.6 mg/kg
Manganese	0.6 mg/kg
Nickel	0.02 mg/kg
Copper	5 mg/kg
Zinc	5 mg/kg
Colorants specific migration in ethanol 10%	> 95%
Colorants specific migration in acetic acid 3%	> 95%
Colorants specific migration in oil	> 95%
Extraction in water 2 hours at reflux	0.2 mg/inch ²
Extraction in ethyl acetate 2 hours at reflux	0.2 mg/inch ²
Extraction in ethanol 50% 2 hours at reflux	0.2 mg/inch ²
Extraction in n-heptane 2 hours at reflux	0.2 mg/inch ²
Fluoride extractives calculated as fluorine in water 2 hours at reflux	0.3 mg/inch ²
Sensory Test	PASS

The product is suitable for the contact (delivery) at any food contact conditions at temperature exceeding 40 °C. or below:

- **With all type of foods**

The company declares the technological suitability of the machine and every component for the purpose to which it is intended.

Please refer to our data sheets for hose area of application and technical information.

The hoses, before any use, must be cleaned in accordance with our "Cleaning and Disinfection" guidelines available at the link: <http://tudertechnica.com/cleaning-and-disinfection/>

This declaration shall be valid from the date present at the end and must be replaced in the presence of substantial changes in the production of the material capable of changing certain essential requirements for compliance or when references Laws are amended so as to require re-verification for compliance purposes.

Date: 23-Jul-20

Signature 
Legal Representative