

# Declaration of Conformity

***For consumer goods intended to come into direct or indirect contact with foodstuffs and for application in pharma plant engineering.***

The product Diaphragm valve with PTFE diaphragm Code 5M and stainless steel valve body is intended to come into contact with foodstuffs.

The product complies with the current version of the following regulations or regulatory codes:

- Regulation (EC) No 1935/2004
- Regulation (EC) No 2023/2006

PTFE face

- Regulation (EC) No 10/2011

EPDM back

- Recommendation of the German Federal Institute for Risk Assessment (BfR) XXI regarding consumer goods based on natural and synthetic rubber

Valve body

- Resolution CM/Res(2013)9 on metals and alloys used in food contact materials and articles

## Materials

If used correctly, the following materials come into contact with foodstuffs:

- PTFE
- Stainless steel

Information about PTFE:

The materials used to manufacture the product comply with the positive list of Regulation (EU) No. 10/2011 in its current version.

No dual use substances are used in accordance with Regulation (EU) No. 10/2011.

If the PTFE face breaks, the food comes into contact with EPDM.

Information about EPDM:

The materials used for the manufacture of the product comply with the recommendation of the BfR (German Federal Institute for Risk Assessment) XXI Category 4.

## BSE/TSE

The above product conforms to EMA/410/01 revision 3 and is free of animal substances.

## Global migration PTFE

The maximum limit values of extractable substances defined in the above rules and regulations are adhered to under the following test conditions and have been verified with an appropriate test.

Food type	Food simulant	Migration conditions
Aqueous foodstuffs	Distilled water	2 h / 100 °C
Acidic foodstuffs	3% acetic acid	2 h / 100 °C
Alcoholic foodstuffs	95% ethanol	3,5 h / 60 °C
Fatty food	Isooctan	1,5 h / 60 °C

The migration tests were carried out for repeated contact with foodstuffs.

The proportion of the surface coming into contact with the foodstuff to volume is approximately 6 dm<sup>2</sup>/l.

**Specific migration PTFE**

There are Specific Migration Limits (SML) for:

TFE: SML = 0,05 mg/kg

PPVE: SML = 0,05 mg/kg

**Global migration EPDM**

When the product is used correctly, global migration is below the limiting values specified in the recommendation of the BfR XXI Category 3.

Conformity has been verified with the following tests:

Type of foodstuff	Foodstuff simulant	Migration conditions
Aqueous foodstuffs	Distilled water	10 Tage / 40 °C
Acidic foodstuffs	3% acetic acid	10 min / 40 °C
Alcoholic foodstuffs	10% ethanol	10 min / 40 °C

The migration tests were carried out for repeated contact with foodstuffs.

The proportion of the surface coming into contact with the foodstuff to volume is approximately 12 dm<sup>2</sup>/l.

**Application**

The plastics listed above are suitable for all foodstuff categories in accordance with Annex III of Regulation (EU) No. 10/2011.

The EPDM listed above is not suitable for foodstuffs containing fat. The EPDM is suitable for short-term food contact (< 10 min).

The stainless steels listed above are suitable for all foodstuff categories in accordance with the guideline for Metals and alloys in food contact materials and articles.

In order to comply with the limiting values stipulated in the guideline Metals and alloys in food contact materials and articles, the valve body must be passivated before or after the valve is installed.

Any restrictions derived from the information contained in the technical documentation relating to the maximum storage time and the temperature limits shall also apply.



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