

# Declaration of Conformity

with Directive (EC) No. 1935/2004 from 27th October 2004  
on materials and articles intended to come into contact with food.

**KIESELMANN GmbH**  
**Paul-Kieselmann-Straße 4-10**  
**D-75438 Knittlingen**

**Designation of equipment**

**Aseptic Double-Seat Mixproof Valve  
Type 5824**

We confirm that the following materials used for our products and intended to be brought into contact with food, comply with the general requirements of the Regulation (EC) No. 1935/2004 of 27 October 2004.

The following materials are used for the mentioned equipment and are intended to come into contact with food:

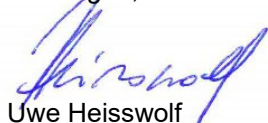
Material Group	Material Designation	Doc.-No.
Metals and alloys	1.4404 X2CrNiMo17-12-2	C Z.1.0100.EN
Plastics	NUE 1056.2 (k-flex)	D Z.1.0100.EN
	TFM™ 1705	D Z.1.0102.EN
Rubbers	85 EPDM 292	C Z.1.0112.EN

The processed materials are thereby permitted to come into contact with dry, moist and greasy foodstuffs. The certificate of conformity with the directives mentioned is based on the information from the respective manufacturer.

According to manufacturer's specifications, all seals and components are manufactured according to Good Manufacturing Practice, taking into account Directive (EC) No. 2023/2006, so that when used for the intended purpose, the foodstuff cannot be altered in a way which is hazardous to health or otherwise unacceptable. Traceability according to Directive (EC) No. 1935/2004 is assured.

Alterations reserved, liability for errors or omissions excluded. This declaration of conformity is valid without expiration, unless revoked.

Signed for and on behalf of Kieselmann GmbH,  
Knittlingen, 09.03.2022



Uwe Heisswolf  
Head of Development

# Declaration of Confirmation

referring to Regulation (EC) No. 1935/2004 of 27 October 2004  
on materials and articles intended to come into contact with food.

**KIESELMANN GmbH**  
**Paul-Kieselmann-Straße 4-10**  
**D-75438 Knittlingen**

We confirm that the following metals and alloys used for our products and intended to be brought into contact with food, comply with the general requirements of the Regulation (EC) No. 1935/2004 of 27 October 2004.

1.4301 X5CrNi18-10	1.4404 X2CrNiMo17-12-2	1.4539 X1NiCrMoCu25-20-5
1.4307 X2CrNi 18-9	1.4435 X2CrNiMo 18-14-3	1.4542 X5CrNiCuNb16-4
1.4401 X5CrNiMo17-12-2	1.4462 X2CrNiMoN22-5-3	1.4571 X6CrNiMoTi17-12-2

Furthermore, these metals and alloys meet the requirements of the following statutory regulations, standards and guidelines in their current valid version:

- **Regulation (EC) No. 2023/2006**
- **Council of Europe Resolution CM/Res (2013)9 on metals and alloys used in food contact materials and articles, 2013 - 1st Edition**
- **EN 1672-1/2 "Food processing machinery"**
- **DIN 10528**
- **EHEDG Guidelines, Doc. 32**

The above-mentioned steel types fulfil the Specific Release Limits (SRL) as specified in Resolution CM/Res (2013)9 on metals and alloys used in food contact materials and articles" of 2013.

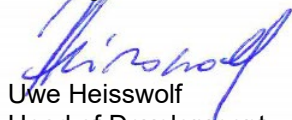
There are no limitations in regards to the type of food stuff which may come in contact with these materials.

The traceability as per Article 18 of the employed materials is ensured by our Quality Management System certified according to ISO 9001.

Alterations reserved, liability for errors or omissions excluded. This declaration of conformity is valid without expiration, unless revoked.

