

**KIESELMANN**

FLUID PROCESS GROUP

# Declaration of Compliance

for products made of plastic intended to come into contact with food.

**KIESELMANN GmbH  
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D-75438 Knittlingen**

We confirm that the products made of Polytetrafluoroethylene (PTFE) material listed below

NUE 1	virginal PTFE
NUE M1	virginal PTFE
NUE 1056.2 (k-flex)	PTFE with mineral filler <10 %

intended to come into contact with food meet the requirements of the following statutory regulations:

(EU) No.10/2011	and repealing Regulations (EU) 1282/2011, (EU) 1183/2012, (EU) 202/2014
(EU) No. 1935/2004	and repealing Regulation (EC) 596/2009
(EU) No. 2023/2006	
FDA	Code of Federal Regulations, Food and Drugs (FDA), 21 CFR 177.1550, 04/2012

The above listed PTFE materials can be used unhesitatingly for manufacturing commodities e.g. sealing intended to come in contact with dry, wet and fatty foodstuff.

The manufacturing of the products is carried out according to the method "Good Manufacturing Practices" (GMP), corresponding to Regulation (EU) No. 2023/2006 of December 2006 applicable for the good manufacturing practices for materials and goods intended to come into contact with foodstuffs. According to Regulation (EU) No. 1935/2004, the traceability of the products is guaranteed.

The above listed PTFE materials are suitable for all kind of foodstuff, without any restrictions. Exposure to foodstuff is unlimited in time for a range of -200 °C to +100 °C. According to Regulation (EU) 10/2011 PTFE materials are subject to specific migration limits (SML) and overall migration limits (OML) for the following monomers:

CAS-No.	Substance Name	SML	OML
116-14-3	Tetrafluoroethylene (TFE)	0,05 mg/kg	10 mg/dm <sup>2</sup>
1623-05-8	Perfluoropropylperfluorovinylether (PPVE)	0,05 mg/kg	10 mg/dm <sup>2</sup>

According to the General Rules for Migration Test according to Regulation (EU) No. 10/2011, the overall migration (OM) of the individual substances will be determined through use of food simulants (Annex 3, Table 1) and pre-defined testing conditions (Annex 5, Table 3). The overall migrations as well as the specific migration for both substances do not exceed the specified limits set out in Regulation (EU) No. 10/2011.

Furthermore, the migration does not exceed the limit values according to FDA requirements. The filler material is recognised as safe (Generally Recognised as Safe, GRAS) according to 21 CFR 177.1550 (b) Therefore, the above listed PTFE materials are approved for contact with foodstuff in the US.

Knittlingen, 06.04.2016

i.V.

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