Declaration of conformity

Hygieneadapter für VEGAPULS C 21, C 22, 21, 31

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

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.

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 hygienic adapter which are in contact with the foodstuff.

The product key, which is located on the adapter, is used to check the conformity of the device version.

Hygienic adapter for G1½" with O-ring seal
HYGADAPT-R(*).F**

Characteristic in product key Process fitting	Wetted materials
C1 / C2 / B1 / B2	1.4404 with EPDM O-ring

Note:

The hygienic adapter HYGADAPT-R can be screwed for example on VEGAPULS C 21, C 22 and VEGAPULS 21, 31 each with process fitting „G“ (thread G1½").

3 Europe - 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.

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 4806.9-2016
For the stainless steels from 1.4404 the food compatibility could be proven by tests on representative test samples according to GB 4806.9-2016. (Intertek Hong Kong test report number HKGH02515909 S1).

Test conditions:	The test conditions for migration tests and organoleptic tests are specified in the standards GB 31604.24-2016, GB 31604.25-2016, GB 31604.33-2016, GB 31604.34-2016, GB 31604.38 and GB 5009.156-2016.

Result - Migration tests:	Compliance with the following migration limit values has been proven: ● Arsenic ≤ 0.04 mg/kg ● Cadmium ≤ 0.02 mg/kg ● Lead ≤ 0.05 mg/kg ● Chrome ≤ 2.0 mg/kg ● Nickel ≤ 0.5 mg/kg
Result - Sensoric tests:	Proof of the sensoric requirements could be provided since the test solution did not exhibit any peculiar odour and the test samples show clean and regular surfaces (free of cracks).

6 Seal materials

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

Seal material	Standard
EPDM 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

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