

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 PTFE diaphragm Code 5M is intended to come into contact with foodstuffs.

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

EPDM back

- FDA 21 CFR 177.2600

PTFE face

- FDA 21 CFR 177.1550
- USP Class VI title 87
- USP Class VI title 88 (50 °C and 121 °C)

Materials

The materials used for the manufacture of the product comply with the current version of the positive list of the FDA regulatory codes listed above.

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

- PTFE

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

BSE/TSE

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

USP Class VI

The tests according to USP Class VI Title 87 and Title 88 (50 °C and 121 °C) were carried out and passed.

Extraction tests

The maximum limiting values defined in the regulatory codes listed above were proven in extraction tests and are complied with.

Foodstuff simulant	Migration conditions
Distilled water	2 hours / reflux temperature
n-Heptan	2 hours / reflux temperature
50 % ethanol	2 hours / reflux temperature

Extraktion tests EPDM

The maximum limiting values defined in the regulatory codes listed above were proven in extraction tests and are complied with.

Foodstuff simulant	Migration conditions
Distilled water	2 hours / reflux temperature
n-Hexane	2 hours / reflux temperature

Application

The product listed above is suitable for any type of food contact.

The EPDM back is not suitable for milk and edible oil.

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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