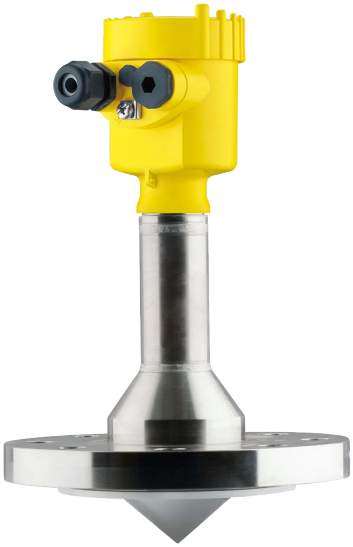
Declaration of conformity
VEGAMIP T61, R61, R62

acc. to VO (EG) 1935/2004 and VO (EU) 10/2011
as well as acc. to FDA 21 CFR 177.1550



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Contents

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1 Explanations of standards and regulations

CFR
FDA stands for Food and Drug Administration, a U.S. authority. Among other things, this authority issues a regulation on the use of product-contacting materials in the pharmaceutical, food and beverage and cosmetics industries (Code of Federal Regulations CFR).

We meet these basic requirements by implementing sensor variants made of materials whose composition corresponds to the relevant 21 CFR's 177.

For materials for which 21 CFR's 177 are not applicable, we refer to the current state of knowledge of independent experts from the pharmaceutical and food sectors or to statements of the Public Health Service of the Food and Drug Administration.

EG 1935/2004
Regulation (EC) No. 1935/2004 of 27.10.2004 is aimed at ensuring a high level of protection of human health as well as the safety of consumers, respecting articles and materials intended to come into contact with food.

Along with this regulation, individual measures can be implemented. For plastics, this is for example regulation (EU) no. 10/2011.

The special focus of the regulation is on compliance with good manufacturing practice. We understand the principal aspect of good manufacturing practice to be making sure that parts with potential food contact are designed so that, at least under foreseeable conditions, the migration of constituent substances is largely avoided or does not occur in quantities that would endanger human health or bring about unacceptable changes in composition or organoleptic properties.

GMP EG 2023/2006
Under the second aspect of good manufacturing practice (GMP) acc. to EG 2023/2006 of 22.12.2006, we understand ensuring the traceability of components and products potentially coming into contact with foodstuffs throughout all stages of manufacturing and sales. This is guaranteed by our quality management system according to ISO 9001 and ISO 14001.

USP
The USP (US Pharmacopial Convention) is a non-commercial organisation for development and formulation of requirements and standards for the identity, quality and purity of drugs as well as food components and supplements.

If confirmations of the supplier for plastics or elastomers on USP Class VI are available, the we confirm this for the respective concerned versions.

ADI-free (BSE/TSE)
Free from substances with animal origin or substances associated with TSE (Transmissible Spongioform Encephalopathy) or BSE (Bovine Spongioform Encephalopathy).

This can also mean the risk assessment of the manufacturer in the case of possible unintentionally introduced ingredients of animal origin and the elimination of ingredients of animal origin by long-term higher processing temperatures according to EMEA/410/01 of July 2011.

If confirmations of the supplier are available that plastics or elastomers are ADI-free, then we confirm this for the respective concerned versions.

GB 4806
The GB 4806 standards contain specifications and limit values of the People's Republic of China for the handling and release of materials and products that come into contact with foodstuffs. There are several individual measures, such as GB 4806.4 for ceramics, GB 4806.6 and GB 4806.7 for plastics, GB 4806.9 for metals and GB 4806.11 for elastomers.

Notes on proper use

To ensure that there is no unintentional contamination to the process through transport, installation or mounting, a rinsing with a suitable cleaning medium (e.g. drinking water) is required before the first contact with the foodstuff.

For process fittings for which the process seal was not supplied, a process seal corresponding to the application-specific requirements must be used.

The seal of Klingersil C-4400 supplied as a standard feature with the threaded version, is not part of this conformity declaration and must be removed before installing into the process.

2 General explanations of the sensor

We herewith declare that the versions of VEGAMIP T61, T62, R61 listed in the following Table 1 are suitable for contact with foodstuffs and comply with the requirements of regulation VO (EC) No. 1935/2004 and VO (EU) 10/2011 as well as the FDA requirements on fluoride extractives acc. to 21 CFR 177.1550.

MPR61.	*	*	N / R	CA / RA / TB / Q1 QB / XC / CD / 1B FC / YD / FD / FK FR / FI / KC / KD KE / KH / KR / AE AK / AM / AO / AN AP / UA / UB / UC UE	8	*	*	*	*

MPT61.	*	*	*	CA / RA / TB / Q1 QB / XC / XD / AB FC / FD / FE / FK FR / FI / KC / KD KE / KH / KR / AE AK / AM / AO / AN AP / UA / UB / UC UE	*	*	*	*	*

MPR62.	*	*	N / R	CA / RA / TB / Q1 QB / XC / XD / 1B FC / YD / FD / FE FK / FR / FI / KC KD / KE / KH / KR AE /AK / AM / AO AN / AP / UA / UB UC / UE	8	*	*	*	*	*	*

3 Europe - Basis of assessment

3.1 PTFE

PTFE TFM 1600
The migration test according to VO (EU) 10/2011 incl. Amendment Ordinance 2020/1245 on a representative PTFE TFM 1600 component proved that the PTFE TFM 1600 is suitable for all types of food under the following test conditions - according to European evaluation criteria.

