Declaration of conformity
Einschweißstutzen für
VEGABAR 18, 19, 28, 29, 38, 39
VEGAPOINT 11, 21, 23, 31
VEGASWING 51, 53

acc. to VO (EG) 1935/2004, VO (EU) 10/2011
FDA, GB 4806

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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).

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, the we confirm this for the respective concerned versions.

ADI-free (BSE/TSE)
Free from substances with animal origin or substances associated with TSE (Transmissible Spongioform Encephalopathy) or BSE (Bovine Spongioform 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 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 or stainless steel alloys (such as e.g. 316L) proven over years in the pharmaceutical and food processing industry.

The requirement acc. to VO (EC) 10/2011 is not applicable because no plastic parts are used in the below listed welded socket which are in contact with the foodstuff.

The product key is used to check the conformity of the device version. The product key can be found on the order confirmation, which is enclosed with the adapter. The product key can then be entered in the search field on the VEGA website (www.vega.com). Under the search results under "*Article number found*", the link "*To product*" takes you to the device configuration.

Welded socket for VEGAPOINT 11, 21, 23, 31
WSPT.G/F***[X/1/3]*

Characteristic in product key Process fitting	Wetted materials
AB / AA / AC / AE / GA / GL / GB / AF / AM / AU / AV / AN / AP / AQ / GC	316L

Welded socket for VEGABAR 18, 19, 28, 29, 38, 39
WSBR.F***[X/F/3]*

Characteristic in product key Process fitting	Wetted materials
C3 / C9 / C5 / AL / DA / LX / LU / DU / DH / DN / AV / AT / AR / ES / EZ	316L

Welded socket for VEGASWING 51, 53
WSSG.G/F***[X/1/3]*

Characteristic in product key Process fitting	Wetted materials
GA / GL / GB / AF / AM / AU / AV / CL / CN / RM	316L

3 Europe - Basis of assessment

Metals
For the metals in contact with the media in process fittings 1.4404, 1.4435, and 1.4462, 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
1.4404	Passed	Tap water / 100 °C / 24 h	Tap water / 70 °C / 24 h
1.4435	Passed	Tap water / 100 °C / 24 h	Tap water / 100 °C / 24 h
1.4462	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
1.4404	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 / 24 hours	5 g/L citric acid / 100 °C / 24 h
1.4462	Passed	5 g/L citric acid / 70 °C / 24 hours	5 g/L citric acid / 70 °C / 24 hours

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

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 People's Republic of China - Basis of assessment

Metals acc. to standard GB 4806.9-2023
For metals 1.4404, 1.4435 and 1.4462 that come into contact with media, the respective limit values were complied with under the test conditions GB 31604.49-2023 listed below:

Material	Sensory inspection	Arsenic, cadmium, lead, antimony	Aluminium, chromium, cobalt, copper, manganese, molybdenum, nickel, tin, zinc
1.4404	Passed	Tap water / 100 °C / 24 h	Tap water / 70 °C / 24 h
1.4435	Passed	Tap water / 100 °C / 24 h	Tap water / 100 °C / 24 h
1.4462	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
1.4404	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 / 24 hours	5 g/L citric acid / 100 °C / 24 h
1.4462	Passed	5 g/L citric acid / 70 °C / 24 hours	5 g/L citric acid / 70 °C / 24 hours

Intertek test report: SHAH01851708, SHAH0185170802

6 Sealing materials

The following table lists the seal versions and the associated statements of conformity from our seal suppliers.

Seal material	Standard
EPDM (A+P 70.10-02)	3-A Standard 18-03 Class 2 EU 1935/2004 Article 3 FDA 21 CFR 177.2600 (a-f) GB 4806.11-2016 USP class VI, <87>; and <88> (121°C) NSF (Standard 51) ADI-free BPA, free of Bisphenol A DEHP, free of Phthalaten
EPDM 70.503-00	3-A Standard N° 18-03 Class 2 FDA 21 CFR - 177.2600 a) - f) NSF 51 for food BfR XXI Category 4 (Migration test BfR XXI Category 3) Dlgs. 25.01.1992 n.108 Art.2 (ex. DPR 777/82 art 2) - Complies with Arsenic content limits EC 1935/2004 (excl. article 15) and EC Regulation 2023/2006 (GMP) GB 4806.11-2016 (Migration test) USP class VI Chapter <87> (In Vitro) and Chapter <88> (In Vivo) - 121 °C BPA, free of Bisphenol A DEHP, free of Phthalaten ADI free (free of Animal Derived Ingredients) resp. TSE/BSE related substances
EPDM AP 310	FDA 21.CFR 177.2600 (e) and (f) VO (EG) No. 1935/2004 ADI-free
FKM (Perlast G748)	EG1935/2004 FDA 21 CFR 177.2600 (e,f) USP class VI, <88> and USP <87> 3-A Standard 18-03 Class 2 Free from Animal Derived Ingredients (ADI)
EPDM 02170F	FDA 21 CFR 177.2600 FSE guideline EMEA/410/01.
FKM Fa. Linnemann	FDA 21 CFR 177.2600
FKM Vi665	FDA 21 CFR 177.2600 (e,f) USP class VI, <88> 121 °C 3-A Standard 18-03 Class 2
FKM 13-75	FDA 21 CFR 177.2600

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