Declaration of conformity
VEGASWING X

according to VO (EG) 1935/2004
as well as acc. to FDA
and USP Class VI as well as ADI-free

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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 statement 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.

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

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

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.

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.

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.

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

In the process, damages on the coating or seal represent a hygienic risk. To avoid this, coatings as well as seal must be checked regularly on damages and appropriate measures must be taken (e.g. exchange), if necessary.

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.

2 General explanations

We herewith declare that the wetted parts of the following versions are made of materials meeting in the composition with regulation VO (EC) No. 1935/2004 and VO (EU) 10/2011 as well as FDA 21 CFR 177.2415/177.1550 or stainless steel alloys (such as e.g. 316L) proven over years in the pharmaceutical and food processing industry.

The product key is used to check the conformity of the device version. This key is located on the device itself, but can optionally also be determined with the aid of the serial number, which is also located on the device. This serial number can be entered in the search field on the VEGA website (**www.vega.com**). In the search results under "*Serial number found*", the link "*Display*" leads to the product key. Alternatively, you can simply scan the QR code on the device.

SGX*S.*--*-*-*-[a]-*-*-*-[b]-[cde]-*-*-*-*-*-*-*-*-*-*-*-*-*-*-*-*-*-***

*	Feature not relevant for this approval

a	**Food/pharmaceutical certificate**
A	FDA
F	FDA, EG1935/2004
D	FDA, EG1935/2004, EHEDG, 3A

b	**Process temperature / process pressure**
C	-50 … +150 °C / max. 40 bar
D	-50 … +150 °C / max. 64 bar
F	-50 … +150 °C / max. 100 bar
G	-60 … +280 °C / max. 64 bar
J	-60 … +280 °C / max. 100 bar

cde	**Process fitting**
	Wetted materials: 316L, Duplex (1.4470,1.4462), Stainless steel (1.4435), Alloy C22 (2.4602)

3 Europe - Basis of assessment

3.1 Metals

For metals 316L, 1.4435, 2.4602 and 1.4470 (1.4462) that come into contact with media, the respective limit values were complied with under the test conditions listed below in accordance with CoE Resolution CM/Res (2020)9:

Material	Sensory inspection	Arsenic, cadmium, lead, antimony	Aluminium, chromium, cobalt, copper, manganese, molybdenum, nickel, tin, zinc
316L	Passed	Tap water / 70 °C / 24 h	Tap water / 70 °C / 24 h
1.4435	Passed	Tap water / 70 °C / 24 h	Tap water / 70 °C / 24 h
1.4470	Passed	Tap water / 70 °C / 24 h	Tap water / 70 °C / 24 h

Material	Test for impurities	Arsenic, cadmium, lead, antimony	Aluminium, chromium, cobalt, copper, manganese, molybdenum, nickel, tin, zinc
316L	Passed	5 g/L citric acid / 70 °C / 24 hours	5 g/L citric acid / 70 °C / 24 hours
1.4435	Passed	5 g/L citric acid / 70 °C / 6 h	5 g/L citric acid / 100 °C / 6 h
1.4470	Passed	5 g/L citric acid / 70 °C / 24 hours	5 g/L citric acid / 70 °C / 24 hours
2.4602	Passed	5 g/L citric acid / 70 °C / 1 h	5 g/L citric acid / 70 °C / 1 h

Intertek test report: SHAH01901841, SHAH0190184102, FUFDCP2026-02770

The 1.4435 and 1.4435 / Basler standard tuning forks complied with the respective limit values under the test conditions listed below in accordance with CoE Resolution CM/Res (2020)9:

Material	Sensory inspection	Arsenic, cadmium, lead, antimony	Aluminium, chromium, cobalt, copper, manganese, molybdenum, nickel, tin, zinc
1.4435	Passed	Tap water / 70 °C / 24 h	Tap water / 100 °C / 24 h
1.4435 / BN2	Passed	Tap water / 100 °C / 24 h	Tap water / 100 °C / 24 h

Material	Test for impurities	Arsenic, cadmium, lead, antimony	Aluminium, chromium, cobalt, copper, manganese, molybdenum, nickel, tin, zinc
1.4435	Passed	5 g/L citric acid / 70 °C / 24 hours	5 g/L citric acid / 70 °C / 24 hours
1.4435 / BN2	Passed	5 g/L citric acid / 70 °C / 24 hours	5 g/L citric acid / 100 °C / 24 h

We can confirm that these metallic materials are free from Bisphenol-A and DEHP/Phthalates.

4 USA - Basis of assessment

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 4806.9-2023

For metals 316L, 1.4435 and 1.4470 (1.4462) that come into contact with media, the respective limit values were complied with under the test conditions according to the standard GB 4806.9-2023 listed below:

Material	Sensory inspection	Arsenic, cadmium, lead, antimony	Aluminium, chromium, cobalt, copper, manganese, molybdenum, nickel, tin, zinc
316L	Passed	Tap water / 70 °C / 24 h	Tap water / 70 °C / 24 h
1.4435	Passed	Tap water / 70 °C / 24 h	Tap water / 70 °C / 24 h
1.4470	Passed	Tap water / 70 °C / 24 h	Tap water / 70 °C / 24 h

Material	Test for impurities	Arsenic, cadmium, lead, antimony	Aluminium, chromium, cobalt, copper, manganese, molybdenum, nickel, tin, zinc
316L	Passed	5 g/L citric acid / 70 °C / 24 hours	5 g/L citric acid / 70 °C / 24 hours
1.4435	Passed	5 g/L citric acid / 70 °C / 6 h	5 g/L citric acid / 100 °C / 6 h
1.4470	Passed	5 g/L citric acid / 70 °C / 24 hours	5 g/L citric acid / 70 °C / 24 hours

The 1.4435 and 1.4435 / Basler standard tuning forks complied with the respective limit values under the test conditions GB 31604.49-202 listed below:

Material	Sensory inspection	Arsenic, cadmium, lead, antimony	Aluminium, chromium, cobalt, copper, manganese, molybdenum, nickel, tin, zinc
1.4435	Passed	Tap water / 70 °C / 24 h	Tap water / 100 °C / 24 h
1.4435 / BN2	Passed	Tap water / 100 °C / 24 h	Tap water / 100 °C / 24 h

Material	Test for impurities	Arsenic, cadmium, lead, antimony	Aluminium, chromium, cobalt, copper, manganese, molybdenum, nickel, tin, zinc
1.4435	Passed	5 g/L citric acid / 70 °C / 24 hours	5 g/L citric acid / 70 °C / 24 hours
1.4435 / BN2	Passed	5 g/L citric acid / 70 °C / 24 hours	5 g/L citric acid / 100 °C / 24 h

Intertek test report: SHAH01901841, SHAH0190184102

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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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