Global migration

Test conditions:	The test for overall migration on PTFE TFM 1600 test samples was performed under the test conditions: 3 x 1 h at reflux temperature in 3 % acetic acid (simulant B), in 10 % ethanol (simulant A) and 3 x for 2 h at 175 °C in sunflower oil (simulant D2), (Test method: DIN EN 1186:2002-07/2002-12).
Result:	Compliance with the limit value for total migration ≤ 10 mg/dm² has been proven.

Specific migration

Substance	**Result**
Tetrafluoroethylene (CAS 116-14-3)	A surface area of 1 dm² was completely immersed in a volume of 100 ml of ethanol 95 % for 24 h. The permitted limit values were not exceeded for the substances.
Perfluoropropyl perfluorovinyl ether (CAS 1623-05-8)	

Specific migration of metals

Test method:	DIN EN 13130-1: 2004-08 / ICP-OES: DIN EN ISO 11885: 2009-09 + ICP-MS: DIN EN ISO 17294-2: 2017-01 + AFS (Hg): DIN EN ISO 17852: 2008-04
Test conditions:	Acetic acid 3 % (24 h/100 °C), complete immersion
Result:	passed

Specific migration of Primary aromatic amines (PAA)

Test method:	DIN EN 13130-1: 2004-08 / LC-MS
Test conditions:	Acetic acid 3 % (24 h/100 °C), complete immersion
Result:	passed

Sensory inspection

Test conditions	Test procedure: § 64 LFGB L 00.90-6 (2015-06) tap water (4 h/100 °C)
Result	Requirements regarding appearance, smell and taste were fulfilled

ADI-free
Furthermore, our semi-finished product supplier confirms to us that no components of animal origin are contained. In addition, the processing temperatures are so high that organic substances are destroyed.

PTFE Inoflon M290, PTFE Inoflon M295
The migration test according to VO (EU) 10/2011 incl. Amendment Ordinance 2020/1245 on a representative PTFE Inoflon M290 and PTFE Inoflon M295 component proved that the PTFE Inoflon M290 and PTFE Inoflon M295 are suitable for all types of food under the following test conditions - according to European evaluation criteria.

Global migration

Test conditions:	The test for overall migration on PTFE Inoflon M290 and PTFE Inoflon M295 test samples was performed under the test conditions: 3 x 1 h at 100 °C in acetic acid 3 %, in ethanol 10 % and 3 x for 2 h at 175 °C in vegetable oil, (Test method: DIN EN 1186:2002-07/2002-12).
Result:	Compliance with the limit value for total migration ≤ 10 mg/dm² has been proven.

Specific migration

Substance	**Result**
Tetrafluoroethylene (CAS 116-14-3)	A surface area of 1 dm² was repeatedly completely immersed in a volume of 100 ml ethanol 95 %. The permitted limit values were not exceeded for the substances.
Perfluoropropyl perfluorovinyl ether (CAS 1623-05-8)	

Specific migration of metals

Test method:	DIN EN 13130-1: 2004-08 / ICP-MS: DIN EN ISO 17294-2: 2017-01 + AFS (Hg): DIN EN ISO 17852: 2008-04
Test conditions:	Acetic acid 3 % (24 h/100 °C), complete immersion
Result:	passed

Specific migration of Primary aromatic amines (PAA)

Test method:	DIN EN 13130-1: 2004-08 / LC-MS
Test conditions:	Acetic acid 3 % (24 h/100 °C), complete immersion
Result:	passed

Sensory inspection

Test method:	DIN 10955: 2004-06
Test conditions:	Tap water (4 h/100 °C), complete immersion
Result:	Requirements regarding appearance, smell and taste were fulfilled

Source: Intertek test reports RE41749, FUFDCP2022-07697, RE38921-2, FUFDCP2022-04519 - RO

ADI-free (BSE/TSE) at PTFE Inoflon M290
Furthermore the supplier of the raw material has provided the statement that the material is ADI-free (BSE/TSE) and the statement on USP Class VI at 70 °C.

3.2 Metals

The metals in contact with the medium are stainless steel alloys (e.g. 316L), which have been tried

and tested over many years in the pharmaceutical and food industries.

The traceability of the wetted parts and materials according to VO (EG) 2023/2006/GMP is guaranteed by our QM system from procurement to production and assembly up to placing on the market.

