

Declaration of conformity

VEGASWING 51, 53

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



Document ID: 32553



VEGA

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, then we confirm this for the respective concerned versions.

ADI-free (BSE/TSE)

Free from substances with animal origin or substances associated with TSE (Transmissible Spongiform Encephalopathy) or BSE (Bovine Spongiform 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

We hereby declare that the materials in contact with the medium of the VEGASWING 51, 53 variants listed below comply with Regulation (EC) No. 1935/2004 as well as the requirements of the Food Drug Administration or are made of stainless steel alloys (e.g. 316L) which have proven themselves over many years in the pharmaceutical and food sectors and are thus suitable for contact with foodstuffs.

Process fittings

Thread

SG51/3.	*	*	*	GA / GB / GR NR / GH / GL GP / NA / NB NF / NH / NL NP / RF	*	*	*	*
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Clamp

SG51/3.	*	*	*	CL / CM / CN	*	*	*	*	*
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Slotted nut

SG51/3.	*	*	*	RL / RM / RN	*	*	*	*
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Hygienic fitting with compression nut

SG51/3.	*	*	*	LA	*	*	*	*
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SMS

SG51/3.	*	*	*	RR	*	*	*	*
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EG 10/2011 is deleted because the versions do not have any wetted plastic materials.

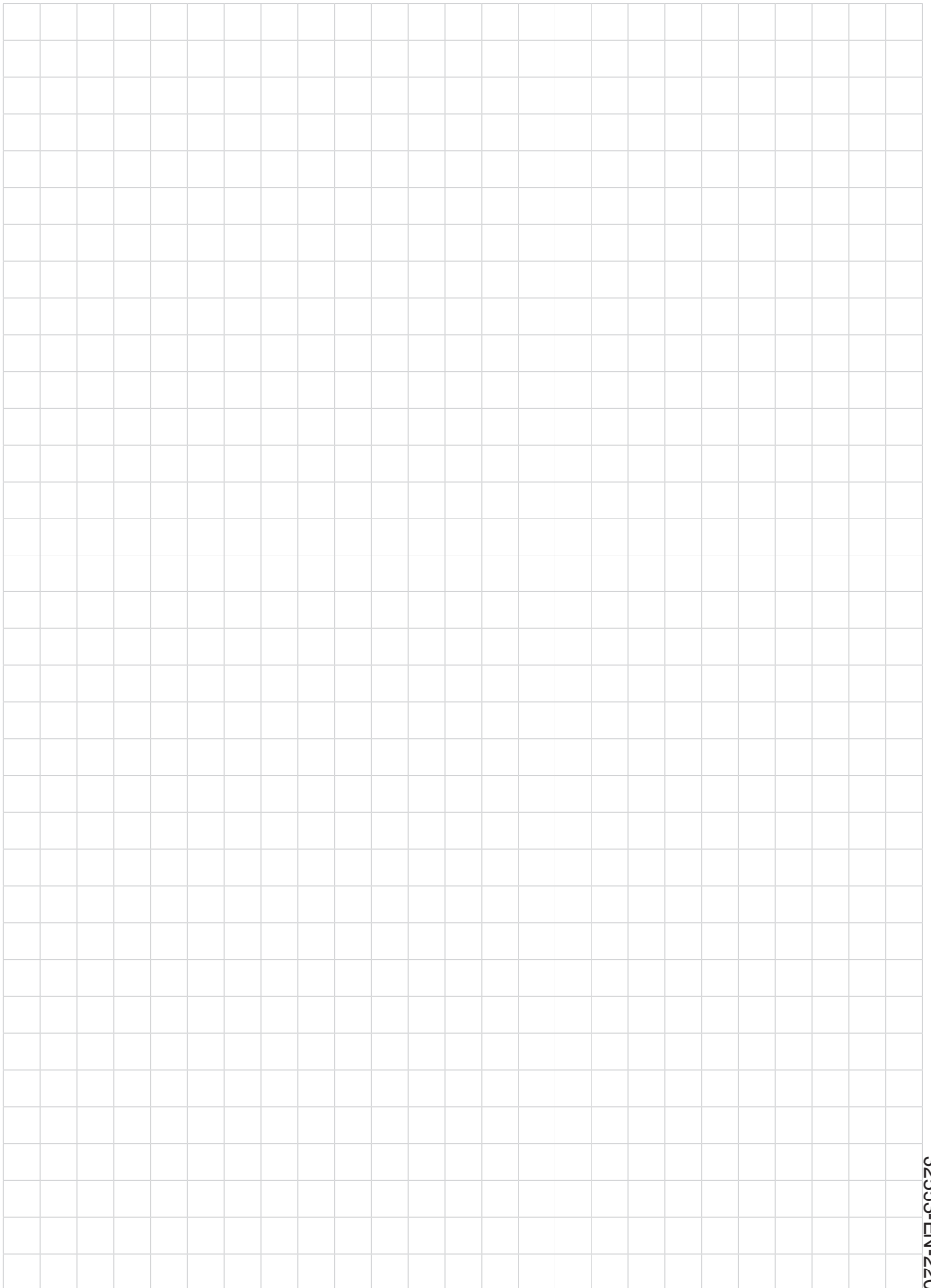
The traceability of the wetted parts and materials according to VO (EG) 2023/2006 (GMP) is guaranteed by our QM system from procurement to production and assembly up to placing on the market!

VEGA Grieshaber KG
Am Hohenstein 113
77761 Schiltach

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i.v. Thomas Deck
Entwicklung







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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

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VEGA Grieshaber KG
Am Hohenstein 113
77761 Schiltach
Germany

Phone +49 7836 50-0
E-mail: info.de@vega.com
www.vega.com