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









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.

Notes on proper use

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

If hygienic design is required, we recommend our instrument versions, for which conformity with "3A or EHEDG" is also confirmed.

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.

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.



Issued by:

VEGA Grieshaber KG

Am Hohenstein 113

77761 Schiltach

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

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

Clamp

SG51/3.	*	*	*	CL/CM/CN	*	*	*	*	*
SG51/3.	"		l	CL/CM/CN		l	· ·	"	

Slotted nut

S	G51/3.	*	*	*	RL / RM /RN	*	*	*	*

Hygienic fitting with compression nut

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

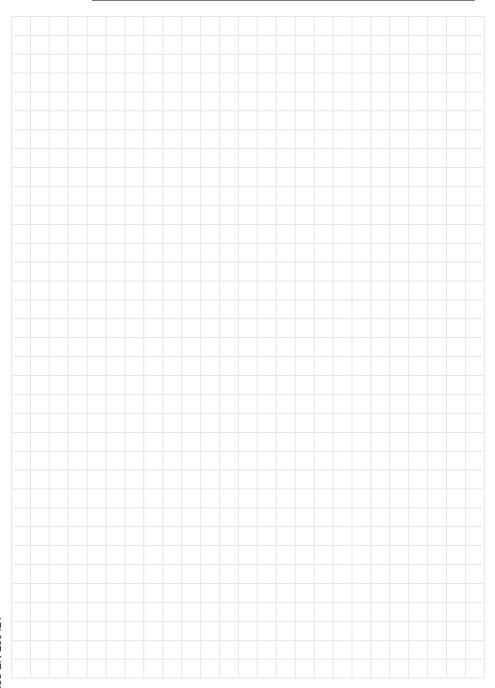
SMS

SG51/3.	*	*	*	RR	*	*	*	*

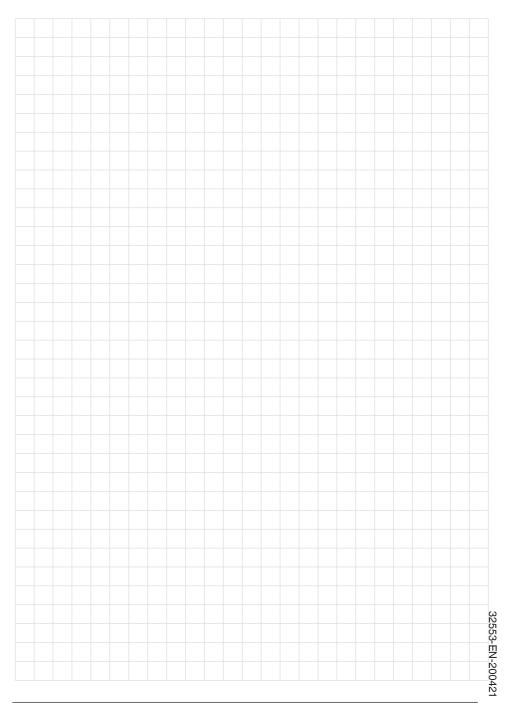
EG 10/2011 is deleted because the versions do not have any wetted plastic materials.

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!









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Printing date:



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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