4 USA - Basis of assessment

4.1 PTFE

PTFE-TFM-1600

Overall extraction

Test conditions	21 CFR Part 177.1550, Paragraph e 3(i) Total extraction in distilled water, ethanol 8 % and n-heptane
Result	Requirement fulfilled, as total extraction < 0.2 mg/in²

fluorid-extractives

Test conditions	21 CFR Part 177.1550 Extraction 2 h with reflux in distilled water, ethanol 50 %, n-heptane and ethyl acetate
Result	Requirement fulfilled, as fluoride extractable substances < 0.46 mg/in²

melt viscosity

Test conditions:	21 CFR Part 177.1550 und ASTM D1238-13 Methode A 372 °C; load 2.16 kg; heating time 420 s; switch-off time 60 s
Result:	Method is not applicable for this material

In addition, our semi-finished product supplier confirms that representative test samples have passed the USP Class VI - 70 °C tests.

PTFE Inoflon M290, PTFE Inoflon M295

The migration tests according to FDA 21 CFR 177.2415 on a representative PTFE Inoflon M290 and PTFE Inoflon M295 component proved that the PTFE Inoflon M290 and PTFE Inoflon M295 are suitable for all types of food under the following test conditions, according to FDA conformity.

Overall extraction

Test conditions:	21 CFR Part 177.1550, Paragraph e (1) & e (3) Total extraction in distilled water, ethanol 50 %, n-heptane and ethyl acetate
Result:	Requirement fulfilled, as total extraction < 0.2 mg/in²

fluorid-extractives

Test conditions:	21 CFR Part 177.1550 Extraction in distilled water, ethanol 50 %, n-heptane and ethyl acetate
Result:	Requirement fulfilled, as fluoride extractable substances < 0.03 mg/in²

Source: Intertek test report SHAH01531211

USP Class VI - 70 °C at PTFE Inoflon M290
Our semi-finished product supplier confirms that representative test samples have passed the USP Class VI - 70 °C tests.

4.2 Metals

The metals in contact with the medium are stainless steel alloys (e.g. 316L), which have been tried and tested over many years in the pharmaceutical and food industries.

5 China - Basis of assessment

5.1 PTFE

PTFE Inoflon M290, PTFE Inoflon M295, PTFE-TFM-1600
For the PTFE Inoflon M290, PTFE Inoflon M295 and PTFE-TFM-1600 the food compatibility could be proven by tests on representative test samples according to GB 4806.7-2016 and GB 4806.6-2016 (Intertek Shanghai test report number SHAH0153121801, SHAH0153121802).

Total migration

Test conditions:	The test conditions for total migration were 4 h at 100 °C each in acetic acid 4 % and ethanol 10 % and 4 h at 100 °C in oil substitute simulant (Test method: GB 31604.8-2021).
Result:	Compliance with the limit value for total migration < 10 mg/dm² has been proven.

KMnO4 consumption

Test conditions:	The test conditions for KMnO4 consumption were 2 h at 60 °C in distilled water (Test method GB 31604.2-2016).
Result:	Compliance with the limit value for KMnO4 ≤ 10 mg/kg has been proven.

Release of lead

Test conditions:	The test conditions for the release of lead were 2 h at 60 °C in acetic acid 4 % (Test method GB 31604.9-2016).
Result:	Compliance with the limit value for the release of lead ≤ 10 mg/kg has been proven.

Decolourisation test

Test conditions:	The food simulants used were pure ethanol, vegetable oil and soaking solution (referred to as " *soaking liquid*" in the test report), (Test method: GB 31604.7-2016).
Result:	In all four food simulants no colour release was detected.

Specific migration of Tetrafluoroethylene (PTFE)

Test conditions:	The test conditions for the migration of Tetrafluoroethylene were 3 x 24 h at 100 °C in acetic acid 4 %, 3 x 24 h at reflux temperature in ethanol 10 % and 3 x 6 h at 250 °C in olive oil (Test method: GCB-3-F-293).

Result:	Compliance with the limit value for specific migration ≤ 0,05 mg/kg has been proven.

Source: Intertek test report SHAH0153121801, SHAH0153121802

Sensors
Passed, as test solution showed no peculiar odour and the test samples were assessed normally with regard to colour and odour.

5.2 Metals

Metals acc. to standard GB 4806.9-2016
For the stainless steels made of 1.4404, 1.4435 and 1.4462, the suitability for use with foodstuffs could be proven by tests on representative test samples according to GB 4806.9-2016. (Intertek Hong Kong test report number HKGH02515908 S1, HKGH02515909-S1 and HKGH02515910-S1).

Test conditions:	The test conditions for migration tests and organoleptic tests are specified in the standards GB 31604.24-2016, GB 31604.25-2016, GB 31604.33-2016, GB 31604.34-2016, GB 31604.38 and GB 5009.156-2016.
Result - Migration tests:	Compliance with the following migration limit values has been proven: ● Arsenic ≤ 0.04 mg/kg ● Cadmium ≤ 0.02 mg/kg ● Lead ≤ 0.05 mg/kg ● Chrome ≤ 2.0 mg/kg ● Nickel ≤ 0.5 mg/kg
Result - Sensoric tests:	Proof of the sensoric requirements could be provided since the test solution did not exhibit any peculiar odour and the test samples show clean and regular surfaces (free of cracks).

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