

# Declaration of conformity

## VEGACAP 64

acc. to VO (EG) 1935/2004 and  
VO (EU) 10/2011

as well as acc. to FDA 21 CFR 177.1550



Document ID: 34258



# VEGA



## **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 (EC) 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 und ISO 14001.

The manufacturer declaration contains no information on additional hygienic aspects or cleanability, 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.

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

Issued by: Issue date: 30.10.2015

VEGA Grieshaber KG

Am Hohenstein 113

77761 Schiltach

We herewith declare that the versions of VEGACAP 64 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.

### Thread

CP64.	*	*	F/G	GA	*	*	*	*
				GI				
				NA				
				GC				
				NC				
				GD				
				GS				
				ND				
				NS				
				R2				
				GE				

### Flange

CP64.	*	*	F/G	1F / AF / AN / DF	*	*	*	*
				DG / EG / EF / EB				
				EN / EM / ET / IF				
				KF / KN / KM / ZF				
				MF / OF / JF / OG				
				QF / EH / QN / TF				
				AK / AQ / DK / CF				
				EK / EL / EQ / KK				
				MK / TP / OK / EV				
				AA / BA / DA / EA				
				EE / EC / ER / FE				
				HA / HE / IA / HE				
				IA / KE / OA / PA				
				PB / 2A / 2J / 4H				
				SA / UA / UE / UB				
				UF / 3A / WA / VA				
				VC / VB / IU / SU				
				AU / AV / FU / CU				
				CW / CV				

## 10 ppb-Screening

PTFE HS11005	[mg/dm <sup>2</sup> ]	[µg/kg] <sup>1)</sup>	[µg/kg] <sup>2)</sup>
Alkane standard (Tridecane)	21.6	129	< 20
Hydrocarbon distribution	45.4	273	< 20
3 % acetic acid (simulant B), (OM 2 hours/130 °C)	< 0.5	< 3.2	< 0.001
Isooctane (6 hours/60 °C)	< 0.5	< 3.2	< 0.001

## Specific provision of Perfluorpropyl - perfluorvinylether (PPVO)

PTFE HS11005	[mg/dm <sup>2</sup> ]	[µg/kg] <sup>3)</sup>	[µg/kg] <sup>4)</sup>
Alkane standard (Tridecane)	< 2.7	< 16	< 0.07

## Organoleptic

The organoleptic test was carried out on a piece of PTFE HS11005 insulation in an external, authorized test laboratory and a trained sensing team (panel) acc. to DIN 10955.

## Transfer of the smell to the water after 30 minutes at +100 °C:

	Description	Intensity
Transfer of the smell to the water after 30 minutes at +100 °C	No difference	0
Transfer of the taste to the water after 30 minutes at +100 °C:	Of plastic, of cardboard, oily, foreign scent, strongly overlaying	2.5

Result: With respect to smell and taste, the test sample shows only slight foreign scents and thus meets the sensoric requirements acc. to § 31 LFGB as well as those of article 3 of Framework Regulation (EC) no. 1935/2005 under the test conditions applied.

## 21 CFR 177.1550 of FDA

## Total Extractives

Extracting agents	Total extractives [mg/dm <sup>2</sup> ]	Total extractives [mg/in <sup>2</sup> ]
Distilled water	No difference	0
50 % ethanol	Of plastic, of cardboard, oily, foreign scent, strongly overlaying	2.5
n-Heptane	2.8	0.2
Ethyl acetate	4	0.3

## Fluoride Extractives

Extracting agents	Fluoride extractives [mg/dm <sup>2</sup> ]	Fluoride extractives [mg/in <sup>2</sup> ]
Distilled water	not definable < 0.2	not definable < 0.01
50 % ethanol	not definable < 0.2	not definable < 0.01

<sup>1)</sup> EU convention: 6 dm<sup>2</sup> packaging material are in contact with 1 kg foodstuffs.

<sup>2)</sup> There are 2.5 dm<sup>2</sup> for a vessel volume of 100 l.

<sup>3)</sup> EU convention: 6 dm<sup>2</sup> packaging material are in contact with 1 kg foodstuffs.

<sup>4)</sup> There are 2.5 dm<sup>2</sup> for a vessel volume of 100 l.

Extracting agents	Fluoride extractives [mg/dm <sup>2</sup> ]	Fluoride extractives [mg/in <sup>2</sup> ]
n-Heptane	not definable < 0.2	not definable < 0.01
Ethyl acetate	not definable < 0.2	not definable < 0.01

**With a surface/volume ratio of 6 dm<sup>2</sup>/1000 ml.**

For the FDA requirements Total Extractives 21 CFR 177.1550, the limit values for distilled water, 50 % ethanol and n-Heptane are maintained.

The limit value for ethyl acetate was exceeded by 0.9 mg/dm<sup>2</sup>.



Printing date:

# 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.

Subject to change without prior notice

© VEGA Grieshaber KG, Schiltach/Germany 2016



34258-EN-160301

VEGA Grieshaber KG  
Am Hohenstein 113  
77761 Schiltach  
Germany

Phone +49 7836 50-0  
Fax +49 7836 50-201  
E-mail: [info.de@vega.com](mailto:info.de@vega.com)  
[www.vega.com](http://www.vega.com)