Signed for and on behalf of Kieselmann GmbH,

Knittlingen, 09.03.2021



Uwe Heisswolf  
Head of Development

# Declaration of Conformity

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

**KIESELMANN GmbH**  
**Paul-Kieselmann-Straße 4-10**  
**D-75438 Knittlingen**

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

Material: NUE 1056.2 (k-flex)  
Usage: Seals for valves, fittings and pipe connections

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

- **Regulation (EU) No. 10/2011**
- **Regulation (EC) No. 1935/2004**
- **Regulation (EC) No. 2023/2006**
- **FDA, Code of Federal Regulations, Food and Drugs (FDA), 21 CFR 177.1550, 04/2012**
- **GB 31604.1 -2015 (National food safety standard)**

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 temperature application up to 121 °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>

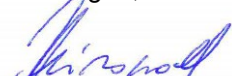
Results of the migration examination:

CAS-No.	Substance Name	SML	OML
116-14-3	Tetrafluorethylen (TFE)	not detectable	< 2 mg/dm <sup>2</sup>
1623-05-8	Perfluorpropyl-Perfluorvinylether (PPVE)	not detectable	< 2 mg/dm <sup>2</sup>

The overall migration (OML) of the individual substances will be determined according to the standard No. 80.30, 1 to 3 (EC) within the Official Collection of Testing Methods to § 64 of the Foodstuff and Animal Feed Code (April 2008) as well as to the series of standards EN 1186, EN 13130 and CEN/TS 14234. The use of food simulants and pre-defined testing conditions refer to the Regulation (EU) No. 10/2011, Annex 3, Table 1 and Annex 5, Table 3, test number OM 6 and OM 7. The specific migration limits (SML) will be determined according to SOP 160.200 using Headspace gas chromatography.

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.

Signed for and on behalf of Kieselmann GmbH,  
Knittlingen, 09.03.2022



Uwe Heisswolf

D Z.1.0100.EN

# Declaration of Compliance

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

**KIESELMANN GmbH**  
**Paul-Kieselmann-Straße 4-10**  
**D-75438 Knittlingen**

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

Material: **TFM™ 1705 PTFE (Enduflon™)**

Usage: **Diaphragm Type 5821 for aseptic valves**

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

- **(EU) No. 10/2011**
- **(EC) No. 1935/2004**
- **(EC) No. 2023/2006**
- **FDA, Code of Federal Regulations, Food and Drugs (FDA), 21 CFR 177.1550, 04/2012**

The above listed PTFE material is 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.

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.

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	Tetrafluorethylen (TFE)	0,05 mg/kg	10 mg/dm <sup>2</sup>
1623-05-8	Perfluorpropyl-Perfluorvinylether (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 and USP requirements. Therefore, the above listed PTFE material is approved for contact with foodstuff in the US.

Signed for and on behalf of Kieselmann GmbH,

Knittlingen, 09.03.2021



Uwe Heisswolf  
Head of Development

D Z.1.0102.EN

# Declaration of Conformity

referring to Regulation (EC) No. 1935/2004 of 27 October 2004  
on materials and articles intended to come into contact with food.

**KIESELMANN GmbH**  
**Paul-Kieselmann-Str. 4-10**  
**D-75438 Knittlingen**

For our seals and components made of the following material,

<b>85 EPDM 292</b>	<b>Ethylene-propylene-diene-rubber (peroxide-linked)</b>
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which are designed to come into contact with foodstuffs, we confirm the conformity with the following applicable legal regulations:

- **Arrêté du 5 août 2020 relatif aux matériaux et objets en caoutchouc destinés à entrer en contact avec des denrées alimentaires**
- **Regulation (EC) No. 2023/2006**
- **Code of Federal Regulations, Food and Drugs (FDA) 21 CFR § 177.2600**
- **3A® Sanitary Standard, Number 18-03, Class II**
- **USP Class VI Ch. 88 – 121 °C**
- **USP Chapter 87 (In vitro)**

The material referred can be used without concern as a seal material and in doing so is permitted to come into contact with dry, aqueous, acidic, alcoholic and greasy foodstuffs when used as intended.

The seals and components made out of the referred material are manufactured according to Good Manufacturing Practice taking into account Directive (EC) No. 2023/2006, so that when used for the intended purpose, no modification of the foodstuff which is hazardous to health or other unacceptable changes can take place. Traceability according to Directive (EC) No. 1935/2004 is assured.

The sealing material does not contain any substances originating from humans or animals (ADI free).

All information provided are solely based on statements given by manufacturer.

Alterations reserved, liability for errors or omissions excluded. This declaration of conformity is valid without expiration, unless revoked.

Signed for and on behalf of Kieselmann GmbH,  
Knittlingen, 09.03.2022



Uwe Heisswolf  
Head of Development