

# 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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**VEGA**

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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).

### **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.

### **FDA**

We meet these general requirements by purchasing parts and materials that potentially come into contact with food with proof of compliance with FDA requirements or, in cases where there are no explicit FDA requirements, with a "No Objection Letter" from the Public Health Service of the Food and Drug Administration, or by obtaining the expert opinion of independent (accredited) laboratories and organizations in cases where uncertainties still exist.

### **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.

The manufacturer declaration contains no information on additional hygienic aspects or cleanliness, e.g. absence of gaps and undercuts, surface quality.

Some process fitting versions of our sensors also have the EHEDG or 3A certification in order to meet hygiene-specific requirements.

To ensure that there is no unintentional contamination through transport, installation or mounting, a rinsing with aqueous medium is recommended before the first contact with the foodstuff.

Always use a suitable process seal that meets the product-specific requirements.

In the process, a leaky seal represents a hygienic risk. To avoid this, the seals should be replaced with new ones at regular intervals and the sensor checked for damage.

### **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.

With elastomers and plastics there is the requirement of USP Class VI for the assessment of the physiological concern.

For sensor versions for which an USP Class VI proof of the material supply is available, this is confirmed in addition.

## 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 and specific 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 $\leq 10 \text{ mg/dm}^2$ has been proven.

## Specific migration

Substance	Result
Tetrafluoroethylene (CAS 116-14-3)	A surface area of 1 dm <sup>2</sup> was completely immersed in a volume of 100 ml of 95 % ethanol for 24 h. The surface area was then submerged.
Perfluoropropyl perfluorovinyl ether (CAS 1623-05-8)	The permitted limit values were not exceeded for the substances.

## 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

The migration test according to VO (EU) 10/2011 incl. Amendment Ordinance 2020/1245 on a representative PTFE Inoflon M290 component proved that the PTFE Inoflon M290 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 and specific migration on PTFE Inoflon M290 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 $\leq 10 \text{ mg/dm}^2$ has been proven.

## Specific migration

Substance	Result
Tetrafluoroethylene (CAS 116-14-3)	A surface area of 1 dm <sup>2</sup> was completely immersed in a volume of 100 ml of 95 % ethanol for 24 h. The surface area was then submerged.
Perfluoropropyl perfluorovinyl ether (CAS 1623-05-8)	The permitted limit values were not exceeded for the substances.

## 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 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/in <sup>2</sup>

##### 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/in <sup>2</sup>

##### 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

The manufacturer confirms compliance with the following paragraphs:

- 21 CFR 177.1550

In addition, 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 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.
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<p>Result - Migration tests:</p>	<p>Compliance with the following migration limit values has been proven:</p> <ul style="list-style-type: none"> <li>● Arsenic <math>\leq 0.04</math> mg/kg</li> <li>● Cadmium <math>\leq 0.02</math> mg/kg</li> <li>● Lead <math>\leq 0.05</math> mg/kg</li> <li>● Chrome <math>\leq 2.0</math> mg/kg</li> <li>● Nickel <math>\leq 0.5</math> mg/kg</li> </ul>
<p>Result - Sensoric tests:</p>	<p>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).</p>

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**VEGA**

All statements concerning scope of delivery, application, practical use and operating conditions of the sensors and processing systems correspond to the information available at the time of printing